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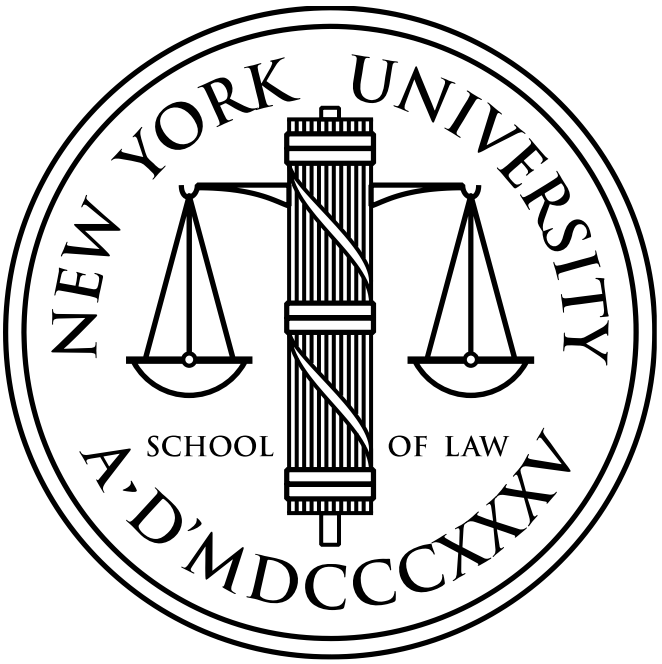
CONTENTS



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Consistent with its unique development, the New York University Journal of Intellectual Property & Entertainment Law (JIPEL) is a nonpartisan periodical specializing in the analysis of timely and cutting-edge topics in the world of intellectual property and entertainment law. As NYU's first online-only journal, JIPEL also provides an opportunity for discourse through comments from all of its readers. There are no subscriptions or subscription fees; in keeping with the open-access and free discourse goals of the students responsible for JIPEL's existence, the content is available for free to anyone interested in intellectual property and entertainment law.

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PREFACE

Our Fall 2022 Issue—Volume 12, Issue 1—focuses on interdisciplinarity in understanding the development and future of intellectual property law.

First, Professor S. Sean Tu and Charles present a study of patent litigation of pharmaceutical patents, modeling their case study after the *Amarin v. Hikma* string of litigation. Their empirical analysis of both parties' patent portfolios reveals a broader pattern of how pharmaceutical companies have adopted novel strategies in developing so-called "patent thickets," increasingly resulting in delayed generic drug entry into the market. The authors argue that brand pharmaceutical companies' exploitation of the complex regulatory frameworks of the FDA and the PTO unjustly extends patent monopoly rights. An induced infringement strategy based on patent thickets stymie generic competition and lead to increased costs for American patients and the federal government. The authors ultimately argue that the Supreme Court of the United States should grant certiorari to *GlaxoSmithKline v. Teva* to correct the confusion created by the Federal Circuit, and that the PTO and FDA should create rules to re-balance the Hatch-Waxman Act to serve its initial purpose of promoting pharmaceutical innovation and lowering drug prices.

Second, Professor Andrew P. Morriss and Professor Roger R. Meiners offer a Coasian perspective on how universities incentivize research among groups of researchers whose aims differ from those of a traditional for-profit firm. A data-driven analysis of patenting activities reveals that university patenting is largely the result of activity by a small subset of U.S. universities, contrary to the Bayh-Dole Act's promise that it would produce a massive technology transfer from universities to the marketplace. The authors conclude that the distinctive nature of research in not-for-profit universities in relation to research conducted in a for-profit context has resulted in inventions' moving from the university to the market via licensing agreements to third parties that have a comparative advantage in assessing the risk and market value of research output.

Third, Dr. Tristan Radtke compares the requirements for influencer marketing in the U.S. and Germany with a particular focus on the disclosure of commercial intent and material connections to sponsors. The article demonstrates that while in the U.S. and Germany similar rules apply, Germany employs a more complex regulatory scheme in scenarios where influencers either promote merely themselves, with the goal of increasing their number of followers, or products without receiving payment. The

author compares both approaches and discusses their advantages and disadvantages.

Finally, Molly Marias offers a note arguing for the creation of a non-fungible tokens ("NFTs") licensing scheme modelled from the Creative Commons paradigm. Neither traditional copyright nor property law conforms to NFT creator or purchaser objectives, resulting in conflicting expectations that hamper the efficiency of NFT sales. These licenses would define, and readily convey, the NFT creator's and purchaser's legal rights in and value of the NFT, and would allow for a more informed and efficient negotiation process. The author finally argues that increased transparency would lower NFT transaction costs by remedying the negotiating parties' information asymmetries, augmenting NFT sales and viability.

Sincerely,

Jacob Golan, Ph.D.
Editor-in-Chief
NYU Journal of Intellectual Property & Entertainment Law

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PHARMACEUTICAL PATENT TWO-STEP: THE ADVERSE ADVENT OF *AMARIN V. HIKMA* TYPE LITIGATION*

S. SEAN TU** & CHARLES DUAN***

Pharmaceutical companies have long sought to maintain exclusivity over market drugs in a myriad of ways including creating patent thickets and evergreening. This article describes a two-step strategy by which pharmaceutical companies attempt to keep market exclusivity and delay generic entry. This new strategy can work in tandem with ANDA litigation and FDA labeling requirements to reclaim exclusive rights that should have expired or been unavailable under patent law.

The "first wave" of litigation involves a typical ANDA litigation, where brand manufacturers sue for patent infringement to prevent generics from entering the market. The "second wave" of litigation involves suing the generic for induced infringement based on the "skinny label" on the generic drug. Notably, this second wave of litigation can act regardless of if the brand firm wins or loses the first wave of litigation.

In this article we use Amarin v. Hikma *as a case study of this strategy. We show that after the generic firm Hikma won the ANDA litigation invalidating a set of patents, they were subjected to a second wave of litigation based on a new set of patents. In this article we examine this new strategy and take a deep dive into the patent portfolios to*

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determine how Amarin was able to create a large method of use-based patent thicket to set up this second wave of litigation.

Although Hikma was able to win both the first and second waves of litigation, these court cases raise transaction costs and may deter or delay generic entry. These delays can amount to billions of added dollars to drug costs. This second wave strategy is especially important after the landmark GlaxoSmithKline v. Teva *case, which could breathe new life into this type of litigation strategy.*

INTRODUCTION

Only in the world of pharmaceutical patents can one have two bites at the litigation apple. Amarin is the patent holder on and manufacturer of the

cardiovascular drug Vascepa (icosapent ethyl).[1] When generic firm Hikma sought to enter the market, Amarin brought a "first wave"[2] patent infringement suit to block the competing product, but lost.[3] In response to this loss, Amarin brought a "second wave" patent infringement suit based on an induced infringement theory.[4] Amarin lost again.[5] Without a meritorious patent case from Amarin, Hikma's cost-saving generic product ought to have been approved and available arguably as early as 2016.[6] And yet with Vascepa earning Amarin roughly $580 million per year, the undue profits from years of litigation made those failed lawsuits worthwhile.[7]

The litigation between Amarin and Hikma exemplifies how brand-name pharmaceutical manufacturers try to extend the life of their exclusive rights to charge supracompetitive prices. The amount of money associated with just one erroneously protected drug can amount to billions of dollars.[8] While previous studies have discussed both "evergreening" and creation of "patent thickets" as strategies for brand firms to delay or prevent generic drug market entry,[9] the patent enforcement strategies based on these patent portfolios has received less attention.

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[1] *Amarin Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update*, Amarin (Mar. 1, 2022), at *4, https://investor.amarincorp.com/news-releases/news-release-details/amarin-reports-fourth-quarter-and-full-year-2021-financial.

[2] The "first wave" and "second wave" terminology is used to avoid confusion with "primary" and "secondary" patents which have a different meaning. First wave patents are those patents that are associated with the ANDA litigation or are the patents that cover the drug product's active ingredient. First wave patents are usually associated with primary patents. Second wave patents for purposes of this article are "methods of use" patents associated with specific Orange Book use codes.

[3] *See* Ian Lopez, *Teva Drug-Label Case Spurs Fresh Litigation as Judges Weigh Redo*, Bloomberg L. News (Mar. 8, 2021, 5:31 AM), https://www.bloomberglaw.com/bloomberglawnews/health-law-and-business/XDL3PJD0000000?bna_news_filter=health-law-and-business#jcite; *see also* Amarin Pharma v. Hikma Pharms. USA Inc. (*Amarin I*), 449 F. Supp. 3d 967, 1015 (D. Nev. 2020) (finding all Amarin infringement claims as invalid).

[4] Amarin Pharma v. Hikma Pharms. USA Inc. (*Amarin II*), 578 F. Supp. 3d 642, 644 (D. Del. 2022) ("Plaintiffs sued Defendants for induced infringement of three patents that describe methods of using icosapent ethyl for the reduction of cardiovascular risk.).

[5] *Amarin II*, 578 F. Supp. 3d at 643 (granting Hikma's motion to dismiss).

[6] *Amarin I*, 449 F. Supp. 3d at 974–75 (noting 2016 as the filing date of Amarin's application for approval of the generic product).

[7] *Amarin Reports Fourth Quarter and Full Year 2021 Financial Results*, *supra* note 1, at *1.

[8] David Miller, Benedic Ippolito, Inmaculada Hernandez & Benjamin Davies, *The Costs of Delayed Generic Drug Entry: Evidence from a Controversial Prostate Cancer Drug Patent*, 37 J. Gen. Internal Med. 668, (2021) (showing that an inappropriately awarded secondary patent cost consumers $2 billion).

[9] Robin Feldman, *May Your Drug Price be Evergreen*, 5 J.L. Biosciences 590, (2018); Bronwyn H. Hall, Christian Helmers & Georg von Graevenitz, *Technology Entry in the Presence of Patent Thickets* (Nat'l

This article focuses on attempts to extend exclusivity or delay generic market entry based on a two-step litigation strategy. First, brand manufacturers will sue generic manufacturers for violating a first wave of patents in the context of Abbreviated New Drug Application (ANDA) litigation.[10] If the brand manufacturers lose the ANDA litigation, then they will try for a second bite at the apple by suing the generic manufacturer on an "induced infringement" theory based on a second wave of patents directed to the drug's "methods of use."[11] A recent Federal Circuit case, *GlaxoSmithKline v. Teva* (*GSK II*), has opened the door for these types of arguments, challenging Supreme Court precedent to the contrary and upending a thirty-year "skinny label" system that has been proven to bring low-cost generics to market.[12] Now there is a wave of lawsuits filed challenging the use of skinny labels and more of these suits will likely be on the way.[13]

We use *Amarin Pharma v. Hikma Pharms.* as a case study to show how brand manufacturers are abusing Food & Drug Administration (FDA) labeling requirements to delay or deter Amarin Igenerics from entering the market.[14] In this paper we examine the patents asserted in both the ANDA litigation and the labeling litigation.[15] We examine the patent prosecution histories as well as the patent filing strategies used to create large portfolios of similar patents created only to delay entry.[16] The patent disclosures for Vascepa's use codes in these secondary patents were minimal, and the validity of the patents under the written description and enablement requirements of patentability are questionable at best.[17] Furthermore, these patents come from large and related patent families only minimally advance innovation and do not justify the exclusive rights associated with patents or the use codes listed in the Orange Book.

Bureau Econ. Rsch., Working Paper No. 21455, 2015) (showing that patent thickets raise entry costs and lead to less entry into technologies regardless of a firm's size).

[10] *See* 35 U.S.C. § 271(e)(2)(A) (2018).

[11] *See infra* Parts I.D–E.

[12] *See* GlaxoSmithKline LLC v. Teva Pharms. USA, Inc. (*GSK II*), 7 F.4th 1320, 1326 (Fed. Cir. 2021) (holding Teva infringed on GSK patents under an inducement theory); *see also* Lopez, *supra* note 3 (highlighting that at least five lawsuits were brought following the Teva patent decision); *but see* Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399 (2012).

[13] Lopez, *supra* note 3.

[14] *Amarin I*, 449 F. Supp. 3d 967, 1015 (D. Nev. 2020).

[15] *See infra* Part III.A.

[16] *See infra* Part III.B.

[17] *See infra* Part III.C-D.

Amarin's tactics suggest a concerted effort to delay generic entry by filing a multi-layered patent thicket based not only the first-wave patent claims, but also the FDA use codes associated with a set of second-wave patents. The U.S. Patent and Trademark Office (PTO) and the FDA need to coordinate examination of these important patents to prevent creation of these large patent portfolios that do not benefit the public with new innovations, but rather serve primarily to delay or deter generics from market entry.[18]

I
The Hatch-Waxman Act: ANDA Litigation & Skinny Label Litigation

ANDA litigation and skinny labeling serve two separate and distinct purposes. ANDA Paragraph IV litigation provides a path for generics to get to market faster by giving generics an incentive to challenge weak patents that may prevent market entry. To forestall generic entry, brand firms have increased the number of patents that cover each drug product, creating "patent thickets." Patent thickets are overlapping sets of patent rights that help prevent market entry by creating uncertainty and added risk for potential market entrants. Many of these patent thickets are stocked with weak secondary patents,[19] many of which are directed towards multiple "methods of use" claims.[20]

Method of use patents present a particular problem for generic manufacturers because they commonly have expiration dates that far exceed the original composition of matter claims (primary patents).[21] For example, in 2012 the drug Vascepa had only one indication (treatment for disease) authorizing use only

[18] S. Sean Tu, *FDA Reexamination: Increased Communication Between the FDA and USPTO to Improve Patent Quality*, Hous. L. Rev. (forthcoming 2023).

[19] Secondary patents are follow-on patents that are usually weaker and invalidated at a higher rate. *See* S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 Wash. U.L. Rev. 1673, 1712 (2022). Secondary patents usually include formulation, methods of use and enantiomer and polymorph claims. *See id.* at 1691. In contrast, primary patents are directed towards the drug's active pharmaceutical ingredient. *See id.* (stating that "primary" patents are "directed to new chemical entities").

[20] Tu & Lemley, *supra* note 19, at 1691 (fig.3, showing that 94% of invalidated Orange Book patents were secondary patents).

[21] Primary patents are directed towards the drug's active pharmaceutical ingredient. Primary patents are usually the strongest patents that usually do not get invalidated during litigation. Generic manufacturers usually wait until the expiration of these patents before entering the market. *See* Reed F. Beall, Jonathan J. Darrow & Aaron S. Kesselheim, *Approximating Future Generic Entry for New Drugs*, 47 J.L., Med. & Ethics 177, 177 (2019).

for reducing triglyceride levels in patients with severe hypertriglyceridemia.[22] Currently, however, Vascepa has 40 indications, with most indications directed to patients with cardiovascular disease.[23] Although the first Orange Book patents listed in 2013 expired in January 2020,[24] current patents based on methods of use attempt to extend the life of the drug to June 2033.[25]

To allow generic companies to overcome these method of use claims, Congress created a process called "skinny labeling."[26] This process allows generic companies to "carve out" those drug indications that are no longer under patent protection, while avoiding infringement of those indications that are still under patent protection.[27] Thus, skinny labels allow generic companies to include only those indications that are unpatented on the label while excluding the patented indications.

In the sections below we briefly outline the new drug approval process, the use codes associated with the new drug applications, and how labeling interacts with the FDA approval process. We then describe the current state of skinny labeling jurisprudence.

A. New Drug Applications (NDAs)

The Hatch-Waxman Act attempts to balance innovation and access to pharmaceuticals. It gives special rights to pharmaceutical patent owners, including longer patent terms[28] and the power to prevent a generic drug from receiving FDA

[22] Letter from Eric Colman, U.S. Food & Drug Admin., to Peggy Berry, Amarin Pharma Inc., NDA Approval: NDA 202057 (July 26, 2012), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/202057Orig1s000ltr.pdf.

[23] *See* Appendix 2 for a list of all the use codes associated with Vascepa.

[24] U.S. Patent No. 8,188,146 listed under NDA 202057. *See* U.S. Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations 1167 (33d ed. 2013) [hereinafter The Orange Book, 2013].

[25] Numerous patents listed under NDA 202057 have an expiration date of June 28, 2033. *See* U.S. Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations 1396-98 (42d ed. 2022) [hereinafter The Orange Book, 2022]; *see also* Appendix 1 (Orange Book patents associated with Vascepa).

[26] *See* Bryan Walsh, *Skinny Labeling: A Pathway for Timely Generic Drug Competition*, Commonwealth Fund (Oct. 19, 2021), https://www.commonwealthfund.org/blog/2021/skinny-labeling-pathway-timely-generic-drug-competition.

[27] *See id.*

[28] *See* 35 U.S.C. § 156 (2018).

approval to enter the market for up to thirty months until any patent litigation is resolved—in effect, an automatic preliminary injunction.[29]

Patents subject to these rules are listed with the FDA in an FDA compendium commonly known as the Orange Book. The rules require that applicants for new drug applications (NDAs)

> shall file with the application the patent number and the expiration date of any patent which claims the drug . . . or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.[30]

In other words, this FDA process requires that all patents associated with new drugs are listed in the Orange Book.[31] Specifically, the FDA requires patents that "consist of drug substance (active ingredient) patents, drug product (formulation and composition patents), and method-of-use patents" to be listed in the Orange Book.[32] Applicants may not list process patents, patents claiming packaging, patents claiming metabolites, or patents claiming intermediates.[33] In addition to the patent number and expiration dates,[34] the FDA requires a description of any method-of-use patents, known as a use code.[35]

Importantly, the FDA does not substantively review the accuracy of the patent information before publishing.[36] This is because the FDA interprets its role in listing patent information as "purely ministerial" and explained that it "lacks both

[29] *See* 21 U.S.C. § 355(j)(5)(B)(iii) (2018). By contrast, actual preliminary injunctions in patent cases are quite rare. *See* High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc., 49 F.3d 1551, 1554 (Fed. Cir. 1995) ("[A] preliminary injunction is 'not to be routinely granted.'" (quoting Intel Corp. v. ULSI Sys. Tech., Inc., 995 F.2d 1566, 1568 (Fed. Cir. 1993))).

[30] 21 U.S.C. § 355(b)(1) (2018)

[31] *Id.* Most new drugs are protected by one or more patents.

[32] 21 C.F.R. § 314.53(b)(1) (2022).

[33] *Id.*

[34] *Id.*

[35] Matthew M. D'Amore, Steve Keane & David C. Doyle, *FDA (Finally!) Issues New Regulations to Clarify Pharmaceutical Patent Litigation: How to Use Patent "Use Codes,"* 29 Intell. Prop. & Tech. L.J. 10, 10 (2017).

[36] D'Amore, Keane & Doyle, *supra* note 35, at 10.

the resources and the expertise to police the correctness…of every patent listing submitted by an NDA holder."[37]

The mere listing of a patent in the Orange Book can delay competition for months, or even years, and drive-up expenses for competitors.[38] Accordingly, drug companies have liberally interpreted those patents that can or should be listed in the Orange Book. For example, some Orange Book patents have included mechanical devices,[39] or even design patents.[40]

B. Abbreviated New Drug Applications (ANDAs)

Under the Hatch-Waxman Act, after the FDA has approved a brand manufacturer's drug, another company may seek permission to market a generic version by filing an ANDA.[41] An ANDA relies on the data the brand firm submitted to the FDA to receive quicker approval for a generic version of the same drug.[42]

The FDA, however, cannot authorize a generic drug that would infringe a brand manufacturer's patent. As part of the ANDA process, the generic manufacturer must review the Orange Book, and then make a certification for non-infringement (for each patent listed in the Orange book).[43] A certification of non-infringement may be made in one of four ways: (1) the NDA holder has not submitted patent information to the FDA for listing in the Orange Book; (2) the patent has expired; (3) the date the patent will expire; or (4) "[the] patent is invalid

[37] aaiPharma Inc. v. Thompson, 296 F.3d 227, 237 (4th Cir. 2002) (noting that the FDA does not substantively review the correctness of the patent information before publication); *see also* Teva Pharms. USA, Inc. v. Leavitt, 548 F.3d 103, 106 (D.C. Cir. 2008); Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1084 (D.C. Cir. 2001); 21 C.F.R. § 314.53(e) (2022); 68 Fed. Reg. 36,683 (June 18, 2003).

[38] Jake Holdreith & Emily Tremblay, *Listing Device Patents in the Orange Book: Can You Do That?*, Robins Kaplan (May 8, 2018), https://www.robinskaplan.com/resources/blog-posts/2018/05/listing-device-patents-in-the-orange-book-can-you-do-that.

[39] *See, e.g.*, U.S. Patent Nos. 7,449,012; 7,794,432; 8,048,035; 8,870,827; 9,586,010; 9,526,844 (epipen automatic injector). Other types of drug device patents listed on the Orange Book include pre-filled syringes and respiratory inhalers.

[40] *See, e.g.*, U.S. Patent No. D468424 (Swabstick).

[41] *See* 21 U.S.C. § 355(j)(2)(A)(ii), (iv).

[42] *Id.*

[43] *See* 21 U.S.C. § 355(b)(2)(A) (requiring certification for applicants submitting a drug for which they did not conduct initial drug trials); see also 21 U.S.C. § 355(j)(2(A)(vii) (ANDA process).

or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."[44]

Thus, ANDAs encourage generics to challenge the branded patents before they expire. When generic firms believe that the relevant patents are either invalid or do not cover the generic product, they may file a "Paragraph IV" certification to challenge these patents as either invalid or non-infringed.[45] If the patent(s) are found to be invalid, then the generic company can enter the market before the patent expires. Filing a Paragraph IV certification is deemed by law to be an act of infringement to which the brand-name firm can respond by filing a patent infringement suit.[46]

To encourage generic firms to engage in Paragraph IV certifications, the first generic applicant who files a Paragraph IV certification is given a 180-day exclusive right to market its product in competition with the brand-name firm before other generic firms may enter the market.[47]

These challenges are expensive, complex, and subject to gamesmanship.[48] Patentees try to extend patent lifecycles by creating large patent thickets and "evergreening" their patents, adding new patents on minor variants as the basic patents expire.[49] The structure of the regulatory regime means that all patents, no matter how weak, pose a significant obstacle to generic market entry.

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[44] 21 U.S.C. §§ 355(b)(2)(A), (j)(2)(A)(vii). This last is commonly referred to as a "Paragraph IV" certification.

[45] C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Empirical Legal Stud. 613, 624 (2011) (fig. 4 showing that 299 out of 692 drugs were subjected to Paragraph IV challenges).

[46] *See* 21 U.S.C. § 355(c)(3)(C) (for 505(b)(2) NDAs); (j)(5)(B)(iii) (for ANDAs).

[47] 21 U.S.C. § 355(j)(5)(B)(iv).

[48] AIPLA 2021 Report of the Economic Survey at 67 and I-158 to I-161 (showing (1) an average cost of $2.608 million when $1-10 million is at risk, (2) an average cost of $6.219 million when more than $25 million is at risk, and (3) an average cost of $774 thousand for filing or defending a PGR/IPR in Life Sciences). *See* Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, Innovation Pol'y & Econ. 145, 145–87 (A.B. Jaffe, J. Lerner & S. Stern eds., 2004); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553 (2006).

[49] Hemphill & Sampat, *supra* note 45, at 615 (2011) (noting that "[b]rand-name firms have sought increasing recourse to ancillary patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug"); Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. Pa. L. Rev. 1, 5–6, 27 (2005); Hall, Helmers & von Graevenitz, *supra* note 9 (showing that patent thickets raise entry costs and lead to less entry into technologies regardless of a firm's size).

Why do brand firms stockpile weak patents that inevitably end up invalidated? One explanation is that even short delays in market entry can garner millions of dollars in added revenues. Since many of these blockbuster drugs make billions of dollars each year, brand firms are incentivized to spend millions of dollars on frivolous lawsuits even if the result is only a short delay in market entry.[50] For example, Abbvie's adalimumab (Humira), which is the world's top revenue-generating brand-name drug, generated $17.3 billion in 2021 alone.[51] Based on that 2021 revenue value, a one-day delay would generate $47.4 million. So long as Abbvie's litigation costs are under $47 million, one day's revenue would pay for the average litigation seven times over.[52]

C. Orange Book: FDA Use Codes

ANDA applicants can attack unexpired methods of use patents using a Paragraph IV certification.[53] Additionally, if the brand firm has unexpired method of use patents, the ANDA applicant can also file a "section viii" statement asserting that it will market the drug for only those methods of use not covered by the brand's patent(s).[54] The ANDA applicant must also propose a label that "carves out" the still-patented method(s) of use.[55] The FDA will not approve an ANDA if the proposed label overlaps at all with the brand's use code.[56]

FDA use codes are how the brand firm tells the FDA how their Orange or Purple Book listed method patents relate to their approved drug indications.[57]

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[50] In reality, brand firms do not even need to bring frivolous lawsuits because under the Hatch-Waxman Act the generic firms are the ones who are required to bring suits to invalidate these weak patents. This regulatory structure rewards brand firms to create large patent thickets composed of relatively weak patents.

[51] Press Release, AbbVie, AbbVie Reports Full-Year and Fourth-Quarter 2021 Financial Results (Feb. 2, 2022) (on file with author), https://news.abbvie.com/news/press-releases/abbvie-reports-full-year-and-fourth-quarter-2021-financial-results.htm.

[52] The AIPLA 2021 Report of the Economic Survey shows that companies spend an average of $6.219 million on litigation costs when more than $25 million is at risk. *See* AIPLA 2021 Report at 67 and I-161.

[53] 21 U.S.C. § 355(j)(2(A)(vii).

[54] 21 U.S.C. § 355(j)(2(A)(viii).

[55] 21 C.F.R. § 314.94(a)(8)(iv) (2022).

[56] *Caraco Pharm*, 566 U.S. at 405 ("[T]he FDA cannot authorize a generic drug that would infringe a patent . . .").

[57] "The Purple Book is a database that contains information about all FDA-licensed biological products regulated by the Center for Drug Evaluation and Research (CDER), including licensed biosimilar and interchangeable products, and their reference products." *Purple Book Database of Licensed Biological Products*, U.S. Food & Drug Admin., https://purplebooksearch.fda.gov/about (last visited, Nov. 1, 2022).

Method patents typically claim how a drug substance or product is used to treat an indication (disease). For example, US Patent No. 6,958,335 is directed to "[a] method of treating gastrointestinal stromal tumors which comprises administering to a human in need of such treatment a dose, effective against gastrointestinal stromal tumors, of <imatinib>."[58]

Each method claim can also have an associated use code. For example, Novartis' imatinib (Gleevec) was initially approved in 2001 for treatment of patients with chronic myeloid leukemia (CML).[59] The first wave patent (US Pat. No. 5,521,184, herein the '184 patent) was directed towards the composition of matter and expired in 2015.[60] By 2018, Novartis listed three different uses for imatinib. US Pat. No. 6,894,051 ('051 patent) had a use code of "U-649"[61] and US Pat. No. 6,958,335 ('335 patent) had use codes "U-1883"[62] and "U-791"[63] and expired on May 23, 2019, and December 19, 2021, respectively.[64] The '051 and '335 patents both had use codes directed towards the use of imatinib to treat Gastrointestinal Stromal Tumors (GIST).[65] By waiting for the '184 patent to expire and then using a skinny label to exclude the patented indications for GIST, generic manufacturers were able to carve out the non-patented indications by using a skinny label.[66] Accordingly, the first generic versions of imatinib became available in February of 2016, almost six years before the expiration of the '335 patent.[67]

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[58] US Patent No. 6,958,335.

[59] Bryan S. Walsh et al., *Indication-Specific Generic Uptake of Imatinib Demonstrates the Impact of Skinny Labeling*, 40 J. Clinical Oncology 1102, 1102 (2022).

[60] *Id.*

[61] U-649 is the use code for "A method for treating a tumor disease." The Orange Book, 2022, *supra* note 25, at 1632; U.S. Patent No. 6,894,051 for Novartis listed under NDA 021335. *See* U.S. Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations 1249 (38th ed. 2018) [hereinafter The Orange Book, 2018].

[62] U-1883 is the use code for "Treatment of gastrointestinal stromal tumors (GIST)." The Orange Book, 2022, *supra* note 25, at 1671. U.S. Patent No. 6,958,335 for Novartis listed under NDA 021335 and NDA 021588. *See* The Orange Book, 2018, *supra* note 61, at 1249-50.

[63] U-791 is the use code for "Gleevec is also indicated for the treatment of patients with KIT (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST)." The Orange Book, 2022, *supra* note 25, at 1637.

[64] The Orange Book, 2018, *supra* note 61, at 1249-50.

[65] *Id.*

[66] Walsh et al., *supra* note 59, at 1103.

[67] *Id.*

In 2016, the FDA instituted regulations to help clarify "overbroad or ambiguous use codes that may delay approval of generic drugs."[68] Specifically, brand firms must identify and defend the method patents that are associated with the indications approved for its prescription drugs.[69]

The Orange Book allows only a 240-character description for the "use code."[70] These use codes, however, do not always match up identically with the patent claims.[71] Litigation invariably arises out of this ambiguity.[72] To address this issue, the FDA now requires that "the NDA holder's description of the patented method of use…must describe only the approved method(s) of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product."[73] Additionally, the brand firm must "identify with specificity the section(s) and subsections(s) of the approved labeling that describes the method(s) of use claimed by the patent submitted."[74] Courts, however, are still left to interpret if the ambiguous term "could reasonably be asserted."[75]

Also in the 2016 regulations, the FDA created a process for third parties to dispute the accuracy or relevance of a patent listing or use code by providing notice to the agency.[76] The FDA will then send this notice to the brand firm, who has 30 days to confirm the correctness of the patent information with a signed verification or withdraw or amend the listing.[77] The brand firm must also provide a narrative description with no more than 250 words "of the NDA holder's interpretation of the scope of the patent that explains why the existing or amended 'Use Code' describes only the specific approved method of use claimed by the patent for which a claim

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[68] Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. 69580 (Oct. 6, 2016) (to be codified at 21 C.F.R. pts. 314, 320).

[69] D'Amore, Keane & Doyle, *supra* note 35, at 10.

[70] *Id.*

[71] *Id.* at 10-11.

[72] *Id.* at 11 (referencing as examples *Caraco Pharm*, 566 U.S. 399 (2012); Hospira, Inc. v. Burwell, 2014 U.S. Dist. LEXIS 123972 (2014)).

[73] *Id.* (quoting 21 C.F.R. § 314.53(b)(1)).

[74] *Id.*

[75] *Id.* (quoting 81 Fed. Reg. 69580, 69581).

[76] *Id.* (referencing 21 C.F.R. § 314.53(f)).

[77] *Id.* (referencing 21 C.F.R. § 314.53(f)(1)(i)(A)).

of patent infringement could reasonably be asserted."[78] The brand's response will then be sent to the challenger and posted onto the FDA's website.[79]

Importantly the FDA does not independently review or evaluate the veracity of the brands firm's response.[80] This is consistent with FDA interpretation of its role in listing patent information as "purely ministerial" and that it "lacks both the resources and the expertise to police the correctness…of every patent listing submitted by an NDA holder."[81]

The use of FDA use codes has increased over the past two decades. In 1988, the Orange Book listed 340 unique patents and 61 distinct use codes, for an average of 0.18 use codes per patent.[82] By 2019, there were 7,919 use codes listed for 4,790 unique patents, or 1.65 codes per patent on average.[83] Between 1988 and 2019, the number of use codes per patent thus increased over ninefold.[84]

D. Induced Infringement & Skinny Labeling

Brand firms may be creating large patent thickets to generate a large number of patent use codes. Although each patent can be associated with any number of use codes, it may be advantageous to separate different patents into families with different use codes. This is because if one patent family is invalidated, brand firms can rely on a second patent family to sue based on the method of uses.[85]

The general rule is that the generic drug label must be the same as the brand's drug label.[86] One exception to this rule is if the brand-name drug is approved

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[78] *Id.* (quoting 21 C.F.R. § 314.53(f)(1)(i)(B)).

[79] *Id.*. (referencing 21 C.F.R. § 314.53(f)(1)(iii)).

[80] *Id.* (referencing 21 C.F.R. § 314.53(f)(1)(i)(B)(1)).

[81] *aaiPharma*, 296 F.3d at 237 (noting that the FDA does not substantively review the correctness of the patent information before publication); *see also Leavitt*, 548 F.3d at 106 ("FDA operates in a purely ministerial role"); *Am. Bioscience*, 269 F.3d at 1084 ("FDA [...] administers the Hatch-Waxman Amendments in a ministerial fashion"); 21 C.F.R. § 314.53(e) (2022); 68 Fed. Reg. 36,683 ("[O]ur patent listing role remains ministerial.").

[82] *See* Amicus Curiae Brief of 42 Professors at 9, Teva Pharm. USA, Inc. v. GlaxoSmithKline LLC, No. 22-37 (U.S. Aug. 10, 2022) [hereinafter Brief of 42 Professors], https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4186947.

[83] *Id.*

[84] *Id.*

[85] *See, e.g.*, Kearns v. Gen. Motors Corp., 94 F.3d 1553, 1555 (Fed. Cir. 1996) ("Each patent asserted raises an independent and distinct cause of action.").

[86] 21 U.S.C. § 355(j)(2)(A)(v).

for more than one use that is protected by separate patents or exclusivities.[87] In that case, generic drugs can omit the protected use from its labeling. In this way, the FDA may approve the generic drug for the use that is not protected by patents or exclusivities, so long as removal of the information does not diminish the information needed for safe use of the drug.[88] Brand manufacturers can obtain multiple patents and multiple FDA approvals for the same drug directed to different uses.[89] Each new "use patent" could be tied to a new indication, such as using the drug in a new patient population or to treat a different disease.[90]

Problems arise, however, when the primary patents expire while the secondary use patents are still unexpired and active. This is problematic because a generic company should be able to enter the market when the primary patents for the initial indication expire. Otherwise, brand firms would be able to extend their monopoly indefinitely by simply patenting new indications for their old drugs.

Congress recognized this issue and created a new generic approval pathway called "skinny labeling."[91] Skinny labeling allows generic manufacturers to seek approval for only the unpatented uses of the drug.[92] Generic manufacturers can "carve out" those uses for which there is no patent protection.[93] In sum, the FDA will approve an Abbreviated New Drug Application (ANDA) with a section viii statement only if (1) there is no overlap between the proposed label submitted by the ANDA applicant and the described use in the Orange Book, and (2) removing the information pertaining to the patented method of use from the label does not render the drug less safe or effective.[94]

These labeling issues are important because a generic company's drug label could result in "induced patent infringement."[95] In the pharmaceutical context,

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[87] 21 U.S.C. § 355(j)(2)(A)(viii).

[88] *Id.*

[89] *See, e.g.*, Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012) (noting "different varieties" of patents on drugs).

[90] 21 U.S.C. § 355(j)(2)(A)(viii).

[91] *See id.*

[92] *See id.*

[93] 21 U.S.C. § 355(j)(2)(A)(viii); *see also* AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1046 (Fed. Cir. 2010); Bayer Schering Pharma AG v. Lupin, Ltd., 676 F.3d 1316, 1318 (Fed. Cir. 2010).

[94] 21 C.F.R. § 314.127(a)(7); *see also*, Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676 and 36,681 (June 18, 2003).

[95] 35 U.S.C. § 271(b).

induced patent infringement requires: (1) a direct infringer (someone who practices the method claimed in the patent), (2) that the defendant *knowingly* induced infringement, and (3) that the defendant possessed the *intent* to encourage another's infringement.[96]

In the pharmaceutical context, a generic manufacturer may be liable for induced infringement of a patented method claim even where the FDA has not approved the generic product for use in accordance with the patented method.

E. The Current State of Skinny Label Litigation

Skinny labels have saved consumers billions of dollars by allowing generics earlier market entry.[97] Between 2015 and 2019, 43% of new generic drugs with multiple indications on their labels employed skinny labeling to avoid unexpired patented method of use claims.[98] Earlier entry has also likely saved consumers billions of dollars.[99] For biosimilars, skinny labels have led to an earlier market entry of 2.5 years with an estimated Medicare savings of $1.5 billion.[100]

This decades-long framework for skinny labeling carve outs has recently been put in jeopardy. The *GSK I* and *GSK II* cases set the stage for brand firms to prevent generics from entering the market using labeling.[101] By overturning the district court's decision, the Federal Circuit found that Teva, the generic manufacturer, induced infringement of GSK's patents.[102] The Federal Circuit found that the skinny label carve outs did not save Teva from liability.[103]

First in 2018, then district court Judge Stark, overturned a $235 million jury verdict finding that Teva induced infringement.[104] In reversing the jury verdict,

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[96] *Id.* (emphasis added); *see also* MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp., 420 F.3d 1369, 1378 (Fed. Cir. 2005).

[97] *See* Bryan S. Walsh et al., *Frequency of First Generic Drug Approvals With "Skinny Labels" in the United States*, 181 J. Am. Med. Ass'n Internal Med. 995 (2021).

[98] *See* Walsh et al., *supra* note 97, at 995; *see also* Alexander C. Egilman et al., *Frequency of Approval and Marketing of Biosimilars with a Skinny Label and Associated Medicare Savings*, 181 J. Am. Med. Ass'n Internal Med. 82 (2023).

[99] Walsh et al., *supra* note 97, at 995 tbl.

[100] Egilman et al., *supra* note 98, at 82.

[101] GlaxoSmithKline LLC v. Teva Pharms. USA, Inc. (*GSK I*), 313 F. Supp. 3d 582 (D. Del. 2018), *rev'd*, 976 F.3d 1347 (Fed. Cir. 2020); *GSK II*, 7 F.4th 1320 (Fed. Cir. 2021).

[102] *GSK I*, 976 F.3d 1347, 1355-57 (Fed. Cir. 2020); *GSK II*, 7 F.4th at 1326.

[103] *GSK II*, 7 F.4th at 1335.

[104] *GSK I*, 313 F. Supp. 3d at 591.

Judge Stark held that "the jury could not reasonably find that Teva caused doctors to infringe."[105] The court also found that there was "no direct evidence…that any doctor was ever induced to infringe the [GSK] patent by Teva's label (either skinny or full).[106] There was no direct evidence that Teva's label caused even a single doctor to prescribe generic [drugs] to a patient to treat [the patent protected indication]."[107]

In October of 2020, the Federal Circuit reversed the district court opinion and held that Teva induced physicians to prescribe a drug for an indication that had been carved out through Teva's skinny label.[108] The Federal Circuit then reinstated a $235 million jury verdict that was initially overturned by the district court judge.[109]

Criticism of the decision, including criticism from Henry Waxman (one of the sponsors of the Hatch-Waxman Act), led the Federal Circuit to reconsider the case in August of 2021.[110] The 2021 decision simply reaffirmed its 2020 decision,[111] and in 2022 the Federal Circuit denied the en banc request to rehear the case.[112]

In its 2021 opinion, the court found that Teva had not adequately removed the carved-out indication from their skinny label.[113] Specifically, the court found that Teva's labeling retained references to clinical trials, instructions for dosing and administration, and indications that could suggest or encourage physicians to prescribe the drug for the carved-out indication.[114] Additionally, the court found that a press release stated the drug was "AB-rated" which can lead to automatic substitution at the pharmacy.[115] Finally, the court found that GSK showed that Teva

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[105] *Id.* at 589

[106] *Id.* at 595

[107] *Id.*

[108] *Id.* at 1355-57 (Fed. Cir. 2020).

[109] *Id.* at 1355-56

[110] *Rehearing Confirms Induced Infringement Liability Despite Skinny Label*, Cooley (Aug. 17, 2021), https://www.cooley.com/news/insight/2021/2021-08-17-gsk-v-teva-federal-circuit-opinion-rehearing-induced-infringement-liability-skinny-label.

[111] *Id.*

[112] GlaxoSmithKline LLC v. Teva Pharms. USA, Inc. (*GSK III*), 25 F.4th 949, 950 (Fed. Cir. 2022) (en banc certiorari denied).

[113] *GSK II*, 7 F.4th at 1326.

[114] *Id.* at 1328-31.

[115] *Id.* at 1324

amended its labeling four years before the remaining patent protection expired to include the previously excluded indications.[116]

This case represents a sea change when it comes to skinny labeling. Judge Prost, in dissent, stated "[n]ow, no skinny-label generic is safe" and "because most skinny labels contain language that (with clever expert testimony) could be pieced together to satisfy a patent claim, essentially all of these cases will now go to trial."[117] Finally, Judge Prost states that:

> [T]he panel majority's decision doesn't just eliminate a generic's ability to depend on the skinny-label system; it also gives brands a powerful tactic: neglect to identify language as patent-covered, then sue a generic for including that very language. Ultimately, if playing by the skinny-label rules doesn't give generics some security from label-based liability, generics simply won't play. And who could blame them? The risk is too great.[118]

Teva has now asked the Supreme Court to review the case.[119]

II
Amarin v. Hikma

Post-*GSK*, brand firms now have a new tool to delay generic entry. Brand firms will likely engage generic manufacturers in a two-step strategy for litigation. The first wave of litigation will be the stereotypical Paragraph IV ANDA litigation. The second wave of litigation will be based on the FDA required labeling. The *Amarin I* and *Amarin II*[120] cases will likely be a prototype for future litigation based on this

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[116] *Id.* at 1325.

[117] *Id.* at 955.

[118] *Id.*

[119] Blake Brittain, *Teva takes $235 mln 'skinny label' dispute with GSK to U.S. Supreme Court*, Reuters (July 14, 2022, 12:24 PM EDT), https://www.reuters.com/legal/government/teva-takes-235-mln-skinny-label-dispute-with-gsk-us-supreme-court-2022-07-13/.

[120] After losing the labeling battle, a group made largely of Amarin shareholders asked the Supreme Court to override the invalidation of the patents claiming that both the Nevada federal judge and the Federal Circuit allowed fraud within the case. See Petition for a Writ of Certiorari at *i, Amarin Pharma, Inc. v. Hikma Pharms. USA Inc., No. 20-1119 (U.S. Feb. 11, 2021). This final attempt to revive the case by an intervenor plaintiff EPA Drug Initiative II (EPADI) was denied for lack of standing both at the district court and the Federal Circuit. *See* Amarin Pharma, Inc. v. Hikma Pharms. USA Inc., No. 2:16-cv-02525-MMD-NJK, 2021 WL 1722896 (D. Nev. Apr. 30, 2021), *aff'd sub nom.* No. 2021-2024, 2022 WL 456912 (Fed. Cir. Feb. 15, 2022) ("Because the Motion is untimely, EPADI was not a party to this case and lacks a

two-step process. However, depending on how broadly courts interpret the *GSK II* ruling, this litigation may delay or deter generics from entering the market.

Amarin's attempt to prevent generic competition came in two waves. In the first wave, Amarin lost its patents in an ANDA Paragraph IV litigation in a Nevada district court.[121] In an attempt to keep its exclusive rights, Amarin then moved venues to bring an induced infringement, in a Delaware court, based on the skinny label.[122]

The first stage was an attempt to sue for patent infringement in an ANDA litigation. Amarin lost this stage when a court invalidated all Amarin's relevant patent claims.[123] The second stage was based on "skinny" labeling. Amarin claimed that Hikma induced infringement of a second set of Amarin's patents because of Hikma's public statements and Hikma's product label.[124] Amarin was again unsuccessful in its labeling arguments as the district court dismissed the case.[125]

Although Amarin was unsuccessful in its bid to prevent the generic company from entering the market, these lawsuits increase the potential costs for competitors to enter the market or delay the entry of these valuable generics. So why would a pharmaceutical firm file a frivolous lawsuit? Vascepa's net sales were roughly $580 million in 2021.[126] Thus, even just a one-week delay would generate $11.2 million for Amarin.

A. Amarin's NDA & Hikma's ANDA

Amarin is the brand manufacturer for the drug Vascepa, a highly purified preparation of EPA (eicosapentaenoic acid), also known as icosapent ethyl.[127] Vascepa is used to treat severe hypertriglyceridemia (HTG), which is a condition

sufficiently protectable interest in it, and as further explained below, the Court will deny EPADI's Motion, and accordingly deny the motion to vacate as well."). This study does not examine the shareholder attempt to invalidate the ANDA judgment.

[121] *Amarin I*, 449 F. Supp. 3d at 971.

[122] *See Amarin II*, 578 F. Supp. 3d at 644.

[123] *Amarin I*, 449 F. Supp. 3d at 971.

[124] *Amarin II*, 578 F. Supp. 3d at 644-45.

[125] *Id.* at 648.

[126] *Amarin Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update*, *supra* note 1.

[127] *Amarin I*, 449 F. Supp. 3d at 973.

in which a patient's fasting triglycerides (TG) rise to very high levels (equal to or over 500 mg/dL).[128] Treating severe HTG patients with Vascepa reduces TGs without increasing low-density lipoprotein cholesterol ("LDL-C" also known as the "bad" cholesterol).[129] Vascepa also can reduce cardiovascular risk in severely hypertriglyceridemic patients on top of a statin, which is the only known treatment shown to confer such a benefit.[130] Thus, Vascepa offers benefits other known treatments cannot in the treatment for severe HTG.

The FDA first approved Vascepa in July 2012 as "an adjunct to diet to reduce triglyceride ("TG") levels in adult patients with severe ($\geq$500 mg/dL) hypertriglyceridemia.[131] The dosage of Vascepa is a 1 gram soft-gelatin capsule, with a daily dose of 4 grams per day taken as two 1 gram capsules twice daily with food.[132] Appendix 1 is a list of patents and expiration dates associated with Vascepa's NDA.[133] Additionally, Appendix 2 contains a list of present and past use codes associated with Vascepa.

In marketing its generic version of Vascepa, Hikma (as required by law) applied the same labeling as Vascepa, which was only approved for severe hypertriglyceridemia at the time of Hikma's ANDA filing.[134] Specifically, Hikma's label states that the product is to be used "as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe ($\geq$500 mg/dL) hypertriglyceridemia."[135] The dosage of Hikma's product is identical to Vascepa. After Hikma's ANDA filing, however, Amarin was able to acquire "FDA approval for a second indication for Vacepa—reducing the risk of adverse cardiovascular events."[136]

As shown in Appendix 1, Vascepa's product is currently associated with 67 patents.[137] These patents' expiration dates range from May 31, 2027, to June 28,

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[128] *Id.* at 972

[129] *Id.* at 973.

[130] *Id.*

[131] *Id.* at 973-74.

[132] *Id.* at 974.

[133] Orange Book Product Details for NDA N202057, Vascepa (icosapent ethyl) (500mg and 1gm) https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=202057#49 (visited July 21, 2022).

[134] *Amarin I*, 449 F. Supp. 3d at 974.

[135] *Id.* at 975 (quoting Hikma ANDA Application No. A209457).

[136] *Id.* at 974.

[137] Orange Book Product Details for NDA N202057, *supra* note 133.

2033. Additionally, these 67 patents are associated with 69 use codes (40 unique use codes). Appendix 2 contains the descriptions of each use code. It is worth repeating that the FDA does not check the substance of any of these patents or the associated uses. The FDA relies on the drug sponsor to honestly and accurately report patents associated with each drug.

B. Amarin's Patents & ANDA Litigation Loss

As described in Section I(B), when a generic wishes to enter the market before the brand firm's patents expire, they commonly file a "Paragraph IV" certification.[138] Under the Hatch-Waxman Act a Paragraph IV certification states that "[the] patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."[139] Thus, in July 2016, after Vacepa's initial period of exclusivity expired, Hikma filed an ANDA seeking FDA approval to market a generic version of Vascepa.[140] In a Paragraph IV certification, Hikma argued that Amarin's relevant patents were either invalid or non-infringed.[141]

Hikma's Paragraph IV certification attacked Amarin's U.S. Patent Nos.: 8,293,728 (the '728 patent); 8,318,715 (the '715 patent); 8,357,677 (the '677 patent); 8,367,652 (the '652 patent); 8,431,560 (the '560 patent); and 8,518,929 (the '929 patent).[142] Each of the patents share the same title, "Methods of Treating Hypertriglyceridemia" and are continuations of U.S. Patent No. 8,293,727 (the '727 patent) filed on February 9, 2010. Importantly, each of these patents share identical or near identical specifications.

In the ANDA litigation, the Nevada district court found that all Amarin's relevant patent claims were invalid because they were obviously over the prior art.[143] Specifically, the court found that the prior art "Lovaza PDR [(Physician's Desk Reference)] disclosed a commercially-available preparation of EPA and DHA

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[138] Hemphill & Sampat, *supra* note 45, at 624 (Figure 4, showing that 299 out of 692 drugs were subjected to Paragraph IV challenges).

[139] 21 U.S.C. §§ 355(b)(2)(A)(iv), (j)(2)(A)(vii)(I)–(IV). This is commonly referred to as a "Paragraph IV" certification.

[140] *Amarin I*, 449 F. Supp. 3d at 974 (stating that "[o]n or about July 26, 2016 Hikma…submitted to FDA an ANDA (ANDA No. 209457) with paragraph IV certifications").

[141] *See id.* at 974-75 (referencing Hikma ANDA Application).

[142] *Id.*

[143] *Id.* at 998

[(docosahexaenoic acid)]."[144] The reference states that "Lovaza is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with very high (>500 mg/dl) triglyceride levels."[145] The difference between the Lovaza reference and Amarin's patent claims was that Lovaza uses both EPA and DHA, while Amarin's patents use "purified EPA, but substantially no DHA."[146]

The Lovaza reference warned that the method of treatment could increase the patient's LDL-C levels.[147] However, a second reference, Mori, taught that DHA increased LDL-C levels, while purified EPA reduced triglycerides without increasing LDL-C.[148] Several other references also "taught that EPA did not increase LDL-C levels."[149] "[T]he Court [found] that a skilled artisan would have wanted to know which active ingredient in Lovaza—EPA or DHA—was responsible for the LDL-C increase (if not both)."[150] The court also found that the Mori reference addressed that exact issue, finding that it was the DHA and not the EPA that increased the LDL-C levels.[151]

Because increases in LDL-C levels could be attributed to DHA and not EPA, the court found that it would have been obvious for a person of ordinary skill in the art to treat patients suffering from severe HTG with purified EPA alone without DHA.[152] Accordingly, the district court found prima facie obviousness had been satisfied to invalidate the patents.[153] After weighing secondary considerations, the

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[144] *Id.* at 985

[145] *Id.*

[146] *Id.* at 992

[147] *Id.* at 992-93

[148] *Id.* at 993 (referencing Mori, et al., *Purified Eicosapentaenoic and Docosahexaenoic Acids Have Differential Effects on Serum Lipids and Lipoproteins, LDL Particle Size, Glucose, and Insulin in Mildly Hyperlipidemic Men*, 71 Am. J. Clinical Nutrition 1085-94 (2000)).

[149] *Amarin I*, 449 F. Supp. 3d at 993 (referencing Hayashi, et al., *Decreases in Plasma Lipid Content and Thrombotic Activity by Ethyl Icosapentate Purified from Fish Oils*, 56 Current Therapeutic Rsch. 24-31 (1995) *and* Kurabayashi, et al., *Eicosapentaenoic Acid Effect on Hyperlipidemia in Menopausal Japanese Women*, 96 Obstetrics Gynecology 521-8 (2000)).

[150] *Amarin I*, 449 F. Supp. 3d at 1007.

[151] *Id.*

[152] *Id.* at 1008-09.

[153] *Id.* at 1009.

court invalidated the patents as obvious.[154] The Federal Circuit later affirmed this ruling.[155]

The Hatch-Waxman Act works by allowing generics to challenge patents to come onto the market earlier, thus dramatically reducing prices for consumers.[156] If the *Amarin v. Hikma* story ended here, it would be a Hatch-Waxman success story. These erroneously granted patents prevented competition and cost consumers billions of added dollars while also harming patient welfare. By invalidating these patents, Hikma provided a service to American consumers. Unfortunately, this was only the first chapter in the *Amarin v. Hikma* story.

C. Amarin's Skinny Label Loss

The second chapter of the *Amarin v. Hikma* story revolves around skinny labeling and the FDA patent use codes. After losing the ANDA litigation in March 2020, Hikma launched its generic product in early November 2020.[157] However, armed with a second wave of new use patents, Amarin sued Hikma on November 30, 2020, for induced infringement on the methods of using Vascepa for the CV indication.[158] Specifically, Amarin alleged that Hikma's skinny label and website press releases induced doctors to infringe these patents.[159] At its heart, this skinny label lawsuit was a second bite at the apple filed with a different legal theory in a different legal forum.[160]

How was Amarin able to employ this strategy? From July 26, 2012, to December 12, 2019, the sole indication for Vascepa was treatment of severe

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[154] *Id.* at 1014-15.

[155] Amarin Pharma, Inc. v. Hikma Pharms. USA Inc., 819 Fed. Appx. 932 (Fed. Cir. 2020) (Rule 36 affirmance).

[156] *See* Aaron S. Kesselheim, Jerry Avorn & Arneet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 J. Am. Med. Ass'n 858, 861 (2016).

[157] Press Release, Hikma Pharm. PLC, Hikma Launches Icosapent Ethyl Capsules (Nov. 5, 2020), https://www.hikma.com/newsroom/article-i4928-hikma-launches-icosapent-ethyl-capsules/.

[158] *Amarin II*, 578 F. Supp. 3d at 643.

[159] Complaint at 92, 100-01, Amarin Pharma, Inc. v. Hikma Pharms. USA Inc., 578 F. Supp. 3d 642 (D. Del. 2022) (No. 1:20-cv-01630) [hereinafter Amarin Complaint]; *see also* Defendants' Opening Brief in Support of Motion to Dismiss at 2, Amarin Pharma, Inc. v. Hikma Pharms. USA Inc., 578 F. Supp. 3d 642 (D. Del. 2022) (No. 1:20-cv-01630) [hereinafter Hikma Defendants' Brief].

[160] The original ANDA case was filed in a Nevada district court. This second skinny label suit was filed in Delaware.

HTG (the "SHTG indication").[161] Thus, when Hikma filed the original ANDA, SHTG was the only indication for Vascepa. However, on December 13, 2019, the FDA approved Vascepa for the treatment of cardiovascular disease (the "CV indication").[162] Amarin was able to exploit a second wave of patents associated with new use codes to argue induced infringement based on Hikma's skinny label and press releases.

The CV indication was protected by a second wave of patents. Specifically, the CV indication patents include U.S. Patent Nos. 9,700,537 (the '537 patent); 8,642,077 (the '077 patent); and 10,568,861 (the '861 patent).[163] The '537 patent was listed on the Orange Book on January 10, 2020, under the use code U-2707 for the "[u]se of VASCEPA as an adjunct to statin therapy to reduce the occurrence of a cardiovascular event in an adult patient with hypercholesterolemia."[164] The '077 patent was listed on the Orange Book on January 6, 2020, under the use code U-2693 for the "[u]se of VASCEPA to reduce triglycerides in a mixed dyslipidemia adult patient with elevated triglyceride (TG) levels ($\geq$150 mg/dL) and on statin therapy."[165] The '861 patent was listed on the Orange Book on March 20, 2020, under the use code U-2756 for the "[u]se of VASCEPA as an adjunct to statin therapy to reduce the risk of cardiovascular death in an adult patient with established cardiovascular disease."[166]

Hikma argued that their skinny labeled product did not "actively induce infringement of patents covering a carved-out indication…because there can

[161] *See* Amarin Complaint, *supra* note 159, at 55.

[162] *See* Letter from John Sharretts, U.S. Food & Drug Admin., to Alex Giaquinto, Amarin Pharma Inc., Supplement Approval: NDA 202057/S-035 (Dec. 13, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/202057Orig1s035ltr.pdf (approving Vascepa "as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels ($\geq$ 150 mg/dL) and established cardiovascular disease or diabetes mellitus or 2 or more additional risk factors for cardiovascular disease" (bullet points removed)).

[163] *See, e.g.*, U.S. Pat. No. 9,700,537, col. 15, ll. 64–65 (claiming "method of reducing occurrence of a cardiovascular event in a hypercholesterolemia patient").

[164] *See* U.S. Food & Drug Admin., *Patent and Exclusivity for: N202057*, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (last visited Jan. 5, 2023) [hereinafter *Patents for N202057*], https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=002&Appl_No=202057&Appl_type=N.

[165] *See id.*

[166] *See id.*

be no inducement based on a generic product label unless it 'encourage[s], recommend[s], or promote[s] infringement.'"[167] Additionally, Hikma noted that "[m]erely describing the infringing use, or knowing of the possibility of infringement, will not suffice [for induced infringement liability]; specific intent and action to induce infringement must be shown."[168] Hikma also noted that not only did they omit the patented CV indication on its label, but they actively discouraged the carved out use in its press release. Specifically, its November 2020 press release stated, "Hikma's product is **not approved** for any other indication for the reference listed drug VASCEPA®."[169]

The Delaware district court found that Hikma's label gave no instructions that their product should be administered for the CV indication.[170] The court discussed labeling issues and public statements. With regards to the labeling, the court found that: (a) Hikma's notice regarding side effects was a warning and not an instruction to use the product for the CV indication, and (b) Hikma's removal of the CV risk reduction limitation was mere silence, and that Hikma did not have a duty to discourage infringing use.[171]

With regard to the press releases, the court also found that although Hikma's press releases might support intent to induce infringement, they do not support actual inducement because there was no inducing act.[172] Specifically, Amarin stated that Hikma's website advertised its product for "hypertriglyceridemia" which is broader than the "severe hypertriglyceridemia" included on the label.[173] The court pointed to the GSK and Gruenthal cases for the proposition that a label that includes both infringing and non-infringing uses does "not specifically encourage

[167] Hikma Defendants' Brief, *supra* note 159, at 2-3 (citing HZNP Meds. LLC v. Actavis Lab'ys. UT, Inc., 940 F.3d 680, 701-02 (Fed. Cir. 2019)).

[168] HZNP Meds. LLC v. Actavis Lab'ys. UT, Inc., 940 F.3d 680, 702 (Fed. Cir. 2019).

[169] Hikma Defendants' Brief, *supra* note 159, at 8 (citing its press release stating "Hikma's product is not approved for any other indication for the reference listed drug VASCEPA®"). (emphasis added) https://www.hikma.com/newsroom/article-i4928-hikma-launches-icosapent-ethyl-capsules.

[170] *Amarin II*, 578 F. Supp. 3d at 646.

[171] *Id.*; *see also* Takeda Pharms. USA, Inc. v. West-Ward Pharm. Corp., 785 F.3d 625, 632 n.4 (Fed. Cir. 2015) ("[T]he [brand firm] needs to show that [the generic firm] took affirmative steps to induce, not affirmative steps to make sure others avoid infringement.").

[172] *Amarin II*, 578 F. Supp. 3d at 647 ("Intent alone is not enough; Amarin must plead an inducing act.")

[173] *Id.*

use" of the generic for the patented treatment.[174] The court distinguished Hikma's disclosure that its product was "AB Rated" from the GSK case, because Hikma did not point to Vascepa's patented uses in describing itself as Vascepa's generic equivalent.[175] The court analogized the case to Gruenthal, where the genus of uses includes species of infringing and non-infringing uses, without specifically encouraging the use of the generic for the non-infringing uses.[176]

The Delaware court dismissed Amarin's case against Hikma because the labels did not recommend, encourage, or promote an infringing use.[177] Additionally, although the press releases might have been relevant to show intent to induce infringement, they did not support actual inducement because they did not instruct an infringing use.[178]

III
Amarin Patent Portfolio & Use Codes

Amarin's patent strategy is well-developed and built on a large patent thicket. Vascepa's patent thicket started out in 2013 with only six patents associated with one use code.[179] The earliest patent in this thicket expired on January 27, 2020. In contrast, in 2021 Vascepa's Orange Book patent thicket is associated with 67 patents associated with 40 different use codes.[180] Patents in the 2021 cohort have much later expiration dates, with many patents expiring on June 28, 2033. Additionally, not all Amarin's patent thicket is currently listed in the Orange Book. Amarin currently has a total of 132 patents directed towards various aspects of the product.[181]

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[174] *Id.* ("[E]ven if severe chronic pain includes polyneuropathic pain, it also includes mononeuropathic pain and nociceptive pain. Therefore, the proposed ANDA labels do not specifically encourage use of tapentadol hydrochloride for treatment of polyneuropathic pain." (quoting Grunenthal GMBH v. Alkem Lab'ys Ltd., 919 F.3d 1333, 1339 (Fed. Cir. 2019))).

[175] *Amarin II*, 578 F. Supp. 3d at 647.

[176] *Id.* (citing Grunenthal GMBH v. Alkem Lab'ys Ltd., 919 F.3d 1333, 1339 (Fed. Cir. 2019)).

[177] *Amarin II*, 578 F. Supp. 3d at 646-47.

[178] *Id.* at 647.

[179] The Orange Book, 2013, *supra* note 24 (U.S. Pat. Nos. 8,188,146, 8,293,727, 8,293,728, 8,298,554, 8,314,086, and 8,318,715. Where the '727, '728, '086 and '715 patents all have the U-1287 use code. The '146 patent expires on January 27, 2020; the '554 patent expires on April 29, 2030. All other patents expire on February 9, 2030.).

[180] See Appendix 1 and 2.

[181] USPTO Patent Full-Text and Image database Search (PatPF).

In this section we examine how Amarin was able to develop this patent thicket and we examine the prosecution history associated with the relevant patents used in the skinny labeling case. This study argues that the Amarin '077 patent family would likely have been invalidated based on lack of written description support for the method of use claims, had a challenge to the patents on these grounds been pursued.

A. ANDA Invalidated Patents / Skinny Label Asserted Patents

1. USPTO Patent Prosecution Event Summary

As of July 2022, Amarin has sixty-eight patents listed in the Orange Book for the Vascepa product.[182] Amarin, however, has 132 patents protecting various aspects of EPA, many of which are not listed in the Orange Book. There are only five original patents in this Orange Book patent thicket.[183] Sixty patents in this thicket arise from continuation applications and three come from divisional applications. These patents have four unique first named inventors: Mehar Manku (33 patents); Ian Osterloh (11 patents); Mitsuhiro Yokoyama (2 patents); and Paresh Soni (22 patents).

These Orange Book patents come from five different art units: 1628 (21 patents); 1615 (17 patents); 1629 (12 applications); 1611 (1 patent); and 1626 (17 patents). These patents were examined by nine unique examiners: Marcos Sznaidman (20 patents); Aradhana Sasan (17 patents); James Anderson (1 patent); Kevin Weddington (4 patents); Michael Schmitt (2 patents); Barbara Frazier (1 patent); Kristin Vajda (17 patents); Jennifer Kim (1 patents); and Savitha Rao (5 patents). The earliest filing date was February 9, 2010[184] and the latest filing date was August 12, 2021.[185] The earliest issue date from this thicket was October 23, 2012[186] and the latest issue date was April 12, 2022.[187]

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[182] The Orange Book, 2022, *supra* note 25, at 1396–98.

[183] Original patents are patents that do not have priority documents. These five patents are: US Patent Nos. 8,293,727; 8,298,554; 9,603,826; and 10,668,042.

[184] U.S. Patent No. 8,293,727.

[185] U.S. Pat. No. 11,298,333.

[186] U.S. Pat. No. 8,293,727.

[187] U.S. Pat. No. 11,298,333.

Among Amarin's patents, rejections for obviousness-type double patenting (ODP) were common.[188] Overall, 53% (37 of 68) patents encounter at least one ODP rejection.[189] However, when we look at the most recent patents filed after January 1, 2015, we see that 74% (23 of 31) patents encounter at least one ODP rejection.[190] These data suggest that as time progresses, the patent portfolio is increasing, but filling up with more secondary follow-on type patents.

2. FDA Event Summary

Amarin started their patent portfolio with patents directed almost exclusively to the use code U-1287, which corresponds to "methods of reducing [triglyceride] levels in patients suffering from severe hypertriglyceridemia."[191] In fact, all six patents that were asserted in the ANDA litigation were only directed to the U-1287 use code.[192] Table 1 summarizes the patents and use codes associated with the patents asserted in the ANDA litigation.[193] Furthermore, as shown in Figure 1, all parent and child patents of the ANDA litigated patents were directed to the U-1287 use code.

[188] To determine these statistics, we obtained records of patent applications for LexisNexis's Patent Advisor service. *See Bring Predictability and Productivity to Your Patent Prosecution Process With LexisNexis PatentAdvisor*, LexisNexis (last visited Jan. 5, 2023), https://www.lexisnexisip.com/solutions/patent-prosecution/patentadvisor/. Patent Advisor identifies, for each patent application, whether it has received an ODP rejection at some point during prosecution.

[189] *See, e.g.*, Non-Final Rejection *in* U.S. Patent Application No. 12/702,889 (June 20, 2011).

[190] *See, e.g.*, Final Rejection *in* U.S. Patent Application No. 16/775,521 (Sept. 1, 2020).

[191] U.S. Food Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations: Orange Book (33rd ed. 2013) (U.S. Pat. Nos. 8,188,146, 8,293,727 8,293,728, 8,298,554, 8,314,086, and 8,318,715. Where the '727, '728, '086, and '715 patents all have the U-1287 use code).

[192] *See* Amarin Pharma v. Hikma Pharms. United States, 449 F.Supp. 3d 967, 971 (2020) (identifying litigated patents); The Orange Book, 2018, *supra* note 61, at ADA123 (noting use codes for patents).

[193] The table is based on data from the FDA's online Orange Book database. *See Patents for N202057*, *supra* note 164.

TABLE 1
PATENTS AND USE CODES INVOLVED IN ANDA LITIGATION

Patent No.	Litigation	Use Code	Patent Expiration Date	FDA Submission Date
8,293,728	ANDA	U-1287	2/9/2030	6/26/2017
8,318,715	ANDA	U-1287	2/9/2030	6/26/2017
8,431,560	ANDA	U-1287	2/9/2030	
8,518,929	ANDA	U-1287	2/9/2030	
8,357,677	ANDA	U-1287	2/9/2030	6/26/2017
8,367,652	ANDA	U-1287	2/9/2030	6/26/2017
8,642,077	Skinny Label	U-2693	4/29/2030	1/6/2020
10,568,861	Skinny Label	U-2756	6/28/2033	3/20/2020
9,700,537	Skinny Label	U-2707	5/31/2027	1/10/2020

FIGURE 1
PATENTS INVALIDATED IN ANDA LITIGATION (IN BOLD) AND RELATED PATENTS

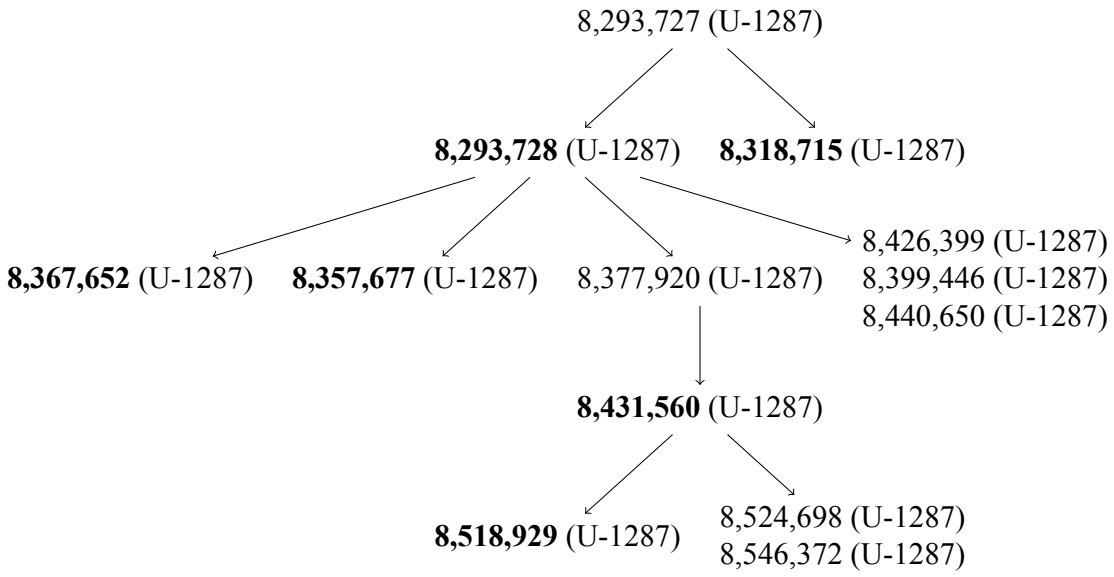


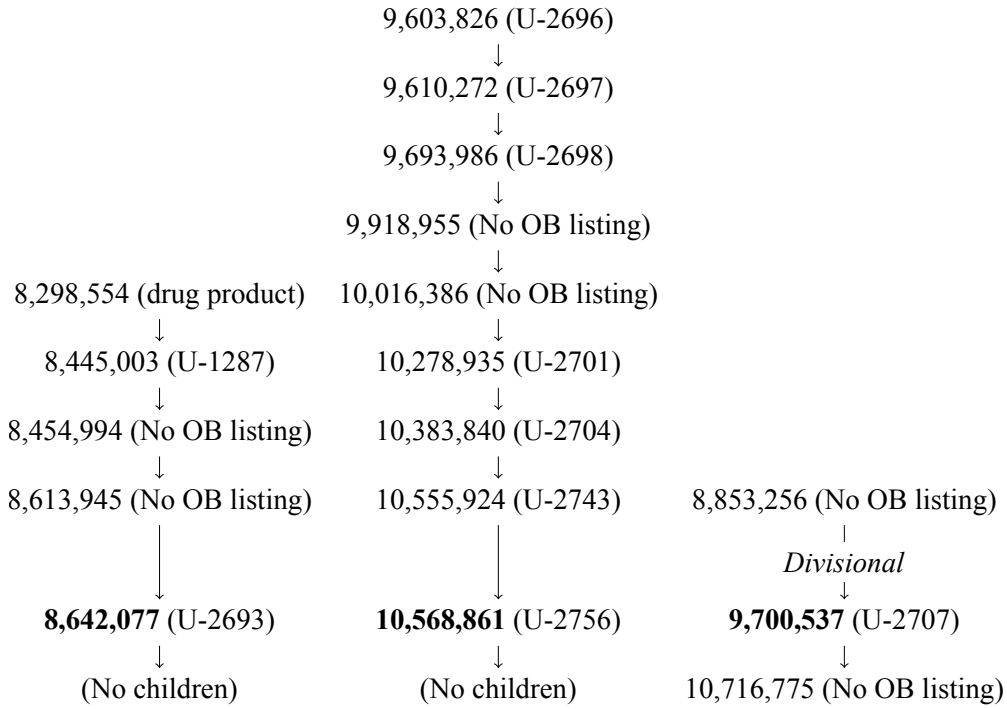
Figure 1 highlights the patent family for the patents that were invalidated (in bold). Most patents that were challenged in the ANDA litigation claimed priority to U.S. Patents Nos. 8,293,727 (the '727 patent), 8,293,728 (the '728 patent) and 8,377,920 (the '920 patent).[194] All patents in the family have the same use code (U-

[194] *See, e.g.*, U.S. Patent No. 8,518,929, at col. 1, ll. 4–13 (filed Feb. 25, 2013) (noting priority claim of patent).

1287).[195] Finally, all patents in this family were continuation applications from the parents to the children. This is significant because these continuation applications have almost identical specifications.[196]

Table 1 and Figure 2 highlight the skinny labeled patent family (patents asserted in bold). US Patent Nos. 8,642,077 (the '077 patent), 10,568,861 (the '861 patent), and 9,700,537 (the '537 patent) were associated with use codes U-2693, U-2756, and U-2707 respectively. Table 2 designates the definitions associated with the relevant use codes. Both the '077 and '861 patents are continuation applications of several patents. In contrast the '537 is a divisional application of US Patent No. 8,853,256 (the '256 patent). For this study, we focus on the '077 patent family and specifically the relationship between the '077 patent and its parent, US Patent No. 8,445,003 (the '003 patent) (Figure 2, in bold).

FIGURE 2
PATENTS ASSERTED IN SKINNY LABEL LITIGATION (IN BOLD) AND RELATED PATENTS



[195] *See* THE ORANGE BOOK, 2018, *supra* note 61, at ADA123.

[196] *See* Transco Prods. Inc. v. Performance Contracting, Inc., 38 F.3d 551, 555–56 (Fed. Cir. 1994) (noting requirement that continuation applications be "based on the same disclosure as an earlier application").

TABLE 2
USE CODE DESCRIPTIONS

Code	Description
U-1287	METHOD OF REDUCING TG LEVELS IN PATIENT SUFFERING FROM SEVERE HYPERTRIGLYCERIDEMIA
U-2693	USE OF VASCEPA TO REDUCE TRIGLYCERIDES IN A MIXED DYSLIPIDEMIA ADULT PATIENT WITH ELEVATED TRIGLYCERIDE (TG) LEVELS (>= 150 MG/DL) AND ON STATIN THERAPY
U-2756	USE OF VASCEPA AS AN ADJUNCT TO STATIN THERAPY TO REDUCE THE RISK OF CARDIOVASCULAR DEATH IN AN ADULT PATIENT WITH ESTABLISHED CARDIOVASCULAR DISEASE
U-2707	USE OF VASCEPA AS AN ADJUNCT TO STATIN THERAPY TO REDUCE THE OCCURRENCE OF A CARDIOVASCULAR EVENT IN AN ADULT PATIENT WITH HYPERCHOLESTEROLEMIA

B. Obviousness & the Skinny-Label Patents

It is important to understand how Amarin was able to create this patent thicket and how they were able to obtain patents directed to so many different use codes. For this study we will focus on the relationship between the '077 patent used in the skinny label litigation and the patents invalidated in the ADNA litigation. Understanding the relationship between the invalidated ANDA patents and the '077 patent asserted for the skinny label litigation explains why Amarin's skinny label litigation was particularly egregious. Figure 3 details the relationship between the '077 patent and the ANDA invalidated patents.

In sum, the '077 patent[197] is the great-grandchild of the '003 patent. The specifications of the '077 and '003 patents are nearly identical. Amarin filed a terminal disclaimer for the '003 patent linking them to the '728, '715, '677 and '652 patents, which were all invalidated in the ANDA litigation. Additionally, as discussed below, written description support for the use of Vascepa to reduce

[197] *See* U.S. Patent No. 8,642,077. The '077 patent is the great great great grandchild of the 61/173,763 provisional application (the '763 provisional). In fact, the '763 provisional serves as the priority document for 26 other Amarin patents. The first child patent to come out of the '763 provisional was U.S. Patent No. 8,298,544 (the '544 patent). Additionally, the '554 patent has 25 patents that claim priority to the '544 patent. The '554 patent is important because it is currently the only patent directed to a drug product (formulation and composition patents). All other patents were directed towards method of uses.). See also Figure 3 and THE ORANGE BOOK, 2022, *supra* note 25, at 1652, 1703-04, 1706.

triglycerides in a mixed dyslipidemia adult on statin therapy with elevated TG levels is not found in either the '003 or the '077 patents.

The '077 patent was likely filed to prevent Hikma from using its product to treat patients on statin therapy with TG levels equal to or above 150 mg/dL (use code U-2693). However, this patent claimed priority to the '003 patent, which was directed towards a method of reducing TG levels in patients with SHTG (use code U-1287), which relates to Hikma's skinny label carved out U-1287 use.

The key problem with the '077 patent is that the '003 great grandparent used a terminal disclaimer to overcome an anticipated obviousness type double patenting rejection from the examiner. On October 2, 2012, the patent examiner identified "double patenting issues with numerous co-pending cases."[198] Furthermore, obviousness-type double patenting issues were discussed in an October 10, 2012 phone call.[199] In response, the applicant filed 17 terminal disclaimers to "obviate a provisional double patenting rejection over a pending 'reference' application."[200] In explaining the rationale for allowance, the examiner stated that Applicants filed Terminal Disclaimers on 10/22/2012 over the following copending applications, thereby obviating the need for any obviousness-type double patenting rejections, as discussed in the telephonic interview of 10/10/2012.[201]

Filing these terminal disclaimers is important because terminal disclaimers can be an admission that the application is obvious over a prior patent in the same family.[202] In this case, it is relevant that the applicant filed a terminal disclaimer for the '003 patent, which suggests that the '003 patent is obvious in light of the '728, '715, '677, and '652 patents. This is important because all these patents were previously invalidated for obviousness in the ANDA litigation.[203] While the

[198] U.S. Patent Application No. 13/458,496, Applicant Initiated Interview Summary filed Oct. 17, 2012 (filed Apr. 27, 2012).

[199] *Id.*

[200] Seventeen terminal disclaimers were filed on October 22, 2012, using the PTO/SB/25 form which is a "Terminal Disclaimer to Obviate a Provisional Double Patenting Rejection Over a Pending 'Reference' Application."

[201] U.S. Pat. Application No. 13/458,496, Notice of Allowance filed Feb. 1, 2013 (filed Apr. 27, 2012).

[202] *See* Letter from Katherine K. Vidal, U.S. Patent & Trademark Off., to Robert M. Califf, U.S. Food & Drug Admin., at 6 (July 6, 2022), https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf (discussing terminal disclaimers used to overcome obviousness-type double patenting).

[203] *See Amarin I*, 449 F. Supp. 3d 967, 1014 (D. Nev. 2020).

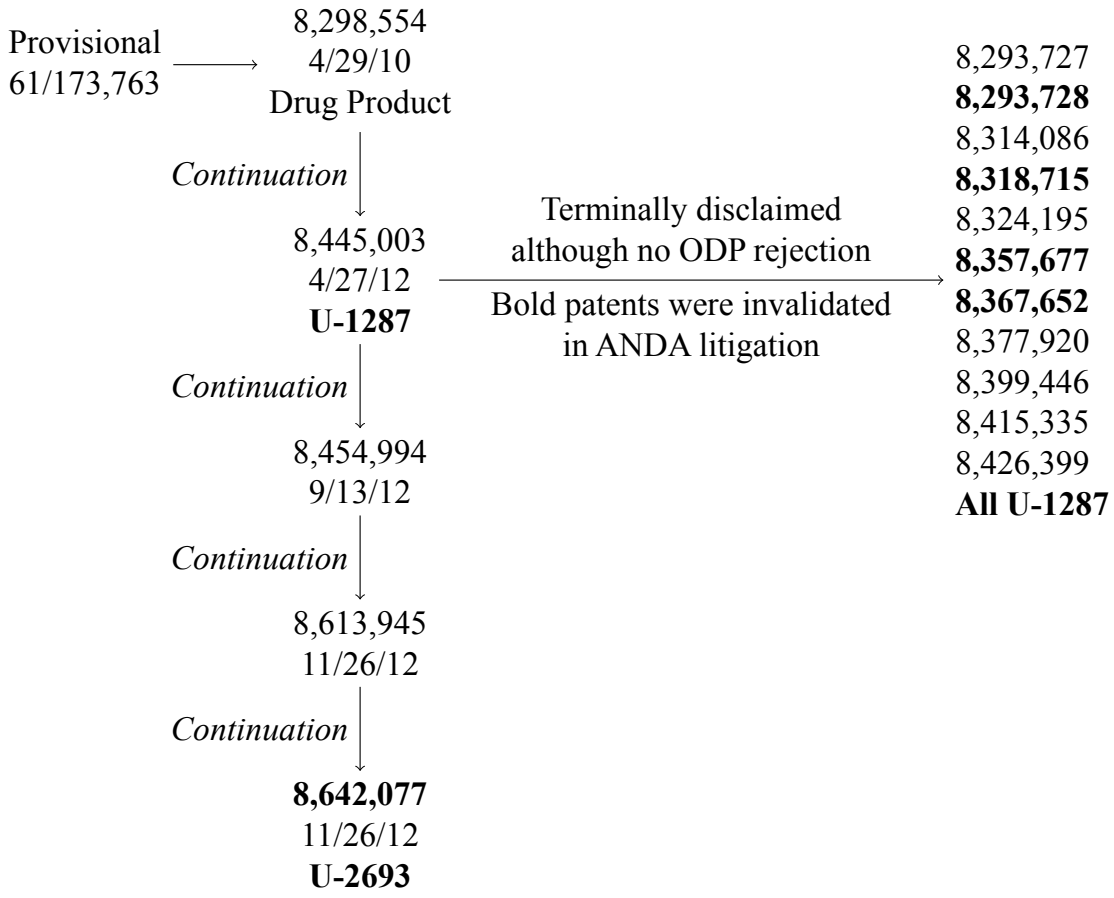
validity of the '003 patent must of course ultimately be determined on their own merits, the close relationship between the '003 patent and the invalidated ANDA-litigation patents suggests, at a minimum, serious questions about the validity of the former.[204]

Interestingly, originally in 2013, Vacepa was listed in the orange book with a "Drug Substance" and "Drug Product" code associated with U.S. Patent No. 8,188,146 (the '146 patent). This patent had the earliest expiration date (January 27, 2020) of the entire Orange Book patent family. Interestingly, the '146 patent discloses the composition of matter but is directed towards the use of Vascepa for psychiatric or central nervous system disorders.[205]

[204] To be sure, there are two forms of "obviousness" at play: The relationship between the '003 patent and the ANDA-litigation patents is based on the judicially created doctrine of obviousness-type double patenting, while the invalidity of the ANDA-litigation patents was premised on obviousness under 35 U.S.C. § 103. Nevertheless, the two doctrines have a relevant relationship. The '003 patent would be invalid for obviousness-type double patenting over an ANDA-litigation patent if the former patent's claims "are obvious over the [latter] patent claims." *In re* Janssen Biotech, Inc., 880 F.3d 1315, 1325 (Fed. Cir. 2018) (quoting *In re* Basell Poliolefine Italia SPA, 547 F.3d 1371, 1376 (Fed. Cir. 1998)). To the extent that the prior art is sufficiently close to the ANDA-litigation patent so as to render that patent obvious under § 103, then the prior art is likely also very close to the '003 patent as well.

[205] U.S. Pat. No. 8,188,146 col. 2, ll. 18–30 (The diseases listed include: "schizophrenia, schizoaffective disorder or a schizotypal disorder; depression or manic-depression (bipolar disorder); anxiety or panic disorder or social phobia, or a sleep disorder or an attention deficit, conduct, hyperactivity or personality disorder; autism; Alzheimer's disease, vascular dementia or another dementia, including multi-infarct dementia, Lewy body disease and diseases attributable to prion disorders; Parkinson's disease, or other motor system disorder; multiple sclerosis; stroke; epilepsy; and Huntington's disease or any other neuro-degenerative disorder.").

FIGURE 3
RELATIONSHIPS BETWEEN THE '077 PATENT AND ANDA LITIGATION PATENTS.



C. Written Description & the Skinny-Label Patents

In addition to the questionable validity of the skinny-label patents in view of obviousness, there are questions about the validity of those patents under the written description requirement of 35 U.S.C. § 112(a). Under that statute, the specification of a patent must "describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application."[206] The written description requirement is satisfied if "the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing

[206] LizardTech, Inc. v. Earth Res. Mapping, Inc, 424 F.3d 1336, 1345 (Fed. Cir. 2005); *See also* 35 U.S.C. § 112(a).

date."[207] A sufficient description of a genus requires the specification to disclose "either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus."[208]

In the pharmaceutical and other medical arts, applications claiming new methods of treatment are typically supported by test results.[209] Applicants cannot satisfy the written description requirement by simply presenting a "laundry list" of compositions that might or might not meet the claimed invention.[210] The Supreme Court stated that "[a] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."[211] Similarly, the Federal Circuit has described the task of meeting the written description requirement as being akin to providing "blaze marks which single out particular trees in a forest, rather than simply pointing to trees."[212]

The '077 patent looks in many ways like that forest with no blaze marks. The specification is directed towards stable pharmaceutical compositions of highly pure eicosapentaenoic acid (EPA). The '077 patent discloses huge laundry lists of concentrations; weights of EPA, purity of EPA; capsule shells with specific baseline peroxide values; film-forming material and plasticizer weight ratios; concentration of degradation products; treatment and/or prevention of cardiovascular disease (as defined as a "disorder of the heart or blood vessels or any symptom thereof, or any disease or condition that causes or contributes to a cardiovascular disease" with 57 non-limiting examples); different treatment groups (at least 89 different groups); treatment periods (1 week to 200 weeks); 25 different outcomes (each outcome having about 12 possible ranges); and dosing amounts (1-10,000 mg and 103 different concentrations).

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[207] Ariad Pharms., Inc. v. Eli Lilly Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

[208] *Id.* at 1350.

[209] *In re* '318 Pat. Infringement Litig., 583 F.3d 1317, 1324 (Fed. Cir. 2009).

[210] Novozymes A/S v. DuPont Nutrition Biosciences APS, 723 F.3d 1336, 1345-46 (Fed. Cir. 2013); Fujikawa v. Wattanasin, 93 F.3d 1559, 1571 (Fed. Cir. 1996); Purdue Pharma L.P. v. Iancu, 767 F. App'x 918, 924 (Fed. Cir. 2019).

[211] Brenner v. Manson, 383 U.S. 519, 536 (1966).

[212] Idenix Pharms. LLC v. Gilead Sci., Inc., 941 F.3d 1149, 1164 (Fed. Cir. 2019) (internal quotation marks omitted).

The specification focuses on a host of different variables, including: (a) EPA amount (50-5000 mg in 102 different possible concentrations)[213]; (b) addition of antioxidants (0.01% to 0.1% or 0.025% to 0.05%)[214]; lack of docosahexenoic acid (DHA)[215]; EPA concentrations (60-100%, with at least 23 different concentrations).[216] The discussion of all of the embodiments of the invention is very general in nature and lacks any disclosure regarding which compositions produce the results set forth in the patents' claim and use code.

The claims of the '077 patent fail the written description requirement on almost every level. Specifically, there are no examples showing how Vascepa is used to reduce triglycerides in patients with mixed dyslipidemia. Mixed dyslipidemia is mentioned three times in the entire specification. The first time mixed dyslipidemia is mentioned is in a laundry list of 57 other indications.[217] The second time mixed dyslipidemia is mentioned is in the framework of a blood lipid therapy.[218] Finally, the '077 patent only states in a conclusory fashion that the invention can treat or prevent mixed dyslipidemia by "administering to the patient one or more compositions as disclosed herein."[219] There are no disclosures regarding which concentrations or formulations are effective. Furthermore, there is no disclosure explaining why patients having triglyceride levels of $\geq$150 mg/dL is relevant. Finally, there is no discussion on why patients need to be on statins therapy. In fact, contradicting the use of statins, the '077 patent discloses that one embodiment of the invention is directed to treatment when a statin is considered inadequate.[220]

The formulation and dosage limitations in the asserted claims of the '077 patent are broad. All the asserted claims recite daily dosages from 2500 mg to 5000 mg.[221] Based on the specification of the '077 patent, it would be difficult to determine which concentrations, which dosage regimens, and which formulations

[213] U.S. Pat. No 8,188,146, col. 3, l. 6-35.
[214] *Id.* at 1. 37-43
[215] *Id.* at 1. 44-55
[216] *Id.* at col. 3-5.
[217] U.S. Pat. No. 8,642,077, col. 15, l. 26-55.
[218] *Id.*, col. 16, l. 7-10.
[219] *Id.* at 1. 1-2.
[220] *Id.* at l. 2-7.
[221] Accordingly, the '077 patent may be invalidated based on the lack of written description support for the claimed ranges. *See* Indivior U.K. Ltd. v. Dr. Reddy's Lab'y, Inc., 18 F.4th 1323, 1328-30 (Fed. Cir. 2021).

would be effective for treating patients with mixed dyslipidemia. Additionally, it is not even clear that all patients with mixed dyslipidemia would benefit from this therapy.[222]

The specification contains a long list of EPA formulations, but does not identify which of these formulations can satisfy the recited functional limitations when administered in the amounts specified in the claims. In fact, there are no examples of administering the drug to any patient. Simply providing lengthy and detailed listings of various excipients and concentrations that can be used to formulate Vascepa does not provide written description support for the asserted method claims.[223] Additionally, the specification does not describe the structural features that might be in common with compositions that would work across the full scope of the claims. In this case, the claims of the patent are broad and there are no operative species disclosed in the specification. Accordingly, the specification of the '077 patent does not identify which formulations would satisfy the recited functional limitations when administered in the specified amount in the claims.[224] To the extent that the '077 patent might pass muster under 35 U.S.C. § 112(a), that suggests that the written description doctrine is failing to sufficiently police these "laundry list" patents of questionable innovative value.[225]

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[222] The '077 patent states that one embodiment of the invention provides "a method of reducing triglyceride levels in a subject or subjects when treatment with a statin or niacin extended-release monotherapy is considered inadequate . . ." U.S. Pat. No. 8,642,077, col. 22 l. 3-6 (suggesting that treatment with statins may be ineffective for some patients).

[223] *See* Novozymes A/S v. DuPont Nutrition Biosciences APS, 723 F.3d 1336, 1345-46 (Fed. Cir. 2013); Fujikawa v. Wattanasin, 93 F.3d 1559, 1571 (Fed. Cir. 1996); Lipocine Inc. v. Clarus Therapeutics, Inc., 541 F. Supp. 3d 435 (D. Del. 2021).

[224] *See also* Lipocine Inc. v. Clarus Therapeutics, Inc., 541 F. Supp. 3d 435, 462-63 (D. Del. 2021) (showing that the testosterone undecanoate drug patent contained a long list of formulations but failed the written description requirement because the specification did not describe which formulations would produce the claimed results).

[225] In *Union Oil Co. v. Atlantic Richfield Co.*, the Federal Circuit declined to invalidate a patent directed to a composition of gasoline under the written description requirement of § 112. *See* 208 F.3d 989, 1001 (Fed. Cir. 2000). In dissent, Judge Lourie questioned how the written description requirement could be satisfied by a patent claim where the features were scattered throughout and "[o]ne must pick and choose among eight different types of fuel characteristics, broadly described, in order to arrive at any of the claimed combinations." *Id.* at 1004 (Lourie, J., dissenting). Insofar as Judge Lourie was in the minority, *Union Oil* suggests that at least some Federal Circuit judges are willing to read the written description requirement especially generously.

D. The Patent Quality Disconnect

Why was Amarin interested in creating a large patent thicket based on secondary method of use patents of questionable validity? Most likely it was to protect Vascepa's revenues, which have recently been about half a billion dollars a year.[226] These patents likely are used to delay generic market entry. For 2021, with Vascepa as its primary product, Amarin made about $1.59 million a day.[227] The cost of filing a complex biotechnology patent thicket is relatively inexpensive, with an average cost of $11,657 per patent.[228] Additionally, the average cost of a litigation when more than $25 million is at risk is approximately $5.7 million.[229] Thus, building and litigating a complex patent thicket pays for itself with about one or two weeks' worth of sales.

Many commentators have focused on the creation of patent thickets to evergreen patents.[230] Previous studies indicate that patent thickets comprised of "secondary" less innovative patents are the ones that are playing a role in delaying generic entry. Creation of these patent thickets may play an important role in delaying or preventing generics from entering the market. The *Amarin* case study shows that these secondary patents can play a role not only in protecting the product during ANDA litigation but can play a role in a "second wave" of litigation based on drug labeling requirements.

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[226] *See* Amarin Corp., Annual Report (Form 10-K), at F-5 tbl. (Mar. 1, 2022).

[227] *See id.* (noting $580 million in revenues for 2021).

[228] Am. Intell. Prop. L. Ass'n L. Pract. Mgmt. Comm., AIPLA 2021 Report of the Economic Survey I-100 Q40c (2021) (showing that the average cost for a complex biotechnology/chemical utility application is $11657, and the median cost is $10,250); *see also* AIPLA 2021 Report of the Economic Survey I-102 Q40g (2021) (showing that the average amendment/argument for a complex biotechnology/chemical patent is $4,574, and a median cost of $3,500).

[229] *Id.* at I-148 Q45Ao (showing that the average cost of patent infringement litigation (including pre-trial, trial, post-trial and appeal) is $5,768,000 with a median of $4,000,000 when more than $25 million is at risk).

[230] *See* Robin Feldman, *May Your Drug Price be Evergreen*, 5 J.L. & Biosciences 5990 (2018); *see also* Bo Wang, Jun Liu & Aaron S. Kesselheim, *Variations in Time of Market Exclusivity Among Top-Selling Prescription Drugs in the United States*, 175 J. Am. Med. Ass'n Internal Med. 635 (2015).

IV
Policy Solutions

A. The PTO Should Institute Enhanced Review of Orange Book Patents

There are several simple solutions that the PTO could institute that would not require Congressional intervention. First, the PTO could require applicants to identify their patents as potential Orange Book patents so that the PTO could give them to the appropriate examiners. These patents could go to a special art unit that uses team examination with added support. Second, the PTO and FDA should collaborate to verify the information that is submitted to the FDA for Orange Book listing. Third, the PTO should increase the fees associated with serial continuation applications. Finally, the PTO could abolish the use of terminal disclaimers to obviate an obviousness type double patenting rejection.

1. Flag Orange Book Applications for Team Examination

The PTO could play a larger role in preventing these patent thickets from developing. The PTO could require applicants to flag patents that would be listed on the Orange Book in advance. Additionally, the PTO could pay closer attention to those patents in large families that would receive obviousness-type double patenting rejections. Congress could create an FDA reexamination procedure to correct incorrectly granted patents based on clinical information and/or disclosures made by the applicant to the FDA. Finally, the FDA could work in conjunction with the PTO to substantively review the Orange Book listings to make sure that the products and methods listed in the Orange Book match with the claims of the patent.

The PTO could require applicants to flag their patents that would be placed in the Orange Book if the claims were to be issued.[231] These applications would then be sent to an Orange Book art unit that would use three experienced examiners instead of just one examiner. Additionally, one team member should be versed in FDA approval procedures to help flag the relevant information for review.

This new art unit could be given access to specialized tools, such as AI prior art searching. Others have suggested that giving examiners more time could result

[231] Tu & Lemley, *supra* note 19, at 1708-12 (arguing for applicant disclosure of Orange Book patent applications).

in better examination.[232] Although we show that added time will likely not result in better examination, this special art unit could be given extra time as a pilot program to determine if added time results in stronger examination.[233]

Using a team examination approach would cost the PTO slightly more than the single examiner approach. However, this cost would be more than offset by preventing patent thickets, where even one erroneously granted patent has been shown to cost the public over $2 billion in added drug costs.[234]

2. PTO & FDA Collaboration to Verify Orange Book Information

Currently, the FDA does not substantively examine or verify the accuracy of information placed in the Orange book. FDA sees its role in managing the Orange Book as "purely ministerial" and that it "lacks both the resources and the expertise to police the correctness. . . of every patent listing submitted by an NDA holder."[235] The FDA should work in conjunction with the PTO to independently review the information submitted by applicants. The PTO has the expertise to examine and determine if the use codes associated match the claims of the patents. If not, they should not be given the use codes. This simple check would help reduce the patent thickets created by new use codes, which currently go unexamined.

3. Increased Fees & Scrutiny for Late-Stage Continuation Applications

The PTO could also target these patent thickets without legislation. The PTO could create a tiered fees system associated with each additional continuation application. These fees would increase stepwise for each new generation. For example, fees associated with child application would only be 1.5 times the normal fees, while fees associated with grandchildren would be four or five times the normal fees. Maintenance fees associated with these patents should also increase

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[232] Michael D. Frakes & Melissa F. Wasserman, *Irrational Ignorance at the Patent Office*, 72 VAND. L. REV. 975, 981 (2019); Michael D. Frakes & Melissa F. Wasserman, *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination* 4–7 (Nat'l Bureau of Econ. Rsch., Working Paper No. 27579, 2020).

[233] Tu & Lemley, *supra* note 19, at 1709-1710.

[234] David Miller et al., *The Costs of Delayed Generic Drug Entry: Evidence from a Controversial Prostate Cancer Drug Patent*, J. GEN. INTERNAL MED. (July 13, 2021) (showing that an inappropriately awarded secondary patent cost consumers $2 billion).

[235] *aaiPharma*, 296 F.3d at 237 (noting that the FDA does not substantively review the correctness of the patent information before publication); *see also Leavitt*, 548 F.3d at 106; *Am. Bioscience*, 269 F.3d at 1084; 21 C.F.R. § 314.53(e) (2022); *see also* 68 Fed. Reg. 36,683.

stepwise with each new patent generation. This would place pressure on applicants to remove fourth or fifth generation patents that may not be adding value but are only used to delay or deter generic market entry.[236] Increasing PTO fees may deter brand firms from filing dozens of follow-on patents to create large thickets that increase competitor transaction costs.

4. Limit Terminal Disclaimers as a Response to Obviousness-Type Double Patenting Rejections

The PTO could apply stricter scrutiny to those continuation applications that come from large patent families to determine if there is something patentably different from other family members. This is especially true if these patent families would receive obviousness type-double patenting rejections and if terminal disclaimers have already been filed for other family members. A group of senators led by Patrick Leahy have suggested the possibility of tying patents together when those patents are linked by terminal disclaimers. They suggest that filing a terminal disclaimer may be considered an admission of obviousness and may make it so that all of these patents would stand and fall together if litigated.[237]

Alternatively, the PTO could impose new limitations on the ability of a terminal disclaimer to overcome an obviousness type-double patenting rejection.[238] With sufficiently effective limitations, applicants would then have to focus on the differences between their current application and their previous patents and show that the claims are non-obvious variations of their previously patented claims.

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[236] One counterpoint is that given the immense value to pharmaceutical companies in even short delays in generic entry, it may be unlikely that higher filing fees will do much to deter abusive filing practices. See Erik Hovenkamp & Stephen C. Salop, *Asymmetric Stakes in Antitrust Litigation* (USC Legal Stud. Rsch. Paper Series No. 20-1, 2020) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3563843.

[237] *See* Letter from U.S. Senators Patrick Leahy, John Cornyn, Richard Blumenthal, Susan M. Collins, Amy Klobuchar, and Mike Braun to Kathi Vidal, Dir. of U.S. Pat. and Trademark Off. (June 8, 2022).

[238] For existing rules for terminal disclaimers, see generally 37 C.F.R. § 1.321(d). The PTO has been deemed to have authority to impose requirements on the content of terminal disclaimers in order to address policy concerns arising out of obviousness-type double patenting. *See In re* Van Ornum, 686 F.2d 937, 947–48 (C.C.P.A. 1982); Daniel Kazhdan, *Obviousness-Type Double Patenting: Why It Exists and When It Applies*, 53 Akron L. Rev. 1017, 1028 (2019) (noting PTO's rulemaking on content of terminal disclaimers to address "public-rights" issues).

B. Congress Should Take Measures to Stop Patent Thickets

Congress could also procedurally stop patent thickets with new PTO rules. Congress could halt most patent thickets by creating laws that limit the applicant's ability to file a continuation application to within two years of the first office action in the priority application. This would prevent serial continuation applications and would force applicants to focus on only those patents that are most valuable to the applicant. It has previously been shown that most patents that are filed to delay generic entry are "secondary" patents, which are usually based on continuation applications.[239]

Congress could also create a new FDA reexamination process to help increase communication between the PTO and FDA.[240] Directly after FDA approval of the drug, NDA information should be sent to the PTO. The PTO should then review this information to determine if there is a substantial new question of patentability. If there is, then the PTO should reopen prosecution with the patentee to determine if the scope of the claims matches the disclosure and whether evidence found in the clinical trials contradicts the patent claims.

Conclusion

The Hatch-Waxman Act has created a carefully balanced set of incentives to help stimulate innovation in the pharmaceutical industry while also allowing generic manufacturers to enter the market, thereby greatly reducing the prices associated with these drugs. However, increasingly brand pharmaceuticals are using the complex regulatory frameworks of both the FDA and the PTO to extend their monopoly rights.

The patent two-step dance is yet another strategy where brand firms are attempting to extend their monopoly rights. Unfortunately, under *GSK II*, the Federal Circuit has resuscitated this once abandoned strategy. If allowed to stand, this induced infringement strategy based on patent use code thickets might stymie generic competition for years to come. This will lead to increased costs for American patients and the federal government.

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[239] Tu & Lemley, *supra* note 19 (Table 1, showing that 73% of invalidated patents were continuation applications).

[240] S. Sean Tu, *FDA Reexamination: Increased Communication Between the FDA and USPTO to Improve Patent Quality*, 60 U. Hous. L. Rev. (forthcoming in 2022).

The Supreme Court should grant certiorari in the *GSK II* case to correct the confusion that the Federal Circuit has created by overturning a system that has been in place for decades.[241] Additionally, the PTO and FDA should create rules to re-balance the Hatch-Waxman Act to serve its initial purpose, namely balancing pharmaceutical innovation and lowering drug prices.

[241] *See* Brief of 42 Professors, *supra* note 82.

Appendix 1: Patents on Vascepa

Use codes apply to both 500mg and 1000mg drug products unless otherwise specified.

Patent	Exp. Date	Use Codes
8,293,727	2/9/30	U-1287
8,293,728	2/9/30	U-1287
8,298,554	4/29/30	Drug product
8,314,086	2/9/30	U-1287
8,318,715	2/9/30	U-1287
8,357,677	2/9/30	U-1287
8,367,652	2/9/30	U-1287
8,377,920	2/9/30	U-1287
8,399,446	2/9/30	U-1287
8,410,086	6/15/30	U-2688
8,415,335	2/9/30	U-1287
8,426,399	2/9/30	U-1287
8,431,560	2/9/30	U-1287 (1000mg only)
8,440,650	2/9/30	U-1287
8,445,003	4/29/30	U-1287
8,445,013	4/29/30	U-1287
8,454,994	4/29/30	U-2689
8,455,472	6/15/30	U-2690 (1000mg only)
8,501,225	4/29/30	U-1287
8,518,929	2/9/30	U-1287
8,524,698	2/9/30	U-1287
8,546,372	2/9/30	U-1287
8,551,521	4/29/30	U-1287
8,563,608	4/29/30	U-1287
8,617,593	4/29/30	U-1287 (500mg only) U-1478 (1000mg only) U-2691
8,617,594	4/29/30	U-1287
8,618,166	4/29/30	U-2689 (1000mg only)

8,623,406	4/29/30	U-1287 (500mg only) U-1478 (1000mg only) U-2692
8,642,077	4/29/30	U-2693
8,669,245	6/15/30	U-2694
8,680,144	2/9/30	U-2695
8,691,871	4/29/30	U-2689
8,703,185	4/29/30	U-2691
8,709,475	4/29/30	U-2689
8,710,041	6/15/30	U-2690
9,198,892	9/25/27	U-2706
9,603,826	6/28/33	U-2696
9,610,272	6/28/33	U-2697
9,623,001	6/28/33	U-2698
9,693,984	6/28/33	U-2697
9,693,985	6/28/33	U-2696
9,693,986	6/28/33	U-2698
9,700,537	5/31/27	U-2707
9,918,954	6/28/33	U-2699
10,010,517	4/29/30	U-2690
10,265,287	4/29/30	U-2700
10,278,935	6/28/33	U-2701
10,278,936	6/28/33	U-2702
10,278,937	6/28/33	U-2703
10,383,840	6/28/33	U-2704
10,555,924	6/28/33	U-2743
10,555,925	6/28/33	U-2744
10,568,861	6/28/33	U-2756
10,576,054	6/28/33	U-2762
10,668,042	6/28/33	U-2841
10,786,478	6/28/33	U-2959 U-2960
10,792,267	4/29/30	U-2961
10,792,270	6/28/33	U-2962

10,842,766	4/29/30	U-2997
10,842,768	6/15/30	U-2688
10,881,632	4/29/30	U-3052
10,894,028	6/28/33	U-3053
11,000,499	6/28/33	U-3126
11,103,477	4/29/30	U-3209
11,116,742	6/28/33	U-3221
11,154,526	4/29/30	U-3240
11,213,504	4/29/30	U-3292
11,298,333	6/28/33	U-3358

Appendix 2: Vascepa Use Codes

Drug Product

Patents: 8,298,554

U-1287: Method of reducing TG levels in patient suffering from severe hypertriglyceridemia

Patents: 8,293,727, 8,293,728, 8,314,086, 8,318,715, 8,357,677, 8,367,652, 8,377,920, 8,399,446, 8,415,335, 8,426,399, 8,431,560, 8,440,650, 8,445,003, 8,445,013, 8,501,225, 8,518,929, 8,524,698, 8,546,372, 8,551,521, 8,563,608, 8,617,593, 8,617,594, 8,623,406

U-1478: Method of reducing TG levels in patient on statin therapy suffering from severe hypertriglyceridemia

Patents: 8,617,593, 8,623,406

U-2688: Use of Vascepa to lower triglycerides and ldl-c in an adult patient with elevated triglyceride (TG) levels (about 200 mg/dl to less than about 500 mg/dl) and on statin therapy

Patents: 8,410,086, 10,842,768

U-2689: Use of Vascepa to treat mixed dyslipidemia in an adult patient with elevated triglyceride (TG) levels ($\geq$ 150 mg/dl) and on statin therapy

Patents: 8,454,994, 8,618,166, 8,691,871, 8,709,475

U-2690: Use of Vascepa to lower triglycerides in an adult patient with elevated triglyceride (TG) levels (about 200 mg/dl to less than about 500 mg/dl) and on statin therapy

Patents: 8,455,472, 8,710,041, 10,010,517

U-2691: Use of Vascepa to treat hypertriglyceridemia in an adult patient with elevated triglyceride (TG) levels ($\geq$ 150 mg/dl) and on statin therapy

Patents: 8,617,593, 8,703,185

U-2692: Use of Vascepa to reduce triglycerides in an adult patient with elevated triglyceride (TG) levels ($\geq$ 150 mg/dl) and on statin therapy

Patents: 8,623,406

U-2693: Use of Vascepa to reduce triglycerides in a mixed dyslipidemia adult patient with elevated triglyceride (TG) levels ($\geq$ 150 mg/dl) and on statin therapy

Patents: 8,642,077

U-2694: Use of Vascepa to lower triglycerides in a mixed dyslipidemia adult patient with elevated triglyceride (TG) levels (about 200 mg/dl to less than about 500 mg/dl) and on statin therapy

Patents: 8,669,245

U-2695: Use of Vascepa to treat mixed hypertriglyceridemia in an adult patient with elevated triglyceride (TG) levels ($\geq$ 150 mg/dl) and on statin therapy

Patents: 8,680,144

U-2696: Use of Vascepa as an adjunct to statin therapy to reduce the risk of cardiovascular death, coronary revascularization, and unstable angina in an adult patient with elevated triglyceride levels (TG $\geq$ 150 mg/dl to about 500 mg/dl)

Patents: 9,603,826, 9,693,985

U-2697: Use of Vascepa as an adjunct to statin therapy to reduce the risk of cardiovascular death and/or unstable angina in an adult patient with elevated triglyceride levels (TG $\geq$ 150 mg/dl to about 500 mg/dl)

Patents: 9,610,272, 9,693,984

U-2698: Use of Vascepa as an adjunct to statin therapy to reduce the risk of cardiovascular death and/or coronary revascularization in an adult patient with elevated triglyceride levels (TG $\geq$ 150 mg/dl to about 500 mg/dl)

Patents: 9,623,001, 9,693,986

U-2699: Use of Vascepa as an adjunct to statin therapy to reduce the risk of a cardiovascular event (coronary revascularization, unstable angina, stroke and/or myocardial infarction) in an adult patient with elevated triglyceride levels

Patents: 9,918,954

U-2700: Use of Vascepa to reduce triglycerides in an adult patient with elevated triglyceride (TG) levels (about 200 mg/dl to less than about 500 mg/dl) and on rosuvastatin therapy

Patents: 10,265,287

U-2701: Use of Vascepa as an adjunct to statin therapy to reduce the risk of coronary revascularization and/or unstable angina in an adult patient with elevated triglyceride levels (TG $\geq$ 150 mg/dl to about 500 mg/dl)

Patents: 10,278,935

U-2702: Use of Vascepa as an adjunct to statin therapy to reduce the risk of a cardiovascular event (cardiovascular death, coronary revascularization and/or unstable angina) in an adult patient with elevated triglyceride levels

Patents: 10,278,936

U-2703: Use of Vascepa as an adjunct to statin therapy to reduce the risk of a CV event (CV death, coronary revascularization, unstable angina, stroke and/or myocardial infarction) in an adult patient with elevated triglyceride levels and diabetes mellitus

Patents: 10,278,937

U-2704: Use of Vascepa as an adjunct to statin therapy to reduce the risk of a cardiovascular event in an adult patient with elevated triglyceride levels and at least one risk factor for cardiovascular disease

Patents: 10,383,840

U-2706: Use of Vascepa as an adjunct to statin therapy to reduce the risk of onset and/or recurrence of cardiovascular events in a patient who has escaped the unstable period after cardiovascular angioplasty

Patents: 9,198,892

U-2707: Use of Vascepa as an adjunct to statin therapy to reduce the occurrence of a cardiovascular event in an adult patient with hypercholesterolemia

Patents: 9,700,537

U-2743: Use of Vascepa as an adjunct to statin therapy to reduce the risk of unstable angina in an adult patient with established cardiovascular disease

Patents: 10,555,924

U-2744: Use of Vascepa as an adjunct to statin therapy to reduce the risk of stroke in an adult patient with established cardiovascular disease

Patents: 10,555,925

U-2756: Use of Vascepa as an adjunct to statin therapy to reduce the risk of cardiovascular death in an adult patient with established cardiovascular disease

Patents: 10,568,861

U-2762: Use of Vascepa as an adjunct to statin therapy to reduce the risk of a major cardiovascular event in an adult patient with diabetes mellitus and two or more additional risk factors for cardiovascular disease

Patents: 10,576,054

U-2841: Use of Vascepa with high intensity statin therapy to reduce the risk of a CV event in an adult patient with elevated triglyceride levels and (1) established CV disease, or (2) diabetes mellitus and two or more additional risk factors for CV disease

Patents: 10,668,042

U-2959: Use of Vascepa as an adjunct to statin therapy to reduce the risk of a third and further cardiovascular event in an adult patient with elevated TG levels ($\geq$150 mg/dl) and established cardiovascular disease

Patents: 10,786,478

U-2960: Use of Vascepa as an adjunct to statin therapy to reduce the risk of a second or further cardiovascular (CV) event in an adult patient with elevated TG levels ($\geq$ 150 mg/dl) and diabetes mellitus and 2 or more additional risk factors for CV disease

Patents: 10,786,478

U-2961: Use of Vascepa as an adjunct to statin therapy to reduce the risk of myocardial infarction, stroke, both in an adult patient with type 2 diabetes mellitus

Patents: 10,792,267

U-2962: Use of Vascepa as an adjunct to statin therapy to reduce the risk of coronary revascularization in an adult patient with established cardiovascular disease

Patents: 10,792,270

U-2997: Use of Vascepa as an adjunct to statin therapy to reduce the risk of stroke in an adult patient with elevated triglycerides and atrial fibrillation

Patents: 10,842,766

U-3052: Use of Vascepa to reduce triglyceride levels in an adult patient on statin therapy and having atrial fibrillation and triglyceride levels of greater than 500 mg/dl

Patents: 10,881,632

U-3053: Use of Vascepa as an adjunct to statin therapy to reduce the risk of myocardial infarction in an adult patient with elevated triglyceride levels and established CV disease or diabetes mellitus and two or more additional risk factors for CV disease

Patents: 10,894,028

U-3126: Use of Vascepa as an adjunct to statin therapy to reduce the risk of a second and further cardiovascular event in an adult patient with established cardiovascular disease

Patents: 11,000,499

U-3209: Use of Vascepa as an adjunct to statin therapy to reduce the risk myocardial infarction in an adult patient having atrial fibrillation or atrial flutter and elevated triglyceride levels

Patents: 11,103,477

U-3221: Use of Vascepa as an adjunct to statin therapy to reduce the risk of a cardiovascular event in a patient with prior percutaneous coronary intervention

Patents: 11,116,742

U-3240: Use of Vascepa to reduce triglyceride levels in an adult patient having triglyceride levels of at least about 500 mg/dl, on anticoagulant/antiplatelet/thrombolytic therapy, and having atrial fibrillation and/or atrial flutter

Patents: 11,154,526

U-3292: Use of Vascepa to reduce triglyceride levels in an adult patient on statin therapy and having atrial fibrillation or atrial flutter and triglyceride levels of about 500 mg/dl to about 2,000 mg/dl

Patents: 11,213,504

U-3358: Use of Vascepa to reduce the incidence of MI in an adult patient on statin therapy and with elevated triglyceride levels (>150 mg/dl), wherein the patient experiences atrial fibrillation and/or flutter instead of an incidence of MI

Patents: 11,298,333

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UNPACKING COASIAN 'RED BOXES': UNIVERSITIES AND COMMERCIALIZATION

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In The Nature of the Firm*, Ronald Coase explains how firms represent a suspension of the market mechanism. The allocation of activities depends on the relative costs of organizing activities within the firm versus direct reliance on the market. Despite Coase's insight, economists often treat firms as black boxes with respect to innovation. Firms take in resources and produce innovations but why firms are successful at innovation is unspecified. As a result, the factors that enable wealth creation within the black boxes of firms, a key factor in economic progress, are little understood. Firms are not the only source of innovation, however. Economically valuable research also emerges from non-profit universities. They represent an alternative (which we term the "red box") to research that occurs within firms' black boxes, an alternative with specific advantages and disadvantages in producing innovations. Using a comprehensive set of patent data, we show that university patenting is largely the result of activity by a tiny subset of U.S. universities, contrary to the Bayh-Dole Act's promise that it would produce a massive technology transfer from universities to the marketplace.*

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In this Article, we argue that research in non-profit universities is distinct from research in a for-profit firm. As a result, the process of moving inventions from the university to the market usually occurs through licensing innovations to firms that have a comparative advantage in assessing possible market value of inventions and can risk capital to exploit innovations. Because successful commercialization of the product of research requires entrepreneurship, we use the insights into entrepreneurship of economists Joseph Schumpeter and Israel Kirzner to begin to unpack the red box of university commercialization efforts. This Article examines the practices that have emerged after the Bayh-Dole Act's grant of intellectual property rights to universities for the results of federally funded research and the many constraints imposed by university structure. It also considers how the differences in the incentive structure with black and red boxes create a role of university research.

INTRODUCTION

Research universities funded by governments, non-profits, for-profits, and internal resources generate ideas.[1] Some ideas are purely intellectual

[1] Tens of billions of dollars are spent annually. R1 universities do most of the work but Carnegie Classification also lists schools with less research. *See* CARNEGIE CLASSIFICATION OF INSTITUTIONS OF HIGHER EDUCATION, https://carnegieclassifications.iu.edu/ (last visited Nov. 2, 2022). Some schools, such as Harvard and Texas A&M, spend more than $1 billion a year on research. *See R&D Expenditures of Harvard University from 2006 to 2020*, STATISTA, (Dec. 2021), https://www.statista.com/statistics/697606/

exercises: interpretations of Shakespeare, understandings of archeological findings, explanations of data on distant stars, or analyses of long-dead philosophers. But considerable resources go to research that has the potential for commercial payoffs: new drugs and medical devices, new seed varieties, improved industrial processes, and new materials. At one time, successful products were largely serendipitous. But since the Bayh-Dole Act gave universities the intellectual property rights to the fruits of federally funded research in 1980, the effort to commercialize research has become both more formalized and more important. Sponsors often want research with potential for commercialization through license agreements or start-ups: "Technology that remains in the lab provides almost no economic benefits."[2] Broader goals include revenue for universities, economic impact for states and communities, and prestige.[3] To get technology out of labs and into the economy, the federal government granted universities intellectual property rights to the federally-funded research conducted by researchers via the Bayh-Dole Act of 1980.[4] This model is spreading internationally as well.[5]

Federal research money has poured into universities since 1980. At the time Bayh-Dole was enacted, the funds up for competition via the National Science Foundation (NSF) and the National Institutes for Health (NIH) were paltry compared to what is at stake now. In fiscal 1980, the NSF was allocated $904

rnd-expenditure-harvard-university/ (last visited Nov. 2, 2022) and Tex. A&M Univ. Rsch. Commc'ns. and Pub. Rels., *First in Texas: A&M Research tops $1 Billion Mark*, Tex. A&M Today (Feb. 10, 2021), https://today.tamu.edu/2021/02/10/first-in-texas-am-research-tops-1-billion-mark/.

[2] Donald E. Stokes, Pasteur's Quadrant: Basic Science and Technological Innovation 85 (1997); *See also* Nathan Rosenberg, *Critical Issues in Science Policy Research*, 18 Sci. & Pub. Pol'y 335 (1991).

[3] Industry trade associations, such as the Association of American Universities publish guides for schools about how to trump the benefits that allegedly come from research, including new businesses. *See* Am. Ass'n of Univs. Econ. Impact Rep., https://www.aau.edu/economic-impact.

[4] Bayh-Dole Act, 35 U.S.C. §§ 200.

[5] Ashley J. Stevens, *The Enactment of Bayh-Dole*, 29 J. Tech. Transfer 93, 93 (2004) ("foreign countries are now adopting the Bayh–Dole model"); Michael S. Mireles, *The Bayh-Dole Act and Incentives for the Commercialization of Government-Funded Invention in Developing Countries*, 76 UMKC L. Rev. 525, 525 (2007); Maria Brouwer, *Entrepreneurship and University Licensing*, 30 J. Tech. Transfer 263, 263 (2005) (European Council points to "U.S. university-business relationships" as "a policy worth imitating"); David C. Mowery & Bhaven N. Sampat, *The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments?*, 30 J. Tech. Transfer 115, 123-124 (2005).

million. In 2021, the allocation was $6,910 billion.[6] Nine schools received more than $100 million in grant money.[7] Adjusting for inflation, this is more than a doubling in real terms of the funds available. The total NIH budget in 1980 was only $3.4 billion.[8] In 2021, its budget was $42.7 billion, more than a fourfold increase in real terms.[9] While not all these funds went to universities, they received the lion's share. The top NIH recipient in 2021, Johns Hopkins University, alone received 1,223 awards totaling $610 million. More than 50 schools received more than $100 million each.[10] Researchers and administrators in non-profit universities aggressively seek more research funding.[11]

Unfortunately, Bayh-Dole was based on an overly simplistic linear model of innovation in which money poured in at the start of an invention pipeline in funding to produce useful commercial innovations at the other end. In some respects, the statute's reliance on a simplistic model is unsurprising – the notion is old.[12] Turning research results into products is not as simple as the linear model makes it out to be; Bayh-Dole took little notice of universities' capabilities. As a result, despite

[6] Off. of Budget Fin. and Award Mgmt., Nat'l Sci. Found., NSF Requests and Appropriations by Account: FY 1951-FY 2022, https://dellweb.bfa.nsf.gov/NSFRqstApproHist/NSFRequestsandAppropriationsHistory.pdf (last visited Nov. 2, 2022.).

[7] Off. of Budget Fin. and Award Mgmt., Nat'l Sci. Found., Award Summary: Top 50 Institutions FY 2021, https://dellweb.bfa.nsf.gov/top50inst2/default.asp (last visited Nov. 2, 2022).

[8] Off. Nat'l Inst. of Health, History of Congressional Appropriations, 1980-1989, https://officeofbudget.od.nih.gov/pdfs/FY08/FY08%20COMPLETED/appic3806%20-%20transposed%20%2080%20-%2089.pdf (last visited Nov. 2, 2022).

[9] *See* Off. Nat'l Inst. of Health, Mechanism Detail, Actual Obligations, FY 2020-2021, https://officeofbudget.od.nih.gov/pdfs/FY22/spending-hist/Mechanism%20Detail%20for%20Total%20NIH%20FY%202000%20-%20FY%202021%20(V2).pdf.

[10] Medical schools dominate the funding. *See* NIH Awards by Location and Organization Report, https://report.nih.gov/award/index.cfm?ot&fy=2010&static&fm&orgid&view=stateorg&sumcol=fun&sumdir=desc (last visited Nov. 1, 2022).

[11] *See, e.g.*, Am. Acad. of Arts. & Scis., The Perils of Complacency: America at a Tipping Point in Science & Engineering 38 (2020). ("Now is a time of unprecedented opportunity for scientific discovery and rapid progress in technology and its applications."). "Investments in research and education . . . can appear unattractive in the competition for funds under the two-year political cycle of government, the one-year federal budgeting process, and the next-quarter fixation of many of today's businesses." *Id.* at 49-50.

[12] Terence Kealey, The Economic Laws of Scientific Research 8 (1996). Note that Kealey points out that university research was largely, and generously, funded before World War II by private interests. *Id.* at 263-265.

pouring enormous amounts of funding into the innovation pipeline, we still struggle to get relevant research out of the laboratory and into the economy.[13]

Bayh-Dole's results have been mixed. In 1980, at the end of the era when patents based on federally funded research were the property of the agency funding the research, universities were awarded 390 patents. Thirty years after universities acquired the patent rights to the results of federally-funded research, they were awarded more than 3,000 patents.[14] By 2018, a survey found that universities had filed over 17,000 patent applications and received over 7,000 patents in that year alone and held a total of 77,880 patents.[15] But patents have often translated into products. A 2010 study by the Association of University Technology Managers (AUTM) identified 657 products that resulted from university research and development, over 5,000 licenses for technologies, and 650 new companies.[16] Even if it did not produce a flood of products, Bayh-Dole led to more research about commercialization: a survey found 173 articles published on the topic of commercializing university-based research between 1981 and 2005, three-quarters of them appearing between 2000 and 2005.[17] This growth is the source of many of the claims that universities serve as engines of economic development. Unfortunately, only a handful of universities excel at commercialization, including Columbia, Stanford, and the Massachusetts Institute of Technology.[18] "Many

[13] Focusing universities on commercializing research is not universally popular even on economic grounds. Henry Etzkowitz, *Research groups as 'quasi-firms': The invention of the entrepreneurial university,* 32 Rsch. Pol'y 109, 116 (2003) [hereinafter Etzkowitz, *Quasi-Firms*].

[14] *Best Practices in Transforming Research Into Innovation: Creative Approaches to the Bayh-Dole Act: Hearing Before the Subcomm. on Tech. and Innovation Comm. on Sci., Space & Tech.*, 112th Cong. 7 (2012) (statement of Rep. Judy Biggert, Vice Chairwoman, H. Subcomm. on Tech. & Innovation Comm. on Sci., Space & Tech.) [hereinafter H.R. Tech & Innovation Hearing]. That is about a seven-fold increase. Patent activity has been rising generally. During that time period the number of patent issues quadrupled annually. *See* U.S. Pat and Trademark Off., U.S. Patent Statistics Chart, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm.

[15] David Hsu et al., *Benchmarking U.S. university patent value and commercialization efforts: A new approach*, 50 Rsch. Pol'y 104076, *1-2 (2021).

[16] H.R. Tech & Innovation Hearing, *supra* note 14, at 5.

[17] Frank T. Rothaermel et al., *University Entrepreneurship: A Taxonomy of the Literature*, 16 Ind. & Corp. Change 691, 695 (2007).

[18] Maria Theresa Larsen, *The implications of academic enterprise for public science: An overview of the empirical evidence,* 40 Rsch. Pol'y 6, 7 (2011). A 2012 Congressional Research Service report found that the vast majority of university-innovation start-up companies over the prior 30 years came from just seven schools. *See* Wendy H. Schacht, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology* 10 (2012) (Congressional Research Service). The seven were: MIT, the

universities (in fact, most) do not have the economic capability, manpower, access to venture capital, nor desire to tend to an invention all the way from discovery to commercialization."[19] We argue that the neglect of entrepreneurship by universities is one reason for this lack of success. Despite frequent claims to be entrepreneurial in exploiting research, the survey of 173 articles noted above found few references to actual entrepreneurship among universities.[20]

Success in patenting (a commonly used measure of university research success) varies considerably and just a small number of universities do the vast majority of it. To measure universities' patent performance, we used the PatentVector™ database. PatentVector™ contains the universe of digitized patent documents (both patents and patent applications) for the entire world.[21] An eigenvector centrality algorithm (the same family as Google's PageRank™ algorithm) provides a score for each patent.[22] The score correlates well with

University of California, Cal. Tech., the University of Minnesota, Johns Hopkins University, the University of Utah, and the University of Virginia.

[19] Brian K. Krumm, *University Technology Transfer – Profit Centers or Black Holes: Moving Toward a More Productive University Innovation Ecosystem Policy,* 14 Nw. J. Tech. & Intell. Prop. 171, 189 (2016); *see also* Andy Lockett & Mike Wright, *Resources, capabilities, risk capital and the creation of university spin-out companies,* 34 Rsch. Pol'y 1043, 1044 (2005).

[20] Exceptions are Henry Etzkowitz et al., *The future of the university and the university of the future: evolution of ivory tower to entrepreneurial paradigm,* 29 Rsch. Pol'y 313, 325-326 (2000), which briefly discusses Schumpeter's conception of the entrepreneur, and Nicos Nicolaou & Sue Birley, *Social Networks in Organizational Emergence: The University Spinout Phenomenon,* 49 Mgt. Sci. 1702 (2003), which discusses Kirzner briefly. The most frequent reference is similar in type to this one: "Since the seminal work of Schumpeter (1934), innovation is considered an important driver of economic growth and welfare," with no further mention of Schumpeter or his works. Bart Leten et al., *Science or graduates? How do firms benefit from the proximity of universities?* 43 Rsch. Pol'y 1398, 1398 (2014). I point to this example not to be critical of the article or to single out these particular authors (who have done excellent work on commercialization and universities) but to illustrate the lack of engagement within the literature with economists writing about what is, after all, a particular form of entrepreneurial behavior. This is even more surprising as the literature on entrepreneurship makes use of work by Schumpeter and Kirzner.

[21] An earlier version of PatentVector™ is described in Andrew W. Torrance & Jevon D. West, *All Patents Great and Small: A Big Data Network Approach to Valuation,* 20 Va. J. L. & Tech. 466 (2017). Although the database has grown in many ways since then, the basic structure remains similar.

[22] Eigenvector centrality "awards a number of points *proportional to the centrality scores of the neighbors*." Mark Newman, Networks 159 (2nd ed., 2018). As a result, "a node can achieve high centrality either by having a lot of neighbors with modest centrality, or by having a few neighbors with high centrality (or both)." *Id.* at 160. On PageRank's relationship to eigenvector centrality, *see* Dhruv Parthasarathy, *PageRank – How Eigenvectors Power the Algorithm Behind Google Search,* Dhruv on Math (20 Mar. 2019) available at https://www.dhruvonmath.com/2019/03/20/pagerank/.

extrinsic measures of value and is scaled to make the average patent have a score of 1.0. That is, a patent with a score of 2.0 is twice as central as a patent with a score of 1.0. We included both current and expired patents as we were interested in universities' total performance across time, not just their current portfolios.

There are roughly 4,000 U.S. colleges and universities. Patenting and research activities are far from equally distributed among them. In our calculations, we include only members of the American Association of Universities (AAU), an organization of research universities with relatively stringent membership criteria, and land grant universities, which have a mission to develop and transfer technology to the public, in our data, to avoid having large numbers of observations with zero patents.[23] (There is overlap among the two categories: fourteen AAU members are also land-grant universities, while forty-one are not). We dropped ten universities on the initial list that had zero patents[24] as well as ten that had ten or fewer patents.[25] This left us with ninety-six universities, less than two percent of all four-year U.S. higher education establishments. We searched a comprehensive database, PatentVector™, for each university's patent documents.[26] Table 1 provides summary statistics for our three measures; Table 2 shows the distribution of schools among the AAU and land grant categories. We also considered the public/private status of the universities (32% are private).

[23] We also deleted Canadian universities (some of which belong to the AAU) and land grant-schools affiliated with U.S. territories and Native American tribes.

[24] Central State University, Haskell Indian Nations University, Langston University, Navajo Technical University, Sinte Gleska University, South Carolina State University, University of Guam, University of the District of Columbia, University of the Virgin Islands, and West Virginia State University.

[25] Fort Valley State University, Southern University and A&M College, University at Buffalo, University of Maryland at College Park, Virginia State University, Kentucky State University, Virginia Tech University, Alcorn State University, Alabama A&M University, and Delaware State University.

[26] Because there are occasional typographical errors in patent documents as well as variants in spellings (universities with an "&" in their names sometimes have a patent listed using "and" instead), we used the spelling with the largest number of documents. This captured virtually all of the relevant patent documents for each school. Further, some universities that are part of systems of universities (various University of California universities, schools that are part of the University of Texas and Texas A&M Systems) hold their intellectual property at the system level, our measure over-counts the portfolios of those systems because there is no way to disaggregate the system level data to the campus level.

TABLE 1:
DESCRIPTIVE STATISTICS

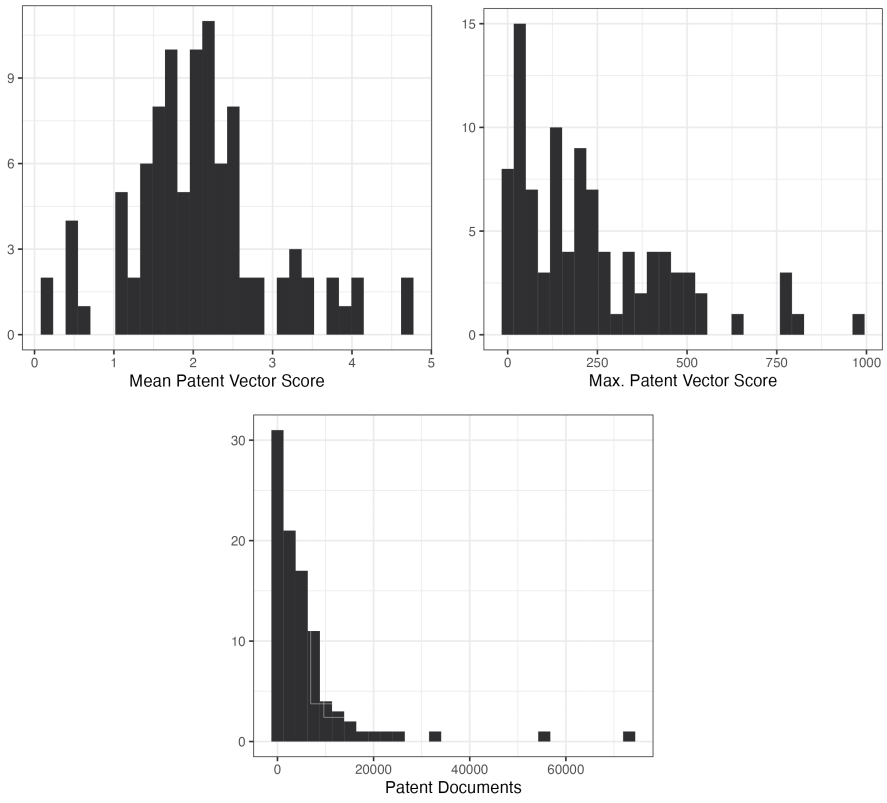
Mean PV Score™	2.08 (0.90)
Max PV Score™	233.47 (212.40)
Patent Documents	6182.58 (10,410)

TABLE 2:
LAND GRANT AAU MEMBERSHIP

AAU \ Land Grant	**Not Land Grant University**	**Land Grant University**
Not AAU Member	0%	0.43%
AAU Member	0.43%	0.15%

Universities perform differently by all three of these measures in Figure 1, which provides histograms for the complete set.

FIGURE 1:
SUMMARY OF UNIVERSITY RESEARCH ACTIVITIES



We see this pattern in Figures 2, 3, and 4 as well, which provide "violin" plots of the data, disaggregated by public, AAU, and land grant statuses. Two conclusions can be drawn from these diagrams and statistics. First, there are substantial differences in the amount of patenting and, more importantly, the amount of patenting of valuable ideas, among universities. Indeed, for measuring the importance of ideas, PatentVector™'s eigenvector-based score is an excellent measure, even better than dollar values, since it represents the centrality of a patent within the network of patented ideas.[27] Just a few universities produce the vast majority of patent documents in our sample: eleven produce half, and twenty-two produce two-thirds.[28] The bottom fifty produce just ten percent of the patent documents.

Examining the patent documents by mean PVScore™ shows that even some small players are successful. Princeton, which is only 35th in total patent documents, tops the list for mean scores at 4.75, followed closely by New Mexico State University, which has only 101 patent documents but an impressive mean of 4.65. Indeed, just MIT and Stanford are in both the top 11 by mean PVScore™ and by number of patent documents. These differences are unsurprising. Even if the University of California System has more high value patents in absolute terms in its more than 73,000 patent documents, it will also have many average or low value ones as well than there will be among Princeton's just over 5,000 or New Mexico State's 101. In calculating the average PVScore™, the thousands of average value ones will dominate the average. In general, the larger bulge higher up for AAU members suggests that those universities are more successful at generating valuable patents. (In future work, we plan to delve more deeply into these statistics and generate additional measures of success.)

[27] Newman, *supra* note 22, at 159. Thus, a patent has a higher score if it is cited by patents which themselves are high scoring. *See also* Zeev Maoz, Networks of Nations: The Evolution, Structure, and Impact of International Networks, 1816-2001 55 (Cambridge, 2011) ("eigenvector centrality weighs the degree centrality of a given node by the degree centrality of the nodes it is connected with.").

[28] The University of California System, Harvard, MIT, the University of Texas System, Stanford, Johns Hopkins, the University of Pennsylvania, the University of Michigan, the California Institute of Technology, the University of Florida, and Columbia are the top 11; the second 11 are Cornell, Northwestern, Duke, the University of Illinois, the University of Wisconsin, the University of Minnesota, the University of Southern California, the University of Washington, the University of North Carolina, Yale University, and the University of Utah.

FIGURE 2:
MEAN PATENT VECTOR SCORE

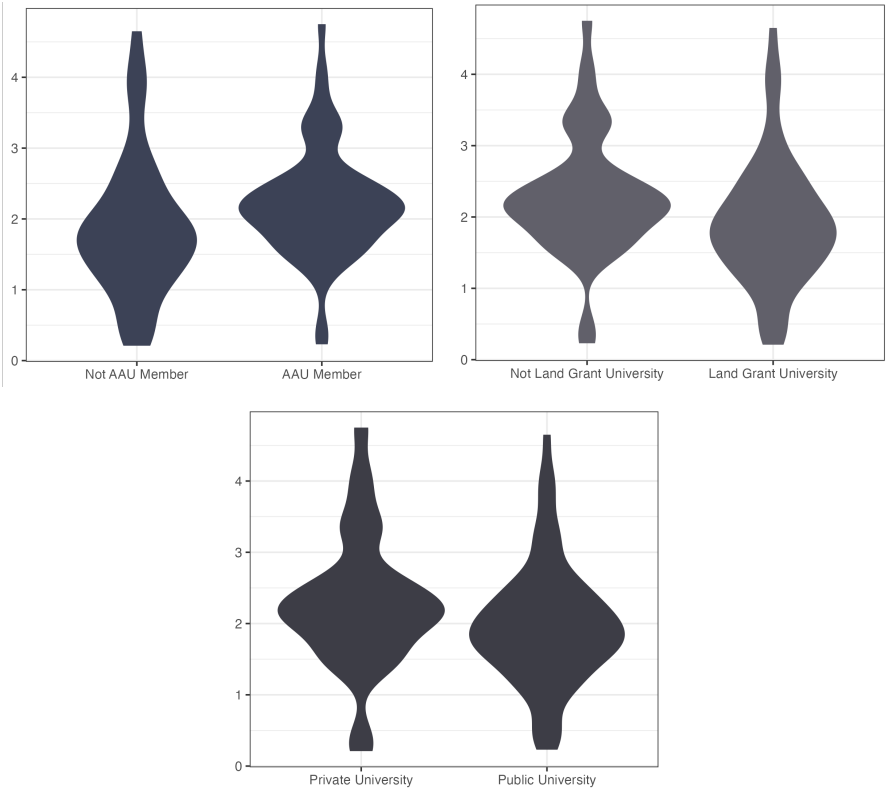
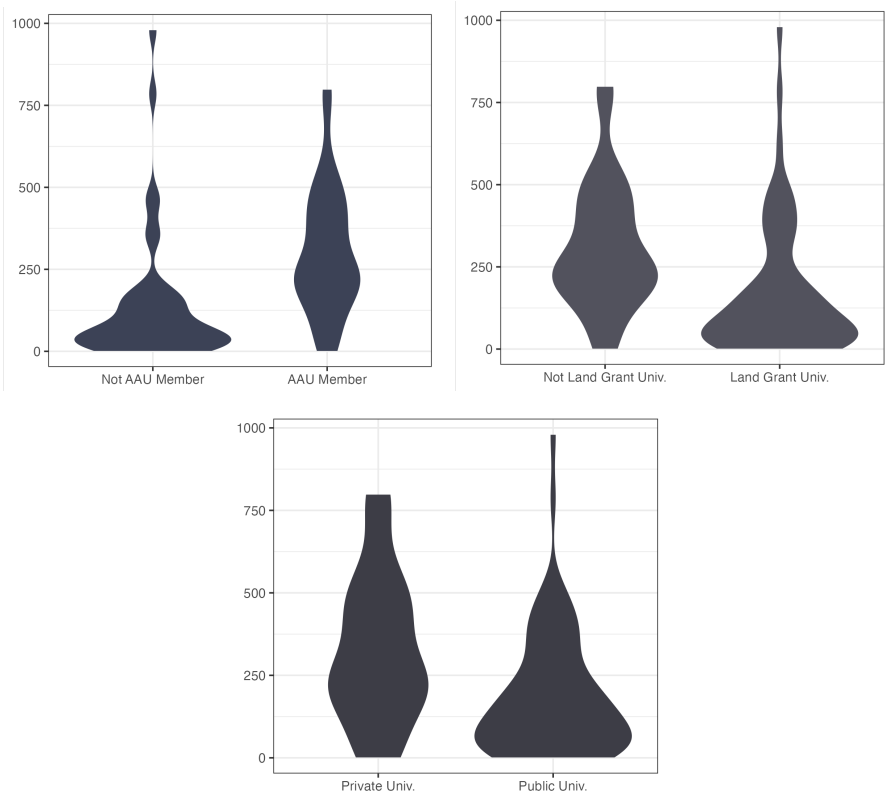


FIGURE 3:
MAXIMUM PATENT VECTOR SCORE



Why haven't the billions of dollars in federal research money led to a broad-based, technology-driven economic boom based on university research? Our argument is that an important reason is that Bayh-Dole, federal policy on innovation, generally, and many university efforts are not built around a realistic model of how innovations become commercial products. In particular, the role of entrepreneurship is neglected by both policymakers and universities. This is unsurprising as, even in the private sector, how firms successfully stimulate innovation is unclear. For the most part, firms are treated in this regard as black boxes, the mechanics of which are skipped over in economic analysis.[29] Even less understood than the private sector is how university research can evolve into market-valued products.

To fill this gap, we turn to the ideas of the economists who studied entrepreneurship, most notably Joseph Schumpeter and Israel Kirzner. Oddly, they are generally ignored in the literature on commercialization of innovations.[30] This

[29] Professor Nathan Rosenberg of Stanford wrote about this some years ago. *See* NATHAN ROSENBERG, EXPLORING THE BLACK BOX: TECHNOLOGY, ECONOMICS, AND HISTORY (1994). He wanted to "to break open and to examine the contents of the black box into which technological change has been consigned by economists." *Id*. at ix. In the following years, there has not been a rich literature in that regard. There is a literature on incentive structures for CEOs, proper option structures for management, and other financial matters. These analyses – as useful as they are – generally ignore the entrepreneurial function and say nothing about *how* to successfully spur innovation in for-profit enterprises.

[30] Schumpeter was a professor of economics at Harvard in the 1930s and 1940s. He was one of the premier economists of his day, but the Great Depression drew much of the attention of economists to that catastrophe. Works such as John Maynard Keynes' GENERAL THEORY OF EMPLOYMENT, INTEREST AND MONEY, published in 1936, dominated the attention of the profession as Schumpeter's work faded into near obscurity. Thomas K. McGraw, in PROPHET OF INNOVATION: JOSEPH SCHUMPETER AND CREATIVE DESTRUCTION 355 (2007), explains that Schumpeter stated in *Capitalism, Socialism and Democracy* that economics failed "to acknowledge that continuous innovation is 'endogenous to' (inherent in) capitalism." Innovation is not well understood, so is set to the side. Another reason to treat firms as black boxes that are set aside in analysis is that perfect competition lends itself so easily to modeling that it is irresistible to the economics profession but comes at the cost of excluding consideration of creative destruction. *Id*. at 70. Kirzner is one of the leading Austrian economists of recent decades. Following Friedrich Hayek, Ludwig von Mises, and others, he has written, among other things, about invention. Non-Austrian economists, most of the profession, are some variants of neoclassical economics. They study market processes, but generally not the workings of the rather mysterious black boxes of firms, and certainly not the red boxes of universities. In neoclassical models, economic agents maximize choice under constraints. That process simply happens. As Kirzner put it, "Choice, for the economist, has come to mean the solution of a maximization problem." ISRAEL KIRZNER, *Entrepreneurship, Choice, and Freedom* (1979), reprinted *in* THE COLLECTED WORKS OF ISRAEL M. KIRZNER: REFLECTION ON ETHICS, FREEDOM, WELFARE ECONOMICS, POLICY, AND THE LEGACY OF AUSTRIAN ECONOMICS 3 (Peter Boettke & Frédéric Sautet, eds., 2018). On the other hand, Austrian

Article is a step to bring their ideas more fully into the discussion of the conditions relevant to greater levels of valuable innovations that help spur economic progress. We focus on Schumpeter and Kirzner as applied to inventions that occur in what we term the "red box" of universities, which, because they are non-profit institutions, differ significantly from the "black boxes" of for-profit firms.[31] In both instances, the institutional incentive structures are absent from the discussion of the generation of valuable innovations and their evolution into products that succeed in the market.

Developing new ideas and turning them into products and services is the core of the entrepreneurial function: Schumpeter identified the essential function of the entrepreneur as the "doing of new things or the doing of things that are already

economists delve into the functioning and design of institutions as they attempt to understand how things work, unpacking the black boxes of firms in neoclassical theory and rendering the internal incentive structures intelligible. Kirzner explained that the role of social science is to study "the unintended consequence of individual human decisions." Israel Kirzner, *On the Method of Austrian Economics* (1976), *reprinted in* The Collected Works of Israel M. Kirzner: Austrian Subjectivism and the Emergence of Entrepreneurship Theory 1-2 (Peter Boettke and Frédéric Sautet, eds., 2015). Unlike standard neoclassical economics, which presumes and studies profit maximization as the core of the functioning of the market economy, in Austrian economics, "[t]he essential element in action is goal pursuit, not maximization, not allocative efficiency, or anything else." Israel Kirzner, *Ludwig von Mises and Friedrich von Hayek: The Modern Extension of Austrian Subjectivism* (1992), *reprinted in* The Collected Works of Israel M. Kirzner: Austrian Subjectivism and the Emergence of Entrepreneurship Theory 40 (Peter Boettke and Frédéric Sautet, eds., 2015). Starting in about 1920, "microeconomic theory attained a significantly higher standard of sophistication [with] economists scarcely paying any attention at all to analyzing the ways entrepreneurial activity affects the course of events in markets." Israel Kirzner, *Entrepreneurship, Economics, and Economists* (1985), *reprinted in* The Collected Works of Israel M. Kirzner: Austrian Subjectivism and the Emergence of Entrepreneurship Theory 139 (Peter Boettke and Frédéric Sautet, eds., 2015). The same is true of participants in the red boxes of universities. They cannot be modeled to pursue profit maximization in the strict sense that may be presumed of firms; the notion of "goal pursuit" by inventors working in universities would seem more apt. Individual goals likely include higher pay, recognition within the institution, prestige in the profession, self-satisfaction, and revenue from innovation exploitation via commercialization. From the perspective of the innovator, managers of TTOs can serve to further or hinder these goals.

[31] The notion of the firm as a black box has been the standard in economics for about a century. "The idea is to model the firm as a 'black box' in which a finite number of externally purchased inputs are transformed into a finite number of outputs to be sold in the market." Ake Andersson & Borje Johansson, *Inside and Outside the Black Box: Organization of Interdependencies*, The Annals of Regional Science 510 (2018). "Red box" is offered to distinguish developments in universities, which are state agencies and non-profit entities, from for-profit "black box" firms.

being done in a new way (innovation)."[32] Finding ways to accomplish this in the context of the university environment requires considering issues raised by the economic theory of entrepreneurship.

Part I of this Article examines how the red box context affects invention. There we develop the analogy to the black box of for-profit firms and explore the differences in incentive structures. Part II describes how U.S. universities approach commercialization. Part III applies an economic perspective to the commercialization process from the perspective of non-profit universities, looking to Schumpeter's and Kirzner's work for guidance on how to understand the process. Part IV concludes with suggestions on how the process might be improved.

I
Invention & Universities

To understand how universities might do a better job at commercializing emerging ideas, we need to be clear about the distinctive features of the red box of the university research environment compared to the black box of the commercial research environment. Hence, we summarize the general state of economic knowledge about working inside firms. This is contrasted to constraints generally faced inside universities. Then we consider how universities treat inventions.

A. Black & Red Boxes

The internal workings of for-profit firms, key actors in market economies and economic progress, were not traditionally well understood by economists. Nobel laureate Oliver Williamson, who works on the issue, notes that economics should "move beyond the older view of the firm as a production function or black box. We need to open the box and examine the mechanisms inside to get

[32] Joseph A. Schumpeter, *The Creative Response in Economic History, in* Essays on Entrepreneurs, Innovations, Business Cycles, and the Evolution of Capitalism 223 (Richard V. Clemence, ed.) (2008 [1947]) [hereinafter Schumpeter, *Creative Response*]. *See also* Joseph A. Schumpeter, *Economic Theory and Entrepreneurial History, in* Essays on Entrepreneurs, Innovations, Business Cycles, and the Evolution of Capitalism 259 (Richard V. Clemence, ed., 2008) (1949) ("entrepreneurship, as defined, essentially consists in doing things that are not generally done in the ordinary course of business routine" and so comes under "the wider aspect of leadership"); Joseph A. Schumpeter, *Capitalism, in* Essays on Entrepreneurs, Innovations, Business Cycles, and the Evolution of Capitalism 199 (Richard V. Clemence, ed., 2008) (1946) [hereinafter Schumpeter, *Capitalism Essay*] (entrepreneurs are not about financing of new firms but about organizational activity).

a better understanding of what is going on and why."[33] He notes further that "Innovation poses special challenges," some of which are addressed by focusing on transaction costs, but there is no "well-rounded explanation."[34] Williamson's work is complemented by that of Oliver Hart, also a Nobel Prize recipient (with Bengt Holmstrom) for "contributions to contract theory."[35] Hart notes that "In modern microeconomics textbooks, the firm is still represented in purely technological terms as a production function or production set."[36] In short, in standard economic theory it is presumed that diligent managers run organizations on behalf of the owners who wish to maximize profits. These managers face perfect competition in completely developed markets.[37] Such assumptions allow effective modeling of activity outside the firm, but do not help understand what goes on inside the not-well-understood black box. Williamson, Hart, and others have advanced our understanding of how firms solve incentive problems (winning two Nobel Prizes while doing so), but how firms innovate remains relatively under-theorized.

The economics of the firm begin with the recognition that because organizing and operating firms is costly, there needs to be an economic rationale for their existence.[38] Nobel Laureate Ronald Coase explained in his 1937 article, *The Nature of the Firm*, that firms exist where the transaction costs of organizing and operating a firm are less than the transaction costs of operating in the market.[39]

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[33] *An Interview with Oliver Williamson*, 3 J Institutional Econ. 373 (Oct. 2007). Williamson was awarded the Nobel Prize "for his analysis of economic governance, especially the boundaries of the firm." *See Sveriges Riksbank Prize in Economic Science in Memory of Alfred Nobel 2009, Oliver E. Williamson Facts*, The Nobel Prize, https://www.nobelprize.org/prizes/economic-sciences/2009/williamson/facts/ (last visited Nov. 2, 2022).

[34] *An Interview with Oliver Williamson, supra* note 33, at 376.

[35] *Sveriges Riksbank Prize in Economic Science in Memory of Alfred Nobel 2016, Oliver Hart Facts*, The Nobel Prize, https://www.nobelprize.org/prizes/economic-sciences/2016/hart/facts/ (last visited Nov. 2, 2022).

[36] That is, the internal process is a mysterious black box. *See* Oliver Hart, *Thinking about the Firm: A Review of Daniel Spulber's The Theory of the Firm*, 49 J. Econ. Lit. 101, 102 (Mar. 2011).

[37] *Id*. Hart notes that economists recognize that this is a near caricature of the real world but is still the most useful model that exists. Other models of firms, from sociology and organizational behavior theorists are "not yet at a stage of theoretical or empirical precision that [they] can be incorporated into mainstream economic thinking."

[38] *An Interview with Oliver Williamson, supra* note 33, at 380 ("[T]he firm is beset with bureaucratic costs that probably deepen over time.").

[39] If markets allocate resources efficiently, such organizations that incur transaction costs in dealing with various parties should not be needed. But they are, precisely because there are transaction costs to operating in the market as well. Ronald H. Coase, *The Nature of the Firm,* 4 Economica 386 (1937).

While Coase's observation was eventually recognized as brilliant, it failed to spur further development by economists about the internal workings of firms for several decades.[40] As that work developed, it yielded some insights. For example, while firms exist to reduce transaction costs, the savings from their creation can be transitory as "bureaucratic costs build up."[41] In more recent years, a rich literature has arisen on the role of contracts as firms deal with each other.[42]

As a result of this work, we know that firms engage in complex processes that no one person can grasp. Parties are brought to work together to further the objectives of the firm. But why firms are designed internally the way they are, where great variation is observed, is not as well understood.[43] With respect to research and innovation within a firm, managers must grant authority to those with superior technical knowledge.[44] This poses challenges to the firm in constraining resources to focus on areas of greater profit potential, because managers rarely have the same grasp of the scientific issues as the researchers they employ. In the context of non-profits like universities, there are even greater challenges to understanding the impact of their organization on the incentives facing researchers and others.[45]

The puzzle we need to address is thus why universities play such a large role (at least in dollar terms) in research. In other words, does funding research in universities serve an important function, distinct from that of for-profit firms,

[40] Hart, *supra* note 36, at 105. Work furthering the questions raised by Coase "resumed" in the 1970s as scholars hypothesized about the different forms of organization firms would take, such as more internal command-and-control work versus dealing through contracts with outside firms.

[41] *An Interview with Oliver Williamson, supra* note 33, at 380.

[42] Hart, *supra* note 36, at 103. Hart discusses issues such as moral hazard, when managers exploit their employing firms for personal gain, and principal-agent issues, when key parties in the firm have divergent interests that cannot be fully accounted for by contract such as in compensation schemes for top managers. Economists do not presume to have "solved" such problems, but the issues are much studied. For example, Hart focuses on efficiency in negotiated contracts across firms that are used to resolve the conflicts that are inherent as self-interested parties come together. This comes into play in issues such as who owns what assets across organizations. Part of the technical literature that has evolved concerns property rights within organizations and the tensions among the parties involved—who gets ownership and control? While there is agreement in the literature that most economic growth arises from value-increasing activities within firms, exactly why this should be so is not well understood. *Id*. at 107.

[43] *Id*. at 107.

[44] *Id*. at 108. Hart does not use the example of complex research, but research clearly fits the situations in which he discusses downward allocation of authority within a firm.

[45] *Id*. at 111. While Hart notes that there is a literature on nonstandard forms of organizations, such as non-profit entities, this does not yet appear to have produced scholarship relevant to the question raised here.

in developing research that leads to commercial products. Significant public and private money are invested in research at universities; why? Are there reasons to believe red boxes have advantages under certain conditions over black boxes?

Table 3 summarizes some key differences in the internal incentive structures within black and red boxes. First, the two organizations have different objective functions. Firms focus on profit maximization and universities on maximizing revenue and prestige (recognized by things such as quality publications, prizes, and student placements). We should thus expect different behaviors from identical researchers depending on which environment the researcher works. We should also expect sorting between black and red box organizations in the characteristics of researchers who seek employment in each.

TABLE 3:
COMPARISON OF BLACK/RED BOXES: FOCUS ON RESEARCH

	"Black Box" / Private Firms	**"Red Box" / Universities**
Objective function	Profit maximizing	Revenue and prestige maximizing
Constraints	Market Budget (investor)	Disciplinary acceptance Budget (donor, funder)
Decisionmaker on research direction	Primary: Directors Secondary: Executives	Primary: Researcher Secondary: Grant making organizations
Primary outputs of research	Primary: Products Secondary: Patents	Primary: Papers Secondary: Patents
Enforcement mechanisms for dealing with researchers	File researcher	Revoke tenure or Reduce quality of work conditions
Ownership of research results	Firm with possible special rewards for researcher	University with profit sharing with researcher

Second, the constraints in red and black boxes differ. While both face budget constraints, the constraints are quite different. Firms must attract investors (different kinds at different stages of development, but all motivated by the desire to profit); investors are interested in firms' potential to grow net revenue. Investors often want to see results within a specific time frame.[46] Universities must attract investments from donors and funding agencies, whose motives are not the same as for-profit investors. Universities generally do poorly at attracting investment in university-developed technologies because they do not operate on the same

[46] Bob Zider, *How Venture Capital Works,* HARV. BUS. REV. (Nov.-Dec. 1998), https://hbr.org/1998/11/how-venture-capital-works ("In essence, the venture capitalist buys a stake in an entrepreneur's idea, nurtures it for a short period of time, and then exits with the help of an investment banker.").

time scale as venture capitalists or other potential profit-minded investors.[47] Firms also are subject to market constraints: they must produce goods people will buy. Universities, on the other hand, seek rewards from scientific (disciplinary) bodies that award prizes and grants, offers of lectureships and publication, etc. for successful faculty.

Third, the decision makers who determine research direction are different. In firms, the primary decision makers are the firm's directors, who decide the overall direction. Secondary (day-to-day) decision makers are executives who allocate resources and approve research projects. In universities, the primary decision-makers are the researchers themselves, who are not assigned to projects but generate their own research agendas and funding. Hence, the research funders play a major role. Few major scientific research endeavors will proceed beyond the pilot stage in a university if they do not receive external funding. (The median NSF grant in FY 2021 to an engineering department was about $127,000).[48] The researcher is the primary decision-maker because the researcher determines whether or not to initiate a project, even if its funding depends on outside sources. The NSF reports that principal investigators submit "about 2.3 proposals for every award they receive."[49]

Fourth, researchers in firms produce ideas that may be patented as part of products offered in the market (possibly yielding revenue streams even if the firm where they are developed does not exploit them). University researchers may also produce research that yields patents, but this is generally less important than the production of scholarly papers. (Some critics of commercialization in universities allege that producing papers and patents are in conflict, although evidence suggests this is false.[50])

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[47] *See* William Hoffman & Leo Furcht, the Biologist's Imagination: Innovation in the Biosciences 181 (2014).

[48] Off. of Budget Fin. and Award Mgmt., Nat'l Sci. Found., Funding Rate by State and Organization from FY 2021 to 2022 for NSF, https://dellweb.bfa.nsf.gov/awdfr3/default.asp (last visited Oct. 31, 2022).

[49] Off. of Budget Fin. and Award Mgmt., Nat'l Sci. Found. Merit Rev. Facts, https://www.nsf.gov/bfa/dias/policy/merit_review/facts.jsp (last visited Oct. 31, 2022).

[50] *See* Bart Clarysse et al., *Academic Spin-Offs, Formal Technology Transfer and Capital Raising*, 16 Indus. & Corp. Change 609 (2007).

Fifth, when a researcher is unproductive or does not follow guidance, a firm can fire them. Universities, on the other hand, have more trouble getting rid of unproductive researchers, particularly once they are tenured.

Lastly, firms and universities differ in ownership of research results. Firms generally own internal or contracted research results; researchers (especially productive ones) may receive a share of the rewards, but this is a matter for individual negotiations. Since Bayh-Dole, universities generally own the intellectual property rights (or have a right of first refusal to it) for research done on campus, but they usually share net profits with the researchers when results are commercially exploited.

The differences between university and corporate approaches are also illuminated by considering the small number of corporate laboratories widely recognized as successful at producing innovation: Bell Labs, IBM Research, and Xerox's Palo Alto Research Center (PARC)[51]. All three bear a striking resemblance to universities in many of the dimensions described above.

These labs focused on getting smart researchers together and then letting them pursue their own agendas. AT&T created Bell Labs to access what its president termed in a 1958 speech a "special brand of brains."[52] Bell Labs freed them from worrying about AT&T's actual businesses: "Researchers were thus free to select their own research topics without worrying about business relevance or

[51] These labs were quite unusual. *See* Robert Buderi, Engines of Tomorrow: How the World's Best Companies are Using Their Research Labs to Win the Future 44 (2000) (noting that "only the biggest and most dominant labs, such as IBM and Bell Labs, ever engaged in this type of basic research – and it was never more than perhaps 1 percent of the total research effort."). Even at these companies, core research and development got far more of the corporate attention than is often realized. William L. Keefauver, *in* Bell Labs Memoirs: Voices of Innovation 267, 279 (A. Michael Noll Michael Geselowitz eds., 2011) ("Bell Labs was best known from its published papers and inventions, most of which came from the research organization. But this was just ten percent of the company. The other organizations performed systems engineering and development."). Michael Hiltzik notes that "No corporate lab exists today that resembles the PARC of the 1970s and 1980s, not even the PARC of the 1990s, where great advances are made in physics, information science, and graphic technologies." He attributes this in part to changes in technology, but also in business: "No company, no matter how wealthy, dares devote even a fraction of its wealth to a search for knowledge that may not produce a return to the bottom line, as Xerox did. The utopian ideal of a corporate laboratory whose scientists are free to roam through Ideaspace draws only ridicule today." Michael A. Hiltzik, Dealers of Lightning: Xerox Parc and the Dawn of the Computer Age 397 (2000).

[52] Narain Gehani, Bell Labs: Life in the Crown Jewel 44 (2003).

management approval. They could even ignore management suggestions or stop working on a topic without the fear of serious negative repercussions, provided the research led to good results."[53] As one Bell Labs researcher put it, AT&T had determined that "freedom to pursue one's own ideas and stable, long-term funding were the best well-springs of innovation."[54] Likewise, PARC's managers believed "that the only way to get the best research was to hire the best researchers they could find and leave them unburdened by directives, instructions, or deadlines. For the most part, the computer engineers at PARC were exempt from corporate imperatives to improve Xerox's existing products. They had a different charge: to lead the company into new and uncharted territory."[55] Similarly, "[f]rom 1945 up until the 1990s IBM Research was funded primarily by headquarters and by the hardware and software divisions. The scientists had their own research agenda with some occasional technology transfer, but this was not the norm."[56] Looking back on over a decade of work there in 1966, IBM's European research director reflected that the company's Swiss facility had proven to be "a breeding ground for ideas that lie outside the mainstream and that, accordingly, would find it difficult to be accepted in the large central organization,"[57] hardly a description of an organization focused on developing commercial products!

Funding in these labs was unrelated to business purposes. While it was an effective monopoly (before the antitrust suit led to the company's breakup),[58] "AT&T was generous in funding Bell Labs [as were IBM and Xerox in funding their laboratories], but until the late 1980s, they did not seem to care what Bell

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[53] *Id*.

[54] Manfred R. Schroeder, *A Dream Come True*, *in* Bell Labs Memoirs: Voices of Innovation 65, 66 (A. Michael Noll & Michael Geselowitz eds., 2011).

[55] Hiltzik, *supra* note 51, at xxii.

[56] Christopher Sciacca & Christophe Rossel, *The Evolution of IBM Research: Looking Back at 50 Years of Scientific Achievements and Innovations*, 45 Europhysics News 16, 18 (2014), https://www.europhysicsnews.org/articles/epn/pdf/2014/02/epn2014452p16.pdf.

[57] Ambros P. Speiser, *IBM Research Laboratory Zurich: The Early Years*, 20 IEEE Annals History Computing 15, 27 (1998).

[58] Gehani, *supra* note 52, at 46 ("It used to be that AT&T was happy to let researchers reach out for the sky and make Bell Labs famous. AT&T basked in reflected glory, which did not cost it anything in the monopoly days, since it was allowed to pass on the costs to its customers. However, when AT&T shed its monopoly status, the rules of the game changed, which meant that AT&T would have to fund Bell Labs from its revenues, thus reducing its profits.").

Labs did or did not do as long as they excelled at science."[59] A similar change happened around the same time at IBM[60] and at PARC, as Xerox's financial position deteriorated.[61]

Many descriptions of these labs explicitly analogize to university environments. For example, Bell Labs is described as being "like a university that had no students, a zero teaching load, no tenure problems, no running around for grants, and plenty of money for equipment and travel. A researcher could focus on building his or her professional credentials and reputation. Within a few years, with Bell Labs on his or her resume, the researcher would have a passport to a tenured position at one of the top universities or would be able to walk into a senior research position at one of the industrial research labs."[62] One Bell researcher recalled that "we had all the benefits of academic freedom, along with good resources, and none of the teaching or administration loads that our counterparts in academia usually faced. Furthermore, compared to academia at that time, the pay was relatively good."[63] PARC's university-like atmosphere was partly the result of most of its staff being recruited from universities.[64] One of its researchers recalled, "A lot of us even came to feel we were sort of like university instructors who got to spend all our time doing research without having to teach classes."[65]

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[59] Gehani, *supra* note 52, at 42. For example, one Bell Labs researcher described how he worked on "[t]he double-stream amplifier," which he described as "a member of a large class of devices and inventions – wonderfully ingenious, and good for nothing." *See* John R. Pierce, *My Career as an Engineer: An Autobiographical Sketch by John R. Pierce* (1988), *reprinted in* Bell Labs Memoirs: Voices of Innovation 21, 39 (A. Michael Noll & Michael Geselowitz eds., 2011). This was not entirely altruistic: as one researcher noted, before 1984, AT&T wrote off its research budget at Bell Labs as a business expense. Schroeder, *supra* note 50, at 86.

[60] *See* Buderi, *supra* note 51, at 27-28; Bart Ziegler, *IBM's Research Cutbacks Now Seem to be Brilliant*, W.S.J. (Oct. 6, 1997), https://www.wsj.com/articles/SB87608804042499500 (describing IBM research cutbacks in early 1990s).

[61] *See* Hiltzik, *supra* note 51, at 377.

[62] Gehani, *supra* note 52, at 44. Indeed, in many ways it was "better than a university, especially for those interested in pursuing a research career and who did not care about teaching." *Id*. at 53. Gehani analogizes to universities for Bell Labs' emphasis on publications, hiring practices, and "freewheeling university-like research." *Id*. at 71, 110, 141-42.

[63] Alan G. Chynoweth, *At the Shining Laboratory on the Hill, in* Bell Labs Memoirs: Voices of Innovation 139, 157 (A. Michael Noll & Michael Geselowitz eds., 2011). *See also* Hiltzik, *supra* note 51, at 147 ("Once accepted into the [PARC] lab, you were immune to the petty harassments common to university departments.").

[64] *See* Hiltzik, *supra* note 51, at 58.

[65] *Id*. at 59.

Financial constraints were loose at these labs. A Bell researcher nostalgically recalled how he would let a computer run for entire weekends at a cost of $600 per hour, with the only consequence being that his budget was increased.[66] Similarly, Hiltzik concludes in his history of PARC that a key factor in its success was "Xerox's money, a seemingly limitless cascade of cash flowing from its near-monopoly on the office copier."[67]

Once ATT's breakup forced the company to behave more competitively, it began to expect "Bell Labs to help it compete by developing technologies that would lead to new products and services."[68], at 46. When much of Bell Labs was spun off to Lucent, one of the successor businesses, a Lucent executive asked a researcher what he did that was of value to Lucent. The researcher could not answer, finally saying, "This is a new way of looking at long-term research for me."[69] Similarly, when IBM Research changed its motto from "famous for its science and technology and vital to IBM" to "vital to IBM's future success," half the physics research team left in response.[70] Even internal IBM researchers note that the shift to focus on "actual customer problems" was "a completely unheard-of concept at the time."[71] Corporate demands for focus were not the only consequence of the breakup; fear of violating antitrust laws made researchers reluctant to collaborate.[72] And when Xerox imposed a more corporate-minded manager on PARC, one of the changes he made was that 50% of researchers' evaluations would be based on how well they worked with the developing and manufacturing units of the company.[73]

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[66] Schroeder, *supra* note 54, at 86.

[67] Hiltzik, *supra* note 51, at xxi.

[68] Gehani, *supra* note 52

[69] *Id*. at 60-61. The Alcatel-Lucent executive who ran Bell Labs noted that "[p]erhaps the most significant difference is our focus on coupling innovation with the needs of the marketplace." Jeong H. Kim, *Foreword*, *in* Bell Labs Memoirs: Voices of Innovation 1, 5-6 (A. Michael Noll & Michael Geselowitz eds., 2011).

[70] Gehani, *supra* note 52, at 147.

[71] Sciacca & Rossel, *supra* note 56, at 19.

[72] Chynoweth, *supra* note 63, at 174 (after breakup, "fear of breaking the anti-trust conditions caused, in effect, an Iron Curtain to descend between hitherto close colleagues. We were afraid to have any discussions with each other except in the presence of lawyers. Gradually, we learned what we could and could not do but it was a very distasteful and dissatisfying experience, to say the least.").

[73] *See* Hiltzik, *supra* note 51, at 377.

The result of this freedom was considerable innovation.[74] Bell Labs produced key breakthroughs in multiple areas, from lasers to semiconductors. PARC invented technologies still at the core of modern computer interfaces, from computer mice to graphical interfaces. IBM Research developed leading edge technologies in hardware and software, but also including the "Deep Blue" system that eventually bested Gary Kasparov at chess and the scanning tunneling microscope.[75] While their corporate parents sometimes benefited from these innovations, the dominant strain in researchers' recollections of their time at these institutions is that the company sponsors cared little about practical uses of what the researchers did.

It is striking that when companies could afford it and sought to "lead the company into new and uncharted territory"[76] as Hiltzik described PARC's mission or Bell Labs' mission "to advance the nation's telecommunications network,"[77] they sought to replicate conditions much like those in universities. This suggests that there is something about the conditions within the red box that produce innovation which is unavailable in the black box.

The different incentive structures we find when we open the black and red boxes thus points to the importance of the different internal incentive structures and decision processes to at least some types of innovation. We should therefore expect that researchers will behave differently in different boxes and that the boxes should attract different types of researchers.[78] The combination of the differences in behavior and the differences in structure likely make the research output of a red box different from the output of a black box. Buying research from a red box supplier rather than from a black box supplier may thus be an appropriate choice under some circumstances but not under others.

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[74] *See* Gehani, *supra* note 52, at 45 ("Bell Labs thus offered its scientists an environment where they could think out of the box in the pursuit of innovation and invention. As a result, Bell Labs scientists came up with numerous inventions many of which, such as the transistor, the active communications satellite, and the laser, had a profound effect on society.").

[75] *See The First Corporate Pure Science Research Laboratory*, IBM, https://www.ibm.com/ibm/history/ibm100/us/en/icons/scientificresearch/ (last visited Oct. 26, 2022).

[76] Hiltzik, *supra* note 51, at xxii.

[77] Gehani *supra* note 52, at 175.

[78] Kealey notes that universities were attracting faculty with the freedom to research at least as early as the 1700s. *See* Kealey, *supra* note 12, at 77.

B. What Makes University Research Different?

University research differs from research at for-profit firms in important ways. First, academic and research faculty, staff, and students, who have significantly more discretion in their research programs than do most black-box researchers, produce most university-based research.[79] Their discretion may include what they research and whether or not they seek intellectual property protection for the fruits of their research.[80]

Unlike employees in a corporate research laboratory, to gain a commercially viable invention, academic researchers must be persuaded to focus attention on problems of interest to the outside world and to conduct research to make it possible to commercialize or otherwise move it into the marketplace.[81] Many rewards in universities are correlated with dissemination of ideas that are potentially inconsistent with commercialization. A common story among TTOs is one of getting phone calls from a researcher about to board a plane for a conference to give a presentation, the contents of which could disclose a potentially patentable idea. The researcher wants to know: "Can we get a patent before my talk tomorrow?"[82]

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[79] *See* Nicholas S. Argyres & Julia Porter Liebeskind, *Privatizing the Intellectual Commons: Universities and the Commercialization of Biotechnology*, 35 J. Econ. Behav. & Org. 427, 431 (1998); *see also* Trevor Grigg, *Adopting an Entrepreneurial Approach in Universities*, 11 J. Eng'g Tech. Mgmt. 273, 282 (1994).

[80] *See* Ajay Agrawal & Rebecca Henderson, *Putting Patents in Context: Exploring Knowledge Transfer from MIT*, 48 Mgmt. Sci. 44, 58 (2002) ("Most faculty…suggest they are engaged in a research stream they find interesting and challenging, and that they make patent or publish decisions on a case-by-case basis."); Richard Jensen & Marie Thursby, *Proofs and Prototypes for Sale: The Licensing of University Inventions*, 91 Am. Econ. Rev. 240, 243 (2001) (survey found "convincing faculty to disclose inventions is a major challenge."). In a survey of 62 TTOs, Jensen, Thursby, & Thursby reported that:

> Many directors believe that substantially less than half of the inventions with commercial potential are disclosed to their office. Faculty may not want to disclose for a variety of reasons ranging from not being able to realize an invention has commercial value to not wanting to take time away from their research. Many faculty may not want to get involved in licensing because, as reported in the survey, faculty involvement in further development (even after a license is executed) is necessary for commercial success for 71% of inventions licensed.

Richard A. Jensen et al., *Disclosure and Licensing of University Inventions*, 21 Int'l J. Ind. Org. 1271, 1272 (2003).

[81] *See* Derek Bok, Universities in the Marketplace: The Commercialization of Higher Education 62 (2003) (if faculty "have to choose between the kind of research they enjoy and earning large sums of money, they rarely prefer the latter.").

[82] Morriss visited over twenty TTOs while working on technology transfer for his university and heard a variation on this story at virtually everyone.

As publications and presentations are primary coins of the realm in academia, that this is a frequent enough experience to enter the broader lore is unsurprising. This also illustrates the difficulty TTOs face in balancing their need to seek intellectual property protections for ideas and faculty members' needs to publish the results of work in a timely way.

Second, researchers in universities are sequestered, at least in part, from market pressures.[83] University administrators worry about budgets, but most research faculty enjoy the freedom to not worry about those pressures[84] and many likely sought positions in the academic world to avoid research dictated by market-driven employers. Indeed, significant freedom from market pressures is an important attribute of faculty culture.[85] They may be able to choose whether to pursue commercialization of a particular research result or to release it into the public domain. A fundamental justification for university-based research is that it provides a public good (basic research) that firms under provide.[86] To demonstrate their economic impact, both methods can provide universities with concrete examples of benefits to persuade federal and state legislatures to provide financial support.

[83] *See* Gary C. Fethke & Andrew J. Policano, Public No More: A New Path to Excellence for America's Public Universities 70 (2012).

[84] That is, university researchers need not worry about general revenue pressures but, individually, they do worry about obtaining funding, such as NSF money, to justify continuing their preferred research programs. There are, of course, exceptions to this. *See, e.g.*, Kealey, *supra* note 12, at 335-36 (describing authoritarian laboratory a colleague worked in and concluding that, although rules like those he describes are a denial of "the intellectual spirit" they are increasingly common).

[85] U.S. universities have closer ties with industry than many other nations, in part because of their dependence on local and private support. *See* David C. Mowery et al., Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act 13 (2004). Kealey notes that the pressure to obtain grants may inhibit this: "[G]rant-giving bodies which are accountable to government try only to give money for experiments that are likely to work. But experiments that are likely to work are probably boring – indeed, if they are predictable, they are barely experiments at all; rather, they represent the development of established science rather than the creation of the new. . . ." Kealey, *supra* note 12, at 87.

[86] Agrawal & Henderson, *supra* note 80, at 45; Argyres & Liebeskind, *supra* note 79, at 431.

Third, university hierarchies are structured differently from firms'.[87] Coase described firms as alternatives to the market organization of transactions;[88] universities are another form of such an organization. Coase quoted economist D. H. Robertson's image of firms as "islands of conscious power in this ocean of unconscious cooperation like lumps of butter coagulating in a pail of buttermilk" to illustrate the differences between firms and the market.[89] In Coase's formulation, firms offer a command-and-control structure in place of a market. Transactions occur within firms when the net advantages of command-and-control are greater than those of the decentralized marketplace and the unconscious coordination of the price mechanism.[90] We posit that universities fall between the solidity of the firms-as-lumps-of-butter and the fluidity of the marketplace-as-buttermilk. Universities' collective governance means that they have 'less conscious power' than most firms but they are nonetheless more 'solid' than the marketplace and they lack the coordinating mechanism of an internal price mechanism.[91] Organizing research within a university in pursuit of some goal is likely less clear than in a 'more solid' for-profit company. The looser constraints universities provide is a

[87] Grigg additionally describes universities as "complex organizations" and having "vague and ambiguous goals", which fits within this categorization. Grigg, *supra* note 79, at 279.

[88] Coase, *supra* note 39, at 389 ("[T]he distinguishing mark of the firm is the supersession of the price mechanism."). That is, the pure competition economic model is based on trades of generic commodities where individual actors matter little. There are many buyers and sellers of the same thing; each making individual decisions but no actors, individually, can dictate outcomes. In firms, as in universities, decisions are hierarchical and dictate at least portions of the outcomes—resources within organizations are distributed by command-and-control (decision makers) who are not controlled by unseen "market forces" setting prices and quantities.

[89] *Id*. at 388 (quoting D.H. Robertson, Control of Industry 85 (1923)).

[90] Coase's explanation of the role of firms, which was a key reason he received the Nobel Prize, has spawned a huge literature in economics. For a summary of his contribution, *see* Ronald H. Coase, Prize Lecture: The Institutional Structure of Production at the Nobel Prize Banquet (Dec. 9, 1991)) (transcript available at https://www.nobelprize.org/prizes/economic-sciences/1991/coase/lecture/). As Coase notes, how things work within firms is still largely treated as a mysterious black box. Coase helped explain why firms exist, not how they function.

[91] Fethke & Policano, *supra* note 83, at 172 ("Research public universities can be characterized as federations of departments run by faculty who make key academic decisions with important financial implications."). In some disciplines, there are clear hierarchies of journals. In others, the hierarchies are less clear. Whether something like a patent "counts" for tenure and merit pay is also unclear. Universities that explicitly acknowledge the possibility that a patent would "count" in reviews (such as Texas A&M) appear to be relatively rare and even in those circumstances the weight to be put on a patent is often left to the department or the individual evaluators.

significant part of the reason why organization is more difficult but, as noted above, may also be a key to enabling a different type of research.

Moving a university toward commercialization is not an easy task. For example, Siegel, et al. found disagreements over whether start-ups should be encouraged at a particular university, where the vice president for research favored them, but a faculty member commented that "we need to stop pretending that academics can be entrepreneurs, or at least good ones." This signaled a need for university officials "to devote more time and effort to ensuring such goals permeate their institutions."[92] Getting those goals to "permeate" university culture is not simply a matter of adopting them – faculty skeptical of the role of commercialization need to be persuaded to participate and/or to not oppose participation by other faculty. The great variety in university research enabled by decentralized research interests can be an organizational strength, as it allows relatively unconstrained pursuit of creative ideas, but it also can make universities less easily focused than firms in pursuit of specific research goals.[93] The highly concentrated nature of university patenting described above suggests that relatively few universities or faculty see pursuit of commercializable intellectual property as particularly important.

Fourth, research within a university is done in pursuit of tenure and prestige (awards, job offers, publications, etc.) rather than in (or perhaps in addition to) pursuit of financial rewards.[94] Like everyone else, university-based researchers

[92] Donald S. Siegel et al., *Toward a Model of the Effective Transfer of Scientific Knowledge from Academicians to Practitioners: Qualitative Evidence from the Commercialization of University Technologies*, 21 J. Eng'g Tech. Mgmt. 115, 130 (2004).

[93] Universities, like corporations, are not monolithic. Organizational forms are created to further various interests. For example, Clemson University, not known for automotive expertise, agreed to establish an automotive research center as part of an effort by the state of South Carolina to attract BMW to build a plant. Its function is largely divorced from the main campus of the university. *See* Clemson Univ. Int'l Center for Auto. Rsch., https://cuicar.com/ (last visited Nov. 15, 2022).

[94] *See* Argyres & Liebeskind, *supra* note 79, at 431 (arguing that governance structures in universities "broadly reflect" commitment to open science); Edward B. Roberts & Donald H. Peters, *Commercial Innovation from University Faculty*, 10 Rsch. Pol'y 108, 118 (1981) (discussing results of faculty survey on motivations); *see also* Alice Lam, *What motivates academic scientists to engage in research commercialization: 'Gold', 'ribbon', or 'puzzle'?*, 40 Rsch. Pol'y 1354, 1357 (2011). Obviously, prestige comes to black box researchers too, such as Physics Nobel laureate Jack Kilby of Texas Instruments who was instrumental in developing the integrated circuit. However, cutting edge developments that may bring glory in academics, whether of any market value or not, is less likely to matter in corporate research.

generally prefer greater to lesser financial rewards, but they know most university-awarded financial rewards likely pale compared to those of their counterparts who pursue research in private industry. They thus clearly value the other attributes of universities over those of for-profit firms sufficiently enough to give up some financial rewards.[95]

Finally, universities can be difficult for outsiders to navigate because they operate so differently from firms.[96] Companies often complain about the problems of negotiating with universities.[97] (Academics also complain about companies' cultures.)[98] To bridge the gap, commentators have identified a "strong need for individuals who can act as intermediaries or boundary spanners" between universities and businesses.[99] As the president of the Maryland Technology Development Corporation testified, in support of the role of intermediary organizations like his, "the university culture is one of fairly complex and byzantine rules and regulations. Intermediaries help the entrepreneurs who have never even known the existence of tech transfer offices to understand what is going on, to help them understand what an express license is versus trying to negotiate on their own."[100] Universities' organizational complexity and differences from the private sector increases the cost of commercialization efforts, making outsiders less willing to work with universities. Mitigating these transaction costs is important

[95] Bell Labs did not separately compensate researchers for their patents, instead paying them $1 on their first day for the rights to all future inventions. This did not bother at least some researchers. *See* Schroeder, *supra* note 54, at 68.

[96] *See* Dianne Rahm, *Academic Perceptions of University-Firm Technology Transfer*, 22 Pol'y Stud. J. 267, 267 (1994) ("Universities and firms have different missions, objectives, structures, organization cultures, and research orientations."). This was true of the corporate labs discussed above as well. *See also* Hiltzik, *supra* note 51, at xxii ("The scientists' unfettered creativity, not to mention their alien habits of mind and behavior, fomented unrelenting conflict with their stolid parent company.").

[97] *See* Virginia Gewin, *The Technology Trap*, 437 Science 948, 948 (2005); Argyres & Liebeskind, *supra* note 79, at 440-441; Siegel et. al, *supra* note 92, at 139.

[98] Siegel et. al, *supra* note 92, at 132.

[99] Donald S. Siegel, Mike Wright & Andy Lockett, *The Rise of Entrepreneurial Activity at Universities: Organizational and Societal Implications*, 16 Indus. & Corp. Change 489, 499 (2007); *see also* Donald S. Siegel, David Waldman & Albert Link, *Assessing the Impact of Organizational Practices on the Relative Productivity of University Technology Transfer Offices: An Exploratory Study*, 32 Rsch. Pol'y 27, 45 (2003) ("Without effective boundary spanning, the needs of customers may not be adequately communicated to suppliers.").

[100] H.R. Tech & Innovation Hearing, *supra* note 14, at 39 (statement of Robert Rosenbaum, President & Exec. Dir., Md. Tech. Dev. Corp.).

to try to expand commercialization efforts. However, such costs are desirable features, not bugs, for some in the university community. One example is the slower pace of decision making in universities due to shared governance; others include seemingly ever-expanding university bureaucracies that slow decision making. The slower pace or larger bureaucracies play important roles in securing support from constituencies within or important to universities.

In economic terms, we can think of the distinctive environment of universities as a series of constraints imposed on inventors' plans to connect their research outputs to the economy. These constraints are not present (although different ones are) in private firms. These constraints raise the transaction costs of doing business with a university.[101] But the constraints of university environments are not simply increased costs imposed by starry-eyed academics who fail to grasp the needs of the marketplace: The environment created in part by these constraints contains conditions for creativity that may enhance innovation. Firms – despite the many obstacles – contract with universities for research. This suggests the university environment offers something firms cannot buy elsewhere for a similar (or lower) price without incurring those transactions costs. In short, if universities were simply inefficient versions of the research environment that firms could create on their own, firms would have no need to contract with them. That firms contract with universities, faculty, and university-affiliated start-ups suggests that there is something valuable about the university environment and the researchers it attracts. This indicates that some research activities are best done through universities. One reason may be that universities are not just research laboratories: "[t]he differentiator for major research universities is the complementarity between teaching and research."[102] As we discuss below, there are reasons to think at least some universities may have a comparative advantage at some types of research.

[101] Another major contribution of Ronald Coase to our understanding of organizational function arises from his discussion of what is referred to as transaction costs. That is, dealing with other people and other organizations involves cost—it is like friction that prevents the wonderful world of a perpetual motion machine. The worse the friction, the less efficient the machine. Making deals, even one-on-one, is costly. That friction, or transaction cost, may arise from differences in languages, location, and legal system. Coase provides an overview in his Nobel address of the consequences of "positive transaction costs" that originated in his article, *The Problem of Social Cost*, J. L. & Econ. 1 (1960).

[102] Fethke & Policano, *supra* note 83, at 11.

C. Bayh-Dole & Incentives to Stimulate Research

Measuring research success is difficult. When a new idea is discovered, the future value is hard to know. Some inventions are not translated into success for some time and others, initially thought to be significant, fail to generate much revenue. One measure of university research output is the stock of inventions. In remarks on the Senate floor during debate over the 1980 Patent and Trademark Amendment Act, known as the Bayh-Dole Act after its cosponsors, Sens. Birch Bayh (D.-Ind.) and Robert Dole (R-Kan.),[103] Bayh described a relatively simple, linear model as the framework for the Act: "Hundreds of valuable medical, energy, and other technological discoveries are sitting unused under Government control, because the Government, which sponsored the research that led to the discoveries, lacks the resources necessary for development and marketing purposes, yet is unwilling to relinquish patent rights that would encourage and stimulate private industry to develop discoveries into products available to the public."[104] The notion of good ideas sitting on the shelf of agencies for lack of investment reflected part of the problem but neglected the full context within which the translation of ideas from the academy to the world could occur. As Terence Kealey, who served as both a scientist at Cambridge and vice chancellor of the University of Buckingham, observes, the linear model did not match reality during the industrial revolution or today.[105]

Universities, which capture some rewards, have more incentive to commercialize the results of research than government bureaucracies do, but, as discussed above, they operate under a wider set of constraints than Bayh's description suggested, which may help explain why so few successfully patent and transfer ideas. Moreover, "[t]he Act's emphasis on patenting and licensing as a critically important vehicle for the transfer to industry of academic inventions lacked a strong evidentiary foundation at the time of its passage, and evidence on the role of patenting and licensing as indispensable components of technology transfer remain mixed."[106] There are plenty of ideas "on the shelf" produced at research

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[103] 94 Stat. 3015 (codified at 35 U.S.C. §§ 200-212).

[104] 95 Cong. Rec. S15,034 (Sept. 13, 1978). Similarly, one comment on Bayh-Dole summarized the issues as focused on "a race from discovery to commercialization with the university obtaining as much control over the invention as they can." Krumm, *supra* note 19, at 189.

[105] Kealey, *supra* note 12, at 73.

[106] Mowery et al., *supra* note 85, at 7-8.

universities but there are obstacles to getting them to the market for which Bayh-Dole's linear model does not account. The supply of ideas that might be commercialized is only a partial answer to why firms would license university-produced ideas or buy university-related firms.

University research generally produces what Schumpeter termed inventions, rather than innovations. The distinction is that inventions alone will not have an economic impact without the transformational genius of the entrepreneur. As Schumpeter noted,

> The inventor produces ideas, the entrepreneur 'gets things done,' which may but need not embody anything that is scientifically new. Moreover, an idea or scientific principle is not, by itself, of any importance for economic practice: the fact that Greek science had probably produced all that is necessary in order to construct a steam engine did not help the Greeks or Romans to build a steam engine; the fact that Leibnitz suggested the idea of the Suez Canal exerted no influence whatever on economic history for two hundred years.[107]

In Schumpeterian terms, what universities have to sell is just part of what is needed for an idea to succeed. To be useful in the marketplace, ideas must be manifested as designs, tools, methods, etc. that solve a problem or offer novelties previously unknown.[108]

Moreover, we need to keep in mind that licensing (or selling a firm with a license) is just one potential method of transferring knowledge from university to the market. As Litan, Mitchell, and Reedy argue,

> Universities have a range of outputs, including information, materials, equipment and instruments, human capital, networks, and prototypes. The means by which these outputs are diffused, especially to industry, vary across universities. The Carnegie Mellon Survey of Industrial R&D found that the most commonly reported mechanisms for diffusion of public research to industry were publications, conferences, and

[107] Schumpeter, *supra* note 32, at 224. Note that ideas alone cannot be patented.

[108] The scale of the investment needed to turn ideas into innovations was one reason that Schumpeter (inaccurately) forecast that innovation would become the province of only large businesses. *See* Joseph A. Schumpeter, Capitalism, Socialism & Democracy 82 (1952).

> informal exchanges. Patents ranked low in most industries except for pharmaceuticals.[109]

Idea transfers from universities to the world can occur independently of commercialization. Faculty generate papers, teach, consult, serve on boards, and so on – all means of knowledge transfer.[110] Firms find value in these channels. A 2011 survey found the top two benefits reported by firms for interactions with universities were "access to fundamental understanding" and "access to direct assistance with problem solving."[111] An analysis of university strategies for interactions with firms therefore needs to incorporate channels besides commercialization. Over-estimates of the value of university-owned intellectual property can restrict faculty's ability to pursue other avenues while fruitless commercialization efforts are made. Nonetheless, Bayh-Dole was created because these other methods were thought insufficient.

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[109] Robert E. Litan et al., *Commercializing University Innovations: Alternative Approaches*, *in* 8 Innovation Pol'y & Econ. 31, 44 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2008) (citations omitted). The other means include "nonpatent innovations, start-up companies launched by university faculty or related parties, and consulting engagements between industry and faculty." *Id*. Different faculty do different types of activities as well. *See* Agrawal & Henderson, *supra* note 80, at 47-52 (based on study of two departments at MIT). In addition, different firms collaborate with faculty on patents and papers. *Id*. at 52-58.

[110] Frank T. Rothaermel & Marie Thursby, *University-Incubator Firm Knowledge Flows: Assessing Their Impact on Incubator Firm Performance*, 34 Rsch. Pol'y 305, 318 (2005) (finding positive correlation in success with firm citation of papers); Valentina Tartari et al., *In Good Company: The Influence of Peers on Industry Engagement by Academic Scientists*, 43 Rsch. Pol'y 1189, 1201 (2014). There are likely other, relatively unexplored channels. Mathies and Slaughter explore the "executive science network" created by the overlap of private American Association of Universities ("AAU") member university and corporate boards and find connections for knowledge transfer. Charles Mathies & Sheila Slaughter, *University Trustees as Channels between Academe and Industry: Toward an Understanding of the Executive Science Network*, 42 Rsch. Pol'y 1286, 1296 (2013).

[111] Kate Bishop et al., *Gaining from Interactions with Universities: Multiple Methods for Nurturing Absorptive Capacity*, 40 Rsch. Pol'y 30, 37 (2011); *see also* Markus Perkmann et al, *Engaging Excellence? Effects of Faculty Quality on University Engagement with Industry*, 40 Rsch. Pol'y 539, 540-41 (2011) [hereinafter Perkmann et al., *Engaging Excellence*] (summarizing literature); Isabel Maria Bodas Freitas et al., *Finding the Right Partners: Institutional and Personal Modes of Governance of University-Industry Interactions*, 42 Rsch. Pol'y 50, 51 (2013) (finding evidence of an important channel of personal contractual relations with faculty in a sample of small Italian firms); Markus Perkmann, et al., *Academic Engagement and Commercialization: A Review of the Literature on University-Industry Relations*, 42 Rsch. Pol'y 423, 424 (2013) [hereinafter Perkmann et al.,*Academic Engagement & Commercialization*] ("[C]ommercialization is often an outcome or follow-on activity, whether intended or unintended, of academic engagement.").

As discussed earlier, treating universities like profit-maximizing firms is a major conceptual error.[112] Universities and firms operate under different legal and political constraints, actors within them face different incentives, and success is evaluated by different metrics both for the institutions and the researchers within them.[113] Pathways for discoveries to move from university research to commercial development must account for those differences. As Gulbrandsen, Mowery, and Feldman (leaders in the academic study of technology transfer from universities to firms) wrote in their introduction to a symposium, "a recognition of the heterogeneity in the characteristics of university–industry linkages among disciplines is crucial to the formulation of intelligent public policy and for more effective management by universities of their relationships with industry."[114] This is challenging as "[p]ractice without process becomes unmanageable, but process without practice damps out the creativity required for innovation; the two sides exist in perpetual tension. Only the most sophisticated and aware organizations are able to balance these countervailing forces in ways that lead to sustained creativity and long-run growth."[115]

[112] Jensen et al., *supra* note 80, at 240 ("In a university setting, profit maximization is rarely the objective."). Former Harvard president, Derek Bok, argues that attempts to "make a profit from teaching, research, and other campus activities" are quite widespread in universities, have occurred over a long period, and are mostly different today in their "unprecedented size and scope." As a result, he contends "[e]ntrepreneurship is no longer the exclusive province of athletic departments and development offices; it has taken hold in science faculties, business schools, continuing education divisions, and other academic units across the campus." Bok, *supra* note 81, at 2-3. Bok uses the terms entrepreneurship and commercialization more broadly than did Schumpeter or does this Article; however his point is an important one. There are many efforts to find additional funding for universities – as Bok put it, "[t]hroughout the 1980s, deans and professors had brought me one proposition after another to exchange some piece or product of Harvard for money—often quite substantial sums of money." *Id.* at x. This phenomenon includes some amount of commercialization as discussed here but is a much broader set of issues.

[113] *See generally* Ryan Amacher & Roger Meiners, Faulty Towers (2004) (discussing some incentives within universities that are often a mystery to those not imbued in those institutions).

[114] Magnus Gulbrandsen, David Mowery, & Maryann Feldman, *Introduction to the Special Section: Heterogeneity and University-Industry Relations*, 40 Rsch. Pol'y 1, 5 (2011); *see also* Perkmann et al., *Engaging Excellence*, *supra* note 107 (discussing differences across disciplines in industry relationships).

[115] Richard Florida, The Rise of the Creative Class, Revisited 26-27 (2012). As Hoffman and Furcht noted, this idea is related to Michael Porter's idea that nations have clusters of related successful technologies. Hoffman & Furcht, *supra* note 47, at 91 (quoting Michael A. Porter, the Competitive Advantage of Nations (1998), that "[n]ations succeed not in isolated industries, however, but in *clusters* of industries connected through vertical and horizontal relationships.").

If the fruits of university research are to make it to the marketplace, we need: (a) a variety of channels for the ideas to reach market actors, including means of commercialization, (b) a means of harnessing entrepreneurial talent from outside universities to innovations from within universities, and (c) methods that fit the unique environment within Coasian red boxes.

D. The University Environment & Innovation

As discussed above, the university environment differs from the environment of for-profit firms. The university is sometimes seen as the best environment for science, but not always.[116] Both entities, though, require innovators to navigate inefficient bureaucracies. Just as the university environment can be challenging, the for-profit environment can also be difficult for innovators as firms too can have inefficient bureaucracies.[117] At for-profit firms, innovators often struggle to adapt their method of project acceptance to the firm's formalized process, causing problems for the organization. As Griffin, et al. noted in their study of "serial innovators" in firms, "the way in which they navigate the politics of project acceptance are so different from the firm's formalized processes, they inherently cause problems for the organization."[118] Different incentive structures should mean that university researchers behave differently from researchers at for-profit firms. Although sarcastic, the account of a chemist hired away from academia by Dow Chemical in the 1920s (at twice his academic salary) in a letter to a friend written soon after the chemist started at Dow's research laboratory captures the difference:

> A week of the industrial slavery has already elapsed without breaking my proud spirit. Already I am so accustomed to the shackles that I scarcely notice them. Like the child laborers in the spinning factories and the coal mines, I arise before dawn and prepare myself a meager breakfast. Then

[116] *But see* Myron S. Allen, *Working Procedures of Creativity*, *in* The Second (1957) University of Utah Research Conference on the Identification of Creative Scientific Talent 192, 194 (1957) ("when the need for creative scientists is so acute, why is an academic climate insisted upon in which creative thinking is inhibited, and in which a man is made to feel so uncomfortable if he exhibits originality?").

[117] Abbie Griffin et al., Serial Innovators: How Individuals Create and Deliver Breakthrough Innovations in Mature Firms 30 (2012) (Innovators in for-profit firms often find that "formal product development processes typically are insufficient to support breakthrough innovation," requiring them to "develop additional process capabilities over and above those already resident in the firm that nonetheless are compatible with existing processes.").

[118] *Id*. at 3.

> off to the terrific grind arriving at 8 just as the birds are beginning to wake up. Harvard was never like this.[119]

In this section we discuss research on creativity and innovation that helps understand why the university environment should be productive for at least some kinds of research.

First, innovation requires creativity.[120] As Richard Florida posits, creativity is "the faculty that enables us to derive useful new forms from knowledge."[121] Moreover, "creativity is often not just a single event or episode; it is sometimes an unplanned sequence of fortuitous events."[122] As a result, "creative success leads to further creativity, which helps to generate corporate funding to continue the work that initially did not appear to have potential—and frequently leads to business opportunities. . . . Working toward a goal can help creativity, but trying to predict or control the paths that link creative acts to useful results may do more harm than good."[123] It is thus a difficult force to control.

Second, we know that creativity is – contrary to popular perceptions of the lone genius toiling in a lab or studio[124] – "heavily dependent on social interaction,

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[119] William H. Starbuck, *How Organizations Channel Creativity*, *in* Creative Action in Organizations: Ivory Tower Visions & Real World Voices 106 (Cameron M. Ford & Dennis A. Gioia, eds., 1995).

[120] *See* Mihaly Csikszentmihalyi, *Society, Culture, and Person: A Systems View of Creativity*, *in* The Collected Works of Mihaly Csikszentmihalyi 47 (2014) (arguing that innovation is the result of "three main shaping forces: a set of social institutions, or *field*, that selects from the variations produced by individuals those that are worth preserving; a stable cultural *domain* that will preserve and transmit the selected new ideas or forms to the following generations; and finally the *individual*, who brings about some change in the domain, a change that the field, will consider to be creative"). *See also* Florida, The Rise of the Creative Class, *supra* note 115, at 88 ("'You cannot motivate the best people with money,' says Eric Raymond, author of *The Cathedral and the Bazaar* and a leading authority on open-source software. 'Money is just a way to keep score. The best people in any field are motivated by passion.'").

[121] Florida, The Rise of the Creative Class, *supra* note 115, at 31. Florida points to Keith Simonton's definition of creativity as "the act of bringing something useful, that works, and is non-obvious into the world, or as he succinctly put it, that is the 'conjunction of novelty, utility, and surprise.'" *See supra* 115, at 6 (citing Keith Simonton, *Creativity: Cognitive, Developmental, Personal and Social Aspects*, 55 Am. Psychologist 151 (2000)).

[122] Walter L. Robb, *Membranes for Gas Separation: A Case Study in Creativity*, *in* Creative Action in Organizations: Ivory Tower Visions & Real World Voices 263 (Cameron M. Ford & Dennis A. Gioia, eds., 1995).

[123] *Id*. at 263.

[124] Mihaly Csikszentmihalyi & Keith Sawyer, *Creative Insight: The Social Dimension of a Solitary Moment*, *in* Mihaly Csikszentmihalyi, the Systems Model of Creativity 74-75 (2014) ("When we look at the complete 'life span' of a creative insight in our subjects' experience, the moment of insight appears as

which takes the form of face-to-face encounters and of immersion in the symbolic system of one or more domains."[125] Matt Ridley sums it up as "a collective, incremental and messy network phenomenon" and "a team sport."[126] As one scientist reported during an interview on the creative process:

> Science is a very gregarious business; it's essentially the difference between having this door open and having it shut. If I'm doing science, I have the door open. That's kind of symbolic, but it's true. You want to be all the time talking with people…it's done by interacting with other people in the building that you get anything interesting done; it's essentially a communal enterprise.[127]

Part of their value is surely that at least some universities are places where such "gregarious business" is relatively easy to conduct.

Third, we know that "[t]he most significant insights (e.g., those that lead to innovative new products or uses for new technology) are often characterized by a synthesis of information from multiple domains, which can be as far apart as chemistry is from social norms, or as close as neighboring branches of

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but one short flash in a complex, time-consuming, fundamentally social process. It is true that the individuals we interviewed generally report their insights as occurring in solitary moments: during a walk, while taking a shower, or while lying in bed just after waking. However, these reports are usually embedded within a more complex narrative, a story that describes the effort proceeding and following the insight, and the overall sense of these complete narratives stresses the salience of social, interactional factors. It seems that the solitary nature of the moment of insight may have blinded us to the social dimension of the entire creative process.").

[125] Mihaly Csikszentmihalyi & Keith Sawyer, *Shifting the Focus from Individual to Organizational Creativity*, *in* Mihaly Csikszentmihalyi, the Systems Model of Creativity 70 (2014). *See also* Robb, *supra* note 122, at 263 ("creativity usually involves other people directly or indirectly, and sometimes they come from other departments or even outside the company; they bring divergent insights to bear on problems that converge on the interests of the company."); Florida, The Rise of the Creative Class, *supra* note 115, at 118 ("Creativity involves the ability to synthesize."); Henry Eyring, *Scientific Creativity*, *in* The Second (1957) University of Utah Research Conference on the Identification of Creative Scientific Talent 159 (1957) ("The lone wolf has solved many problems, but an increasing number of scientific enterprises are becoming highly cooperative and require social integration. On team projects no degree of talent can fully compensate for an impossible personality inside the large scientific laboratories which are doing an ever-increasing proportion of the creative work of the world.").

[126] Matt Ridley, How Innovation Works and Why it Flourishes in Freedom 93, 256 (2020).

[127] Csikszentmihalyi & Sawyer, *Creative Insight: The Social Dimension of a Solitary Moment*, *supra* note 124, at 86.

mathematics."[128] Ridley refers to this as "ideas having sex,"[129] a metaphor that captures the environment in universities where 'DNA' from other fields is close at hand.

Fourth, there are "hot spots" as "access to the field is not evenly distributed in space. The centers that facilitate the realization of novel ideas are not necessarily the ones where the information is stored or where the stimulation is greatest."[130] These centers are "communities of practice" which are linked by "process and structure" to transfer knowledge, achieve scale, and generate growth.[131] This is well-illustrated by a scientist's description of the Berkeley chemistry department in 1930: "Successful research was the badge of honor. To not try to do research was unthinkable."[132] More broadly, Florida developed a theory to explain the success of cities due to the presence of a "creative class."[133] Although he focused on urban centers, he also contended that "Universities are the intellectual hubs of the creative economy. America's vital university system is the source of much of our

[128] Csikszentmihalyi & Sawyer, *Shifting the Focus from Individual to Organizational Creativity*, *supra* note 125, at 70; *see also* Csikszentmihalyi & Sawyer, *Creative Insight: The Social Dimension of a Solitary Moment*, *supra* note 124, at 82 ("Revolutionary creative insights seem to be based on the random convergence of ideas from different domains, usually facilitated by interaction with individuals from different fields."); Matt Marx & David H. Hsu, *Revisiting the Entrepreneurial Commercialization of Academic Science: Evidence from 'Twin' Discoveries* 18 (Nat'l Bureau of Econ. Rsch. Working Paper No. 28203, 2020) (noting that interdisciplinary teams are more likely to commercialize).

[129] Ridley, *supra* note 126, at 251.

[130] Mihaly Csikszentmihalyi, Creativity: The Psychology of Discovery and Innovation 130 (1996). As Csikszentmihalyi notes, "Even with our dazzling electronic means for exchanging information, New York is still the best place for an aspiring artist to find out firsthand what's happening in the art world, what future trends other artists are talking about now. But New York is not the best place to learn oceanography, or economics, or astronomy. Iowa might be the best place to learn creative writing or etching, and one can learn things about neural networks in Pittsburgh that one cannot learn anywhere else." *Id. See also* Hoffman & Furcht, *supra* note 47, at 10-11 ("Even in an era of globalization, place matters for innovation. The world's cities and surrounding regions are where the lion's share of new scientific knowledge is produced and technical innovation is spawned. That has been true ever since the scientific revolution in Western Europe during the seventeenth century.").

[131] Florida, The Rise of the Creative Class, *supra* note 115, at 26-27. As Hoffman and Furcht noted, this idea is related to Michael Porter's idea that nations have clusters of related successful technologies. Hoffman & Furcht, *supra* note 47, at 91 (quoting Michael A. Porter, The Competitive Advantage of Nations (1998), that "Nations succeed not in isolated industries, however, but in clusters of industries connected through vertical and horizontal relationships.").

[132] Eyring, *supra* note 125, at 164.

[133] Richard Florida, The Flight of the Creative Class: The New Global Competition for Talent (2007).

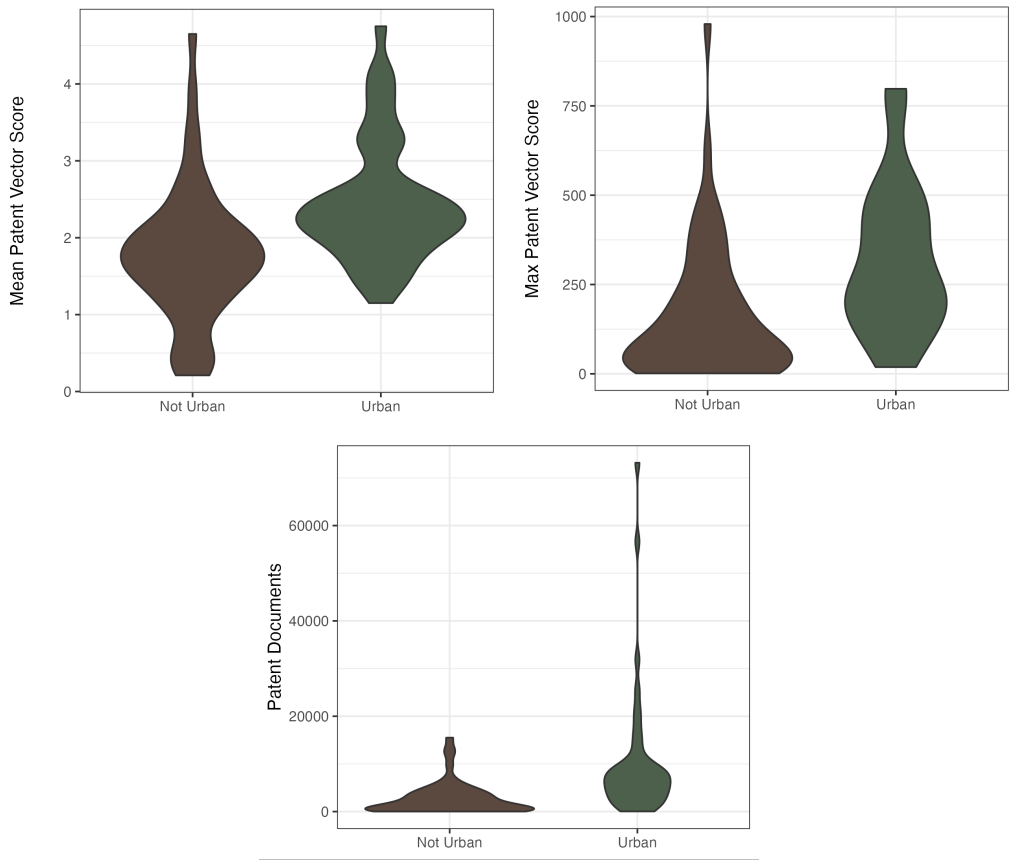
best scientific, social, and creative leadership." Because they promoted talent and tolerance, as well as research, they too drew a creative class.[134] These communities are also important because this is where tacit knowledge can be exchanged. Tacit knowledge plays an important role in transforming inventions into innovations.[135] Universities often build clusters of faculty with related interests, making them into 'hot spots' for those fields.

With our data, we find there is more high-value patent activity in universities in urban areas than those in non-urban areas, which might be due to an effect akin to Florida's "creative class" argument. Figure 4 shows the patent data broken down by urban/non-urban, with quite different patterns of patenting.

[134] *Id*. at 251.

[135] Hoffman & Furcht, *supra* note 47, at 92 ("the tacit dimension of knowledge is intangible and highly local. It permeates the culture of clusters. The relationship between explicit and tacit knowledge may take the form of an equation: The more easily transferable codified knowledge is, the more valuable is the tacit form of knowledge. This is the location paradox and what Michael Porter means when he says that the more things are mobile, the more decisive location becomes.").

FIGURE 4:
URBAN V. NON-URBAN UNIVERSITIES



Although universities in non-urban areas, particularly large ones, create their own community of creative individuals, it may be that with respect to the specific types of creativity necessary to transform research into marketable intellectual property (a subset of entrepreneurial abilities), the lack of a sizeable urban center is problematic.

Fifth, individuals differ in creativity. Research suggests that individuals who have strong intrinsic motivation are more creative, and giving these individuals the freedom to explore ideas is also important.[136] People must also be curious

[136] Csikszentmihalyi & Sawyer, *Shifting the Focus from Individual to Organizational Creativity*, *supra* note 125, at 70-71 ("The most important individual characteristics are strong interest, curiosity, or intrinsic motivation that drive a person or group to commit attention to a — problematic area in a domain, and beyond generally accepted boundaries of knowledge."); *Id*. at 71 ("It is essential not to fill schedules with goal-directed, conscious, rational problem solving, so as to allow for the serendipitous combination of ideas.");

to be creative: "Without a good dose of curiosity, wonder, and interest in what things are like and in how they work, it is difficult to recognize an interesting problem."[137] They need to be able to engage in both divergent and convergent thinking[138] and be able to engage in the "hard work" that is "necessary to bring a novel idea to completion and to surmount the obstacles a creative person inevitably encounters."[139] Creative people have different powers of attention.[140] They also need to be able to discard bad ideas.

> Practically all creative individuals say that one advantage they have over their peers is that they can tell when their own ideas are bad, and that they can immediately forget the bad ideas without investing too much energy in them. Linus Pauling, the winner of two Nobel prizes, was asked at his sixtieth birthday party how he had been able to come up with so many epochal discoveries. "It's easy," he is said to have answered, "You think of a lot of ideas, and throw away the bad ones." To be able to do so, however, implies that one has a very strong internal representation of which ideas are good and which are bad–a representation that matches closely the one accepted by the field.[141]

David C. McClelland, *The Calculated Risk: An Aspect of Scientific Performance*, *in* The 1955 University of Utah Research Conference on the Identification of Creative Scientific Talent 96, 96 (1955) ("[V]ery often, when we are dealing with high-level scientific creativity, the real criterion is whether or not people create spontaneously whether they are asked to or not.").

[137] Csikszentmihalyi, Creativity, *supra* note 130, at 53; *see also* J.P. Guilford, *The Relation of Intellectual Factors to Creative Thinking in Science*, *in* The 1955 University of Utah Research Conference on the Identification of Creative Scientific Talent 69, 72 (1955) ("Sensitivity to problems is an ability in which, in the writer's experience, there are gross differences among graduate students.").

[138] Csikszentmihalyi, Creativity, *supra* note 130, at 60 ("Furthermore, people who bring about an acceptable novelty in a domain seem able to use well two opposite ways of thinking: the *convergent* and the *divergent*. Convergent thinking is measured by IQ tests, and it involves solving well-defined, rational problems that have one correct answer. Divergent thinking leads to no agreed-upon solution. It involves fluency, or the ability to generate a great quantity of ideas; flexibility, or the ability to switch from one perspective to another; and originality in picking unusual associations of ideas.").

[139] *Id*. at 61.

[140] *Id*. ("When asked what enabled him to solve the physics problems that made him famous, Hans Bethe answered with a smile: 'Two things are required. One is a brain. And the second is the willingness to spend long times in thinking, with a definite possibility that you come out with nothing.'").

[141] Mihaly Csikszentmihalyi, *Creativity and Genius: A Systems Perspective*, *in* Mihaly Csikszentmihalyi, The Systems Model of Creativity 121 (2014).

Moreover, some people are better at identifying and solving problems that demand creative solutions, where "the nature of the problem to be solved is less clear; in fact, the problem itself might not be formulated until the moment of insight."[142] Identifying such problems is a key challenge.[143] If universities are better than firms at attracting individuals with these skills, then universities will have a comparative advantage in producing creative ideas. Further, the hiring of creative people is not something that ever ends: talent is not a stock but a flow.[144] Hiring processes must therefore focus on continually replenishing the flow. University hiring processes are generally driven by departments and so focused on excellence in particular fields, a focus which is likely to keep the flow moving.

Sixth, there must be an environment that fosters creativity for researchers,[145] a part of the analysis of creativity that has often been neglected.[146]

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[142] Csikszentmihalyi & Sawyer, *Creative Insight: The Social Dimension of a Solitary Moment*, *supra* note 124, at 79. This is the distinction between "presented problem solving" and "discovered problem finding." *Id*. The former occurs when "a problem is known and preexisting in the domain and all that needs to be focused is a solution to it." *Id*. The latter is what is discussed in the text. *See also* Csikszentmihalyi, Creativity, *supra* note 130, at 95 ("there are also situations in which nobody has asked the question yet, nobody even knows that there *is* a problem. In this case the creative person identifies both the problem and the solution. Here we have a 'discovered' problem.").

[143] Csikszentmihalyi, Creativity, *supra* note 130, at 95-96 (quoting Freeman Dyson that "It is characteristic of scientific life that it is easy when you have a problem to work on. The hard part is finding a problem to work on.").

[144] Florida, The Rise of the Creative Class, *supra* note 115, at 233 ("Most economists tend to see technology and talent as fixed stocks, like raw materials or natural resources, but the reality is that they are flows.").

[145] Karl G. Hill & Teresa M. Amabile, *A Social Psychological Perspective on Creativity: Intrinsic Motivation and Creativity in the Classroom and Workplace*, *in* Understanding and Recognizing Creativity: The Emergence of a Discipline (Scott G. Isaksen, Mary C. Murdock, Roger L. Firestien, & Donald J. Treffinger, eds.) 425 (1993) ("the individual's intrinsic motivation can be influenced not only by his own initial spark of interest in the task, but also by everything in the organization which might lead that initial interest to sputter away or to burn even more brightly."); Eyring, *supra* note 125, at 159 (""even the gifted individual requires a stimulating environment, including freedom from distractions which deflect attention from the question at issue and freedom from an authoritarian society which prevents unbiased enquiry.").

[146] Cameron M. Ford, *Creativity is a Mystery: Clues from Investigators' Notebooks*, *in* Creative Action in Organizations: Ivory Tower Visions & Real World Voices 21 (Cameron M. Ford & Dennis A. Gioia, eds., 1995) ("[T]his love affair with creators has led researchers to focus too narrowly on characteristics of individuals that lead them to commit creative acts. They have almost ignored the search for opportunities *when and where* creative acts are most likely to occur. This approach has certainly reduced the impact of creativity research in real-world settings. In organizational settings, this oversight is almost crippling. Organizations need not look so intently for heroes. Instead, we need to provide talented and motivated individuals with opportunities to enact creative solutions.").

> Based on what we now know about creativity, this is what managers should do to foster creativity in organizations. First, they should work to eliminate the environmental obstacles—the turf battles, the caustic reactions to new ideas, the lack of commitment to innovation. Second, they should create an environment where the stimulants are richly, redundantly present: an orientation toward innovation and risk taking, from the highest levels of top management on down; strategic direction for projects, coupled with procedural autonomy for those doing the projects; work that people perceive as challenging, interesting, and important; rewards and recognition for creativity; frequent, work-focused feedback; stimulating, diverse work teams; open communication and collaboration across the organization; and commitment of adequate resources and time for projects.[147]

While universities can be far from ideal in this regard, with disciplinary barriers, rigidity in existing conceptions of disciplines, and barriers to collaboration that range from the relatively mundane (parking) to deeply problematic (tenure standards that discourage cross-disciplinary work),[148] they can also be good places for creative work. One key advantage is that universities house smart, creative people from a variety of fields. This is important as a critical part of the creative process is interaction with people in "neighboring fields."[149]

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[147] Teresa M. Amabile, *Discovering the Unknowable, Managing the Unmanageable*, *in* CREATIVE ACTION IN ORGANIZATIONS: IVORY TOWER VISIONS & REAL WORLD VOICES 81 (Cameron M. Ford & Dennis A. Gioia, eds., 1995). This description echoes the descriptions of PARC, Bell Labs, and IBM Research discussed above.

[148] *See, e.g.*, HOFFMAN & FURCHT, *supra* note 47, at 218 ("What is clear is that rigid institutional boundaries in hierarchal, tradition-bound universities and companies are inhibiting a more open flow of information to foster innovation in the pharmaceutical and biopharmaceutical arenas.").

[149] Csikszentmihalyi, *Society, Culture, and Person, supra* note 120, at 54 ("the model suggests that without people in neighboring fields who become attracted to the new idea, the creative process will be aborted.... In a setting with not enough mechanics interested in flying, the Wrights' efforts would eventually have been forgotten, and aeronautics would not have developed."); Csikszentmihalyi & Sawyer, *Creative Insight*, *supra* note 124, at 77 ("In our interviews, we found that creative individuals had a strong subjective awareness of external social or discipline influences at each creative stage. When asked to describe a moment of creative insight, they typically provided extended narratives that described not just a single moment but a complex, multi-stage process, with frequent discussions of interpersonal contact, strategic or political considerations, and awareness of the paradigm, of what questions were interesting as defined by the discipline. This was particularly salient in the preparation stage and in the evaluation and elaboration stage. Although the moment of creative insight usually occurs in isolation, it is surrounded and contextualized within an ongoing experience that is fundamentally social, and the insight would be, meaningless out of that context.").

The freedom of the university environment is also an important ingredient in this environment.[150] Indeed, Ridley says that freedom generally is the "secret sauce" that produces innovation: "[f]reedom to exchange, experiment, imagine, invest and fail; freedom from expropriation or restriction by chiefs, priests and thieves; freedom on the part of consumers to reward the innovations they like and reject the ones they do not."[151] This is not just the ability to choose an area of research but something broader. Creativity researchers identified "an environment where project goals are clear, challenging, and personally interesting, where they are given autonomy in deciding how to achieve project goals, where their new ideas are met with encouragement and enthusiasm, where they are not burdened with impossible project schedules or resource limitations" as important to fostering creativity.[152]

Finally, approaching the problem from the other end, Csikszentmihalyi and Sawyer argued that creativity is unlikely to be found where any of the following conditions are met:

- "The absence of a strong interest, curiosity, or intrinsic motivation that drives the person to commit attention to a problematic area in a domain. *A person who is not intrinsically motivated has no incentive to push beyond generally accepted boundaries of knowledge*.
- The absence of a thorough grounding in at least one symbolic domain, presumably as an apprentice to an expert, and not having experienced the colleagueship of other expert apprentices. *Creative insights typically involve the integration of perspectives from more than one domain*.
- The absence of interaction with other individuals who are experts in the domain or in potentially relevant other domains. *At every stage of the process,*

[150] Dennis A. Gioia, *Contrasts and Convergences in Creativity: Themes in Academic and Practitioner Views*, *in* Creative Action in Organizations: Ivory Tower Visions & Real World Voices 317, 328 (Cameron M. Ford & Dennis A. Gioia, eds., 1995) ("Traditional bureaucratic hierarchies are impediments to creativity. Organizational creativity often takes the form of creatively transforming the organization structure in ways that facilitate the activities of people looking for an opportunity to be creative.").

[151] Ridley, *supra* note 126, at 359.

[152] Hill & Amabile, *supra* note 145, at 425. *See also* Florida, the Rise of the Creative Class, *supra* note 115, at 107 ("You can't pump work out of creative people, assembly-line style. Motivating this kind of mental work requires a new kind of workplace—one that at the very least appears to be nurturing, attuned to individuality, and 'fun.'").

the stimulation and feedback of peers is necessary to select and evaluate potential insights.

- A schedule in which a person is always busy, goal-directed, involved in conscious, rational problem-solving. *Incubation is facilitated by periods of idling, leisure, and involvement in activities such as walking, gardening, driving* (i.e., activities that require some attention but are automated enough to permit subconscious processes to work just below the threshold level of awareness)."[153]

The barriers they describe are less likely to be present within universities. Universities thus have some comparative advantages in hiring people likely to produce creative solutions to problems. This provides an incentive for firms to harness that human capital to solve problems or to purchase the results of faculty research.

E. The Results of Innovation in Universities

Most university research falls into two of the types of innovation Schumpeter described in The Theory of Economic Growth: (1) "The introduction of a new good—that is one with which consumers are not yet familiar—or of a new quality of a good"; and (2) "The introduction of a new method of production, that is one not yet tested by experience in the branch of manufacture concerned."[154] These innovations require skills he attributes to entrepreneurs: "doing of new things or the doing of things that are already being done in a new way." There is considerable opportunity to do "new things" or do things "in a new way" as a result of university-related research. As a result of outside research funding, which grew substantially in the United States after World War II primarily from federal sources, university researchers sought to both help solve specific problems (produce new technologies for defense, etc.) and foster the development of basic science. This built on a

[153] Csikszentmihalyi & Sawyer, *Creative Insight: The Social Dimension of a Solitary Moment*, *supra* note 124, at 96.

[154] Joseph A. Schumpeter, The Theory of Economic Development 66 (Redvers Opie trans. 1983) (1934). The other three are: "[t]he opening of a new market, that is a market into which the particular branch of manufacture of the country in question has not previously entered, whether or not this market has existed before"; "[t]he conquest of a new source of supply of raw materials or half-manufactured goods, again irrespective of whether this source already exists or whether it has first to be created"; and "[t]he carrying out of a new organization of any industry, like the creation of a monopoly position (for example through trustification) or the breaking up of a monopoly position." *Id.*

tradition of public investment in practical research, starting with the Morrill Act and the creation of the land-grant university system.[155]

University researchers regularly make contributions to industry,[156] although as noted earlier, it is only a small minority of universities that do so. Such research is an important source of "key ideas" in many industries, "ideas that generate significant technological opportunities through fusion of knowledge of what's doable with knowledge of what needs to be done."[157] It also makes important indirect contributions from areas outside a given industry.[158] A survey of Advanced Technology Program projects suggested that industry invites universities into research projects that "involve what we have called 'new' science. Industrial research participants perceive that the university could provide research insight that is anticipatory of future research problems and that it could be an ombudsman anticipating and communicating to all parties the complexity of the research being undertaken."[159] Universities also produce inventions that "could not be developed independently by either the inventor or the firm."[160]

One differentiator for university-based research is that the results are generally "done" –from the point of view of the university – at an earlier stage than much

[155] 7 U.S.C. § 301 (1862). Agricultural research at land grant universities was the first large-scale targeted research project. It is not covered here as it generally operates outside the TTO model that can serve as a blanket covering research from a variety of research efforts at universities.

[156] Jerome H. Grossman et al., *Contributions of Academic Research to Industrial Performance in Five Industry Sectors*, 26 J. Tech. Transfer 143, 145 (2001) ("The breadth of research contributions have ranged from graduates trained in modern research techniques, to fundamental concepts and key ideas out of basic and applied research, to the development of tools, prototypes, and marketable products, processes, and services.").

[157] *Id*. at 146. *See also* Jeffery L. Furman & Megan J. MacGarvie, *Academic Science and the Birth of Industrial Research Laboratories in the U.S. Pharmaceutical Industry*, 63 J. Econ. Behav. & Org. 756 (2007).

[158] Grossman et al., *supra* note 156, at 146-147 ("Advances in information systems are critical to the technical and market performance of commercial aircraft and their components. Similarly, advances in medical devices, although occurring in the medical/life sciences sector, benefit strongly from developments in the mathematical and physical sciences and engineering. Computer-related technologies such as intelligent sensors, computer-aided diagnosis, and robotics flow into medical devices from other industry sectors.")

[159] The ATP, a program within the National Institute of Standards and Technology, is a combination of "public funds with private investments to create and apply generic technology needed to commercialize new technology rapidly." Bronwyn H. Hall et al., *Universities as Research Partners*, 85 Rev. Econ. & Stat. 485, 486, 491 (2003).

[160] Jensen & Thursby, *supra* note 80, at 242.

commercial research.[161] As Jensen and Thursby put it, "when they are licensed, most university inventions are little more than a 'proof of concept.'"[162] Early-stage results are less certain to become commercial products – that is, they carry greater uncertainty about both their technological and commercial potentials. They are riskier investments than ideas from later-stage research.[163] As a result, they are "fraught" with incentive problems and so are difficult to contract about. Licensing agreements are more time-consuming to conclude for early-stage status.[164] In brief, the investments needed to commercialize embryonic research from universities have three basic characteristics:

1. the investment is substantially sunk and is rarely recouped;
2. the technical and market uncertainties may diminish as information becomes available about the technology; and
3. the opportunity to invest is generally not completely dissipated by competition among rivals.[165]

These characteristics create incentives for market-driven investors to delay investments.[166] The slowness of development makes valuation difficult[167] and requires additional investment to bring products to the manufacturing stage.[168]

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[161] Litan et al., *supra* note 109, at 53 ("The majority of university-industry agreements relate to technologies that are many years away from being commercialized, and universities cannot take on the burden of forecasting uncertain commercial returns.").

[162] Jensen & Thursby, *supra* note 80, at 240. This occurs both because universities focus more on basic research than do firms and because academics have greater discretion to open up new inquiries.

[163] Hsu et al., *supra* note 15, at 6 (noting universities capture less of the value of patents in part because of the embryonic stage of the technologies they are commercializing).

[164] Scott Shane, Academic Entrepreneurship: University Spinoffs and Wealth Creation 113-14, 122 (2004); *See* David H. Hsu & Tim Bernstein, *Managing the University Technology Licensing Process: Findings from Case Studies*, 9 J. Ass'n Univ. Tech. Managers 1(1997); Emmanuel Dechenaux, Jerry Thursby & Marie Thursby, *Inventor Moral Hazard in University Licensing: The Role of Contracts*, 40 Rsch. Pol'y 94, 102 (2011); *See* Jerry G. Thursby, Richard Jensen & Marie C. Thursby, *Objectives, Characteristics and Outcomes of University Licensing: A Survey of Major U.S. Universities*, 26 J. Tech. Transfer 59, 63 (2001). Trust between the parties is significant in being able to come to an agreement. Paul H. Jensen, Alfons Palangkaraya & Elizabeth Webster, Trust and the Market for Technology, 44 Rsch. Pol'y 340 (2015).

[165] Andrew A. Toole & Dirk Czarnitzki, *Biomedical Academic Entrepreneurship Through the SBIR Program*, 63 J. Econ. Behav. & Org. 716, 720 (2007).

[166] *Id*. at 720.

[167] Clarysse et al., *supra* note 50, at 612.

[168] Jensen & Thursby, *supra* note 80, at 243.

Commercialization depends in large part on the university's ability to reduce commercial risk, which is more likely when there is a market "pull," the invention has become technically feasible, and production is predicted to be cost-effective.[169] As discussed below, these are difficult risks for early stage technologies.

What is missing from a university invention awaiting commercialization is what the entrepreneur brings to the table. As a result, connecting university research ideas to business partners is widely recognized as a critical step in enabling the ideas to have an impact. As one tech transfer expert put it, "if we can't get a commercial partner, those good ideas are going to sit on shelves."[170] Finance for development is a necessary but not sufficient part of the solution. As economist Fritz Machlup noted in his 1958 analysis of the patent system, the incentive provided by the patent monopoly generally is intended to motivate the additional investment to bring ideas to market: "Financing the work that leads to the making of an invention may be a relatively small venture compared with that of financing its introduction, because costly development work, experimentation in production and experimentation in marketing may be needed before the commercial exploitation of the invention can begin. The risks involved may be too great to be undertaken except under the shelter of a monopoly grant."[171] These risks are greater when much of the research comes from universities, due to the early stage of development. Giving patent rights to universities provides rewards long before much of the work is done, which is a potential problem with the Bayh-Dole model.

Moreover, a related major challenge with the ideas coming out of universities is that "new information tends to be produced in tacit form, increasing in tacitness as a function of distance from prior knowledge .... Tacit knowledge tends to be highly personal, initially known only by one person (or a small team of discovering scientists) and is difficult to transfer to others."[172] Universities do well at producing tacit knowledge that can be an advantage in commercialization because greater

[169] Yong Lee & Richard Gaertner, *Technology Transfer from University to Industry: A Large-Scale Experiment with Technology Development and Commercialization*, 22 Pol'y Stud. J. 384, 389 (1994).

[170] H.R. Tech & Innovation Hearing, *supra* note 14, at 49 (statement of Catherine Innes, Dir., Off. of Tech. Dev., Univ. of N.C. at Chapel Hill).

[171] Staff of Subcomm. on Pats., Trademarks & Copyrights of the S. Comm. on the Judiciary, 85TH Cong., an Economic Review of the Patent System, at 36-37 (Comm. Print 1958).

[172] Lynne G. Zucker, Michael R. Darby & Jeff S. Armstrong, *Commercializing Knowledge: University Science, Knowledge Capture, and Firm Performance in Biotechnology*, 48 Mgmt. Sci. 138, 140 (2002).

tacitness offers greater opportunities by providing a firm with a competitive advantage.[173] However, greater tacitness also requires greater participation by faculty (who have the tacit knowledge) in further development of the research.[174]

F. The Challenge of Incentivizing University Invention

Some politicians saw the research produced in universities as a potential economic development tool. Through a combination of aligned interests and personality-based politics, the primary legal framework became vesting ownership of intellectual property rights arising from federally-funded research in universities via the Bayh-Dole Act.[175]

Bayh-Dole promised to unlock technological treasures that federal agencies funded but failed to push into the marketplace. By some measures, the statute is a success: it dramatically increased the number of patents awarded to universities, university-related start-up companies, and licenses from universities to outside entities for faculty-developed technologies.[176] In 2002, The Economist praised Bayh-Dole for creating incentives to invest private money "to turn a raw research idea into a marketable product" rather than allowing ideas of university researchers to be left "in warehouses gathering dust."[177] The then-director of the Wisconsin Alumni Research Foundation, the oldest and one of the most successful of the entities focused on commercializing university research, praised it for stimulating partnerships between government, universities, and start-up firms, and claimed that almost a third of the value of the NASDAQ (in 2007) came from university-

[173] *Id*. at 141-42.

[174] *Id*. at 151.

[175] *See* Stevens, *supra* note 5 (describing the personality-driven politics of the statute's passage).

[176] There is some dispute over the impact of Bayh-Dole. Coupé argues that the evidence points to the establishment of a TTO as the key in increasing patents, although he notes that the statute may have motivated the creation of TTOs. Tom Coupé, *Science is Golden: Academic R&D and University Patents*, 28 J. Tech. Transfer 31, 43 (2003). *See also* Rebecca Henderson, Adam B. Jaffe & Manuel Trajtenberg, *Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965-1988*, 80 Rev. Econ. & Stat. 119, 121-22 (1998) (noting difficulty in disentangling Bayh-Dole, TTO formation, and increased industry funding for research due to simultaneity); Mowery & Sampat, *supra* note 5, at 120 ("there is no evidence of a structural break in trends in patent propensity after Bayh-Dole."); David C. Mowery, Richard R. Nelson, Bhaven N. Sampat & Arvids A. Ziedonis, *The growth of patenting and licensing by U.S. universities: an assessment of the effects of the Bayh-Dole act of 1980*, 30 Rsch. Pol'y 99, 116 (2001) ("Bayh-Dole, while important, was not determinative.").

[177] *Innovation's Golden Goose*, The Economist (Dec. 14, 2002), https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose.

based, federally-funded research.[178] Further, an evaluation of time-to-market found a faster translation of research to market in 1986-1994 relative to 1975-1984, which could reflect improved commercialization or greater emphasis on applied research by universities.[179] Not everyone sees the statute as a complete success: some studies of the value of the increased patents concluded that average quality was lower due in part to increased patenting of "losers"—patents that receive zero subsequent citations.[180]

Bayh-Dole's approach, and the claims made for it, focus on the development potential of inventions stuck behind a wall of federal red tape combined with a more straightforward model of how research investments could turn ideas into marketable products. This approach neglects the Schumpeterian insight that this is not a linear or simple process. We need to appreciate "how multiple, unevenly paced, and nonlinear are the paths between scientific discovery and new technology."[181] What is needed is not just investment (although often quite a lot is needed) but what Schumpeter called the "creative response." He distinguished that from the managerial "adaptive response" in three ways:

> First, from the standpoint of the observer who is in full possession of all relevant facts, it can always be understood *ex-post*; but it can practically never be understood *ex-ante*; that is to say, it cannot be predicted by applying the ordinary rules of inference from the pre-existing facts. This is why the 'how' in what has been called above the 'mechanisms' must be investigated in each case. Secondly, creative response shapes the whole course of subsequent events and their 'long-run' outcome.... Creative response changes social and economic situations for good, or, to put it differently, creates situations from which there is no bridge to those situations that might have emerged in its absence. That is why

[178] Carl E. Gulbrandsen, *Bayh-Dole: Wisconsin Roots and Inspired Public Policy*, 2007 Wis. L. Rev. 1149, 1151 (2007).

[179] Edwin Mansfield, *Academic Research and Industrial Innovation: An Update of Empirical Findings*, 26 Rsch. Pol'y 773, 774 (1998).

[180] Henderson, Jaffe, & Trajtenberg, *supra* note 176, at 126 (decline); Bhaven N. Sampat, David C. Mowery, & Arvids Ziedonis, *Changes in University Patent Quality after the Bayh-Dole Act: A Reexamination*, 21 Int'l J. Ind. Org. 1371 (2003) (no decline). *See also* J.B. Powers & P. McDougall, *Policy Orientation Effects on Performance with Licensing to Start-ups and Small Companies*, 34 Rsch. Pol'y 1028, 1030 (2005) [hereinafter Powers & McDougall, *Policy Orientation*].

[181] Stokes, *supra* note 2, at 75.

> creative response is an essential element in the historical process; no deterministic credo avails against it. Thirdly, creative response—the frequency of its occurrence in a group, its intensity and success or failure—has something, be that too much or little, to do (a) with quality of the personnel available in a society, (b) with relative quality of personnel, that is, with quality available to a particular field of activity relative to quality available at the same time, to others, and (c) with individual decisions, actions, and patterns of behavior. Accordingly, a study of creative response in business becomes coterminous with a study of entrepreneurship. The mechanisms of economic change in capitalist society pivot on entrepreneurial activity.[182]

We argue that university researchers often produced research results that were candidates for leading to a "new thing" or a "new way of doing things" *because* conditions gave university-based researchers more freedom in their research. However, this boost to creating good ideas was not without its costs. This enhanced potential makes translating the idea into the marketplace a greater challenge because the research demands financial investment, additional intellectual development, and, crucially, entrepreneurial talent to make that transition. Such investments require costly contracting to accomplish, given the early stage of most university-connected ideas. Such contracting is difficult for universities reliant on general counsel offices that lack sophisticated IP legal talent in the private sector.[183]

The most difficult input is entrepreneurial talent. Schumpeter thought entrepreneurial skills were in short supply: "It is in most cases only one man or a few men who see the new possibility and are able to cope with the resistances and difficulties which action always meets with outside of the ruts of established practice."[184] The challenge for universities wishing to see researchers' ideas take

[182] Schumpeter, *Creative Response*, *supra* note 32, at 222.

[183] For example, hiring outside IP counsel at Texas A&M requires selecting firms from a pre-approved list (approved by both the Texas Attorney General and the Texas A&M System Office of General Counsel). Firms must apply to be on the approved list, which is opened only every two years. Even with the best of intentions and thoughtful, apolitical screening of firms, this still imposes a hurdle that private sector firms do not face in choosing IP counsel.

[184] Schumpeter, *Creative Response*, *supra* note 32, at 224.

root in the economy is to find how to connect the opportunity an idea offers with financial capital and entrepreneurial skill.

II
How Universities Commercialize Research

Universities have changed how they approach research commercialization as a result of Bayh-Dole. Understanding this helps us assess the current process and how it might be improved, as well as understanding the impact of recent changes to universities.

A. The Institutional Context

Formal university commercialization efforts started with the University of Wisconsin's rejection of a faculty member's offer of an invention to the university based on legal advice that the university could not spend state resources on patenting an idea. Prof. Harry Steenbock then created the Wisconsin Alumni Research Foundation (WARF) and assigned his invention (a way to increase the vitamin D content of food) to it in 1925. The invention was a success and WARF brought in millions of dollars.[185] WARF later pioneered agreements with the federal government allowing Wisconsin to take title to patents based on research funded by agencies.[186] That success served as a model for the Bayh-Dole Act.[187]

Among the goals of Bayh-Dole were to reduce the complexity would-be commercializers faced in dealing with agency licensing procedures, to clarify who held rights to patents, and to place ownership where there would be an incentive to license.[188] University patenting increased dramatically.[189] The number of TTOs increased from 25 at the time the statute was passed to 3,300 twenty-five years

[185] Gulbrandsen, *supra* note 178, at 1156.

[186] *Id*. at 1157.

[187] *Id*.

[188] *See* Daniel E. Stern, *Stalled Patents: Re-Incentivizing Universities to Review Their Portfolios of Unlicensed Patents to Achieve the Bayh-Dole Act's Unfunded Mandate*, 45 Hofstra L. Rev. 1017, 1027-28 (2017).

[189] Charles R. McManis & Brian Yagi, *The Bayh-Dole Act and the Anticommons Hypothesis: Round Three*, 21 Geo. Mason L. Rev. 1049, 1057 (2014). Some have suggested that universities routinely patent technologies that prove to have no commercial value, responding to faculty demand for patents. *See generally* Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 Houston L. Rev. 1373, 1422 (2007).

later.[190] As Litan, Mitchell, and Reedy noted, TTOs "were the product—more than likely the *unintended consequence* of" Bayh-Dole.[191]

AUTM, formerly the Association of University Technology Managers, which has an interest in portraying the outcome of Bayh-Dole as favorable, estimated in 1999 that academic licensing of technologies led to $33 billion in economic activity and 280,000 jobs in the United States.[192] A study commissioned by the National Academy of Engineering more modestly claimed that the impact of academic research on the medical device, financial services, and network systems and communications industry had been "large" and the impact on the transportation, distribution, and logistics and aerospace industries had been "moderate."[193] There is evidence that faculty entrepreneurs are highly cited and productive, suggesting that entrepreneurial activity need not reduce academic achievement.[194] However, the effects differ across fields.[195]

[190] de Larena, *supra* note 189, at 1412. That includes TTOs at hospitals and other non-university research entities that may compete for federal funds. Another measure is the rapid increase in membership in the Association of University Technology Managers, which went from under 100 in 1980 to over 2,000 in 1998. Siegel et al., *supra* note 92, at 116.

[191] Litan et al., *supra* note 109, at 41.

[192] AUTM, AUTM Licensing Survey: FY 1998. Unsurprisingly, perhaps, university tech transfer offices report they are understaffed. Scott Shane, Academic Entrepreneurship: University Spinoffs and Wealth Creation (2004).

[193] Grossman et al., *supra* note 156, at 148.

[194] Robert A. Lowe & Claudia Gonzalez-Brambila, *Faculty Entrepreneurs and Research Productivity: A First Look*, 32 J. Tech. Transfer 173, 189 (2007) ("[E]ntrepreneurs are more likely to be among the most highly cited researchers in their field than control samples and the population of science and engineering faculty at the universities in our study" but highly cited entrepreneurs are still "a minority among all entrepreneurs."); *see also* Karen Seashore Louis, David Blumenthal, Michael E. Gluck & Michael A. Soto, *Entrepreneurs in Academe: An Exploration of Behaviors Among Life Scientists*, 34 Admin. Sci. Q. 110, 127 (1989) ("[S]cientifically productive scholars are more entrepreneurial on several dimensions."); Siegel et al., *supra* note 92, at 132; Bart Clarysse, Valentina Tartari & Ammon Salter, *The Impact of Entrepreneurial Capacity, Experience and Organizational Support on Academic Entrepreneurship*, 40 Rsch. Pol'y 1084, 1092 (2011) ("[A]cademic excellence, reputation and entrepreneurial activity go hand-in-hand.").

[195] Lowe & Gonzalez-Brambila, *supra* note 194, at 189.

Bayh-Dole spurred a focus on patenting by universities.[196] This alone may be a benefit of the statute, even with respect to traditional views of the role of the university, as some research suggests patents are a reaffirmation of the originality of a scientist's work.[197] Azoulay, Ding, and Stuart argue that "patents and publications correspond to two types of output that have more in common than previously believed" and "encode similar pieces of knowledge."[198] Agrawal and Henderson's study of two MIT departments found considerable differences between publications and patents.[199] Specifically, faculty who patented also published work with more impact. Similarly, Magerman, Van Looy, and Debackere analyzed biotechnology patent-paper pairs and found no negative citation effects associated with patents.[200] Papers associated with a patent received more citations, leading them to conclude that "patenting does not jeopardize one's scientific footprint."[201] Patent rights may be "necessary to drive commercialization, particularly in the biomedical context," because turning an idea into a product requires large investments.[202]

Fans of the statute argue that it gives university researchers an incentive to push ideas into the marketplace, enabling them, and society, to reap the rewards that come with patent licensing.[203] Hellman suggests a model that yields a

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[196] Richard R. Nelson, *Observations on the Post-Bayh-Dole Rise of Patenting at American Universities*, 26 J. Tech. Transfer 13, 13-14 (2001). It was not just Bayh-Dole that prompted the dramatic increase in patenting and licensing by universities. Nelson argues it was also due to the rise of biotechnology, "where research results often seem to promise significant commercial value down the road." *Id*. at 14. Nelson also attributes some of the rise to overall strengthening of IP rights in the United States. *Id*.

[197] Jason Owen-Smith & Walter W. Powell, *To Patent or Not: Faculty Decisions and Institutional Success at Technology Transfer*, 26 J. Tech. Transfer 99, 108 (2001).

[198] Pierre Azoulay et al., *The determinants of faculty patenting behavior: Demographics or opportunities?*, 63 J. Econ. Behav. & Org. 599, 621 (2007).

[199] Agrawal & Henderson, *supra* note 80, at 77.

[200] Tom Magerman, Bart Van Looy & Koenraad Debackere, *Does Involvement in Patenting Jeopardize One's Academic Footprint? An Analysis of Patent-Paper Pairs in Biotechnology*, 44 Rsch. Pol'y 1702, 1709 (2015). A study of UK academics found that above a certain point, increased patenting did become a substitute for both publishing and interaction with firms. Gustavo Crespi, Pablo D'Este, Roberto Fontana & Aldo Geuna, *The Impact of Academic Patenting on University Research and Its Transfer*, 40 Rsch. Pol'y 55, 65 (2011).

[201] Azoulay et al., *supra* note 198, at 621; Agrawal & Henderson, *supra* note 80, at 59. *See also* Guilford, *supra* note 137, at 83 (quoting a comment by a seminar participant that productivity is the rule rather than the exception for people who produce valid and original ideas: "If you produce one, you're very likely to produce a lot.").

[202] Ian Ayres & Lisa Larrimore Ouellette, *A Market Test for Bayh-Dole Patents*, 102 Cornell L. Rev. 271, 277 (2017).

[203] Birch Bay & Joseph P. Allen, *Our bipartisan bid to spur medical research still bearing fruit after 35 years*, Stat (Dec. 9, 2015) available at https://www.statnews.com/2015/12/09/medical-research-bayh-dole/

"science to market gap" in which firms are unaware of what scientific discoveries might meet their needs.[204] This is bridged by communication between researchers and firms–which is encouraged by patenting's incentive to researchers to push discoveries out to industry–with TTOs serving as the agents.[205] How much this has succeeded is not clear, although data on university patents suggests it has not succeeded outside of a small subset of universities: one report suggested that 95 percent of university patents are unlicensed.[206] If true, this signals a weakness in either (or both) the process or the value of the research pursued.

Not everyone cheers the focus on intellectual property, commercialization and the creation of TTOs. Critics challenge the reliance on exclusivity in licensing. Nelson argues that companies are willing to invest without exclusive rights to university-developed research because they anticipate being able to patent their own improvements and so reap rewards.[207] Others raise concerns that increased patenting based on university research leads to an "anti-commons" in which a patent thicket slows or blocks future research.[208] Empirical research suggests there is little evidence that patent licensing blocks research (in part because academic researchers often ignore patents) but there is evidence that materials and data access agreements pose problems.[209] Eisenberg, one of the main proponents of the anti-commons interpretation, explained this to be the result of the high transaction costs

("The law has become a recognized best practice adopted by many countries to integrate university research into their economic development efforts.").

[204] Thomas Hellmann, *The Role of Patents for Bridging the Science to Market Gap*, 63 J. Econ. Behav. & Org. 624 (2007); *see also* Siegel et al., *supra* note 92, at 130 (elaborating on role of TTO as bridge).

[205] *Id*.

[206] Heidi Ledford, *Universities Struggle to Make Patents Pay*, 501 Nature 471, 472 (2013). A 1995 NSF survey showed higher rates of conversion of patents into grants and commercialized products for scientists and engineers in industry than for those in education (three in ten versus one in five). Robert P. Morgan, Carlos Kruytbosch & Nirmala Kannankutty, *Patenting and Invention Activity of U.S. Scientists and Engineers in the Academic Sector: Comparisons with Industry*, 26 J. Tech. Transfer 173, 178 (2001). *But see* Daniel W. Elfenbein, *Publications, Patents, and the Market for University Inventions*, 63 J. Econ. Behav. & Org. 688, 713 (2007) (describing study of Harvard's inventor disclosures over several decades which found that the grant of a patent significantly increased the likelihood that a license partner would later be found, especially for less experienced inventors).

[207] Nelson, *supra* note 196, at 16.

[208] *See, e.g.*, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698 (1998); *see also* Nelson, *supra* note 196, at 18 (arguing against patenting fundamental research results and techniques).

[209] Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 Hous. L. Rev. 1059, 1098 (2008).

of enforcing patents against researchers and the low transaction costs of denying researchers access to materials and data unless they agreed to restrictions on use.[210]

Other critics raise concerns about universities using patents "not for purposes of fostering commercialization, but instead to extract rents in apparent holdup litigation."[211] Some argue that university TTOs focus on short-term 'lottery' patents to get the quickest payback, over long-term investments in ideas that may have greater potential.[212] Others claim that a focus on commercialization steers universities away from their proper role in society,[213] and some contend that commercialization prioritizes applied research over the traditional goal of pure knowledge.[214] Some are concerned that commercialization will restrict communication among scientists.[215] The NAE study cautioned that

[210] Eisenberg, *supra* note 209, at 1098-99. There is some evidence that patenting reduces future citations (at least, in the life sciences), suggesting there may be some anti-commons effect. Fiona Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis*, 63 J. Econ. Behav. & Org. 648, 683-84 (2007). In addition, suits against state universities must overcome Eleventh Amendment sovereign immunity issues.

[211] Arti K. Rai, John R. Allison & Bhaven N. Sampat, *University Software Ownership and Litigation: A First Examination*, 87 N.C. L. Rev. 1519, 1519 (2009).

[212] Litan et al., *supra* note 109, at 43. Patent litigation over university IP can disrupt TTO operations by taking "time and attention of licensing officers away from . . . marketing, search, and negotiation activities" and can crowd out some licensing activity. Scott Shane & Deepak Somaya, *The Effects of Patent Litigation on University Licensing Efforts*, 63 J. Econ. Behav. & Org. 739, 741 (2007). In a survey of university patent offices, Shane and Somaya found that the office directors "were unanimous that university-led patent litigation caused significant dislocation in the operation of the technology licensing office," both through the time demands on office personnel and due to the stress and morale impacts on staff. *Id*. at 746. Shane and Somaya's data bear this out, showing a drop in licensing while litigation is underway. *Id*. at 750.

[213] A prominent such critic is Jennifer Washburn; *see* Jennifer Washburn, University, Inc.: The Corporate Corruption of American Higher Education (2005); *see also* Mark A. Lemley, *Are Universities Patent Trolls?*, 18 Fordham Intell. Prop. Media & Ent. L.J. 611, 625 (2008); Siegel, Wright & Lockett, *supra* note 99, at 497 ("There is an inherent conflict of interest between the traditional academic reward system, which is focused on peer reviewed publication of basic research, and the technology transfer reward system. . . ."); G.R. Evans & D.E. Packham, *Ethical Issues at the University-Industry Interface: A Way Forward?*, 9 Sci. & Eng'g Ethics 3, 8 (2003); James J. Duderstadt, *Commercialization of the Academy: Seeking a Balance Between the Marketplace and Public Interest*, Sam Nunn Pol'y F. (2002), http://milproj.dc.umich.edu/publications/academy_comercialization/download/academic_commercialization.pdf; Donald Kennedy, Academic Duty (Harvard Univ. Press 1997).

[214] Dovid A. Kanarfogel, *Rectifying the Missing Costs of University Patent Practices: Addressing Bayh-Dole Criticisms Through Faculty Involvement*, 27 Cardozo Arts & Ent. L.J. 533, 544-45 (2009).

[215] Larsen, *supra* note 18, at 9. *But see* Carolin Haeussler, *Information-Sharing in Academia and the Industry: A Comparative Study*, 40 Rsch. Pol'y 105, 117 (2011) (finding few differences in information sharing between those involved in commercialization and those not).

commercialization efforts raise questions about whether "the entrepreneurial university and the new interest in financial gain are distorting the traditional values, goals, and the identity of the university with negative consequences."[216] These concerns are not merely rhetorical: there is evidence that publications associated with patents lead to slower rates of forward citations.[217] Backward citations in industrial patents are increasing as university patenting increases, suggesting "a slowdown in the pace of firm knowledge exploitation."[218]

Commercialization may be beyond the ability of universities. They may not be able "to adapt to, to articulate, and to pursue new directions in basic and applied research and training" to keep up with industry needs "while continuing to jump-start new areas of basic, long-term research and generate the key ideas that will provide the foundation for tomorrow's industries."[219] More generally, Bayh-Dole has been criticized as a "poorly targeted institution" because intellectual property rights are "a blunt and costly mechanism for facilitating technology transfer from the government to industry when compared to alternatives."[220]

There seems to be little empirical support for the sharpest criticism of university focus on TTOs and commercialization.[221] There is evidence that licensing has *not* shifted university research away from basic research and that licensing promotes additional basic research.[222] Azoulay, Ding, and Stuart found that "patenting is often accompanied by a flurry of publication activity in the year preceding the patent application, even after accounting for the lagged stock of publications" and, controlling for scientist-fixed effects, suggest that "surges

[216] Grossman et al., *supra* note 156, at 150; *see also* Etzkowitz, Quasi-Firms, *supra* note 13, at 116-17.

[217] *See* McManis & Yagi, *supra* note 189, at 1065.

[218] McManis & Yagi, *supra* note 189, at 1068; Kira R. Fabrizio, *University Patenting and the Pace of Industrial Innovation*, 16 Indus. & Corp. Change 505, 521 (2007).

[219] Grossman et al., *supra* note 156, at 150.

[220] Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 Vt. L. Rev. 347, 352 (2000).

[221] Rosa Grimaldi et al., *30 Years After Bayh-Dole: Reassessing Academic Entrepreneurship*, 40 Rsch. Pol'y 1045, 1046 (2011) ("Academic research has found little systematic evidence of a destruction of the open culture of science or to support the assertion that universities are performing less basic research.").

[222] Jerry G. Thursby & Marie C. Thursby, *Has the Bayh-Dole Act Compromised Basic Research?*, 40 Rsch. Pol'y 1077, 1083 (2011); Jerry G. Thursby & Marie C. Thursby, *University Licensing: Harnessing or Tarnishing Faculty Research?*, 10 Innovation Pol'y & Econ. 159, 159 (2010); Jerry G. Thursby & Marie C. Thursby, *Who is Selling the Ivory Tower? Sources of Growth in University Licensing*, 48 Mgmt. Sci. 90, 102 (2002).

of scientific productivity, not steady research performance, is most likely to be associated with patenting," a finding they interpret to mean that "uncovering of new, productive areas of scientific inquiry is an important precursor to the act of patenting."[223] They also found a relationship between what they term the "latent patentability" of faculty research and the propensity to patent, having derived the former from a keyword analysis of publications of scientists already patenting in the same area.[224] Thursby and Thursby found recent disclosure activity had an overall positive impact on both public and private faculty research funding and publication rates.[225]

Much of the university interest is, of course, about money. A 2000 review of the literature on university-industry partnerships found that university motivations were "largely financially based" while industry motivations focused on "access to complementary research activity and research results" and "access to key university personnel."[226] Despite the creation of many TTOs, commercialization efforts did not produce a financial windfall, which is unsurprising when we take into account how few universities are patenting extensively or patenting high value ideas. Reinforcing our conclusions from the patent data, one study of 2012 data found 130 of the 155 universities reporting data did not cover expenses for the year.[227] Another concluded that "[v]ery few university 'inventions' garner significant

[223] Azoulay et al., *supra* note 198, at 600.

[224] *Id*.

[225] Jerry G. Thursby & Marie C. Thursby, *Faculty Participation in Licensing: Implications for Research*, 40 Rsch. Pol'y 20, 29 (2011).

[226] Hall et al., *supra* note 159, at 486; *see also* Jerry G. Thursby, Richard Jensen & Marie C. Thursby, *Objectives, Characteristics and Outcomes of University Licensing: A Survey of Major U.S. Universities*, 26 J. Tech. Transfer 59, 65 (2001); Joseph Friedman & Jonathan Silberman, *University Technology Transfer: Do Incentives, Management, and Location Matter?*, 28 J. Tech. Transfer 17, 18-19 (2003) (summarizing surveys); Jensen & Thursby, *supra* note 80, at 245 (explaining that TTO staff perceive university administrators to believe licensing revenue is top goal).

[227] Walter D. Valdivia, University Start-Ups: Critical for Improving Technology Transfer 9 (2013), https://www.brookings.edu/wp-content/uploads/2016/06/Valdivia_Tech-Transfer_v29_No-Embargo.pdf; *see also* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 Va. L. Rev. 1663, 1713 (1996) (concluding from analysis of 1990s data that universities are not making large profits above costs); P. Conceição et al., *University-Based Technology Licensing in the Knowledge Based Economy*, 18 Technovation 615, 618 (1998) (predicting licensing revenue at most schools will"remain small"); Bok, *supra* note 81, at 77 ("The financial results are reminiscent of intercollegiate athletics. Most universities have not earned much money from royalties; the odds of making anything substantial from patenting a new discovery are extremely small.").

license incomes. . . . Many universities are [likely] paying significantly more to run their patenting and licensing offices than they are bringing in license revenues."[228] One survey found that the top five inventions licensed by each university accounted for 78 percent of gross licensing revenue.[229] Litan, Mitchell, and Reedy concluded that "[t]his is not an outcome one would expect from a nation rich in scientific talent at many universities" while Aldridge and Audretsch claim that the "paucity" of university start-ups post-Bayh-Dole is "startling and disappointing."[230] The dominance of a few patents should not be a surprise. At many firms, a few key products dominate revenue streams. However, maintaining money losing TTOs is another matter.[231]

Efforts to shift research into the economy at large pose three key challenges. First, it is not a major revenue source for universities. Aside from the occasional blockbuster (such as Gatorade™), earning enough licensing revenue to cover operating the TTO and paying for intellectual property is likely the best outcome for many inventions. Second, there are persistent concerns about the impact of pursuing commercialization opportunities on core university missions in research and teaching.[232] "The incorporation of 'extension of knowledge' into a compatible relationship with 'capitalization of knowledge' is a profound normative change in science."[233] While we are skeptical of these concerns, their persistence means they need to be addressed to get faculty buy-in (or, at least, acquiescence) to the commercialization effort. Third, a focus on protecting intellectual property may have a deleterious effect on innovation outside the university.[234] The evidence does

[228] Nelson, *supra* note 196, at 17.

[229] Jensen & Thursby, *supra* note 80, at 243.

[230] T. Taylor Aldridge & David Audretsch, *The Bayh-Dole Act and Scientist Entrepreneurship*, 40 Rsch. Pol'y 1058, 1059 (2011). Litan et al. conclude that it *is* the product of a centralized TTO process where the office is rewarded for revenue rather than the volume of inventions transferred or commercialized. Litan et al., *supra* note 109, at 41. Like any monopoly, they argue, TTOs maximize revenue over output. *Id*. at 43.

[231] Only a small number of universities are major-league recipients of federal grant money, but many schools would like to be, so they ape the behavior of big-time research institutions by putting in place TTOs and other features that are observed. Showing that a school improved federal grant revenue can be helpful for administrators who want to work their way into jobs at more prestigious schools. Rate of return on such expenditures is rarely discussed, as such metrics are rarely used for anything done at universities.

[232] *See, e.g.*, Conceição et al., *supra* note 227, at 621-22; Grigg, *supra* note 79, at 288.

[233] Henry Etzkowitz, *The Norms of Entrepreneurial Science: Cognitive Effects of the New University-Industry Linkages*, 27 Rsch. Pol'y 823, 824 (1998) [hereinafter Etzkowitz, *Norms*].

[234] For example, Bok notes that in a few instances TTOs have impeded sharing of important research tools with other universities by demanding a share in the royalties from inventions resulting from the tools' use

not suggest this is a major problem, but more investigation must be done before the concerns can be addressed.[235]

The institutional context in which university commercialization efforts take place is complex. It is shaped in part by a statute built around an overly simplistic model of the production and translation of knowledge. Its primary effect appears to be the creation of university TTOs, which poses problems (e.g., how will they be paid for?) and focuses on solutions (licensing, patenting, creating new ventures) but does not solve the fundamental puzzle: that the vast majority of research universities are not producing research that takes the important initial step of being patented. We next turn to how this affects universities' operations.[236]

B. Current Practice

The first step in commercialization is the discovery of an idea.[237] The focus of the researcher is likely to be producing a paper, not commercialization.[238] That process begins when the faculty member files a disclosure form with the university's TTO.[239] The form describes the idea and triggers the TTO process. "Faculty decisions to disclose, then, are shaped by the mixture of individual incentives, local organizational procedures, and institutional milieus. The meanings academic researchers attach to IP and their perceptions of the local patent process color decisions to disclose potentially valuable inventions within the

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or by exclusively licensing discoveries too far upstream from applications, and so have "prevented a healthy competition to exploit the patented knowledge." Bok, *supra* note 81, at 141.

[235] Jerry G. Thursby & Sukanya Kemp, *Growth and Productive Efficiency of University Intellectual Property Licensing*, 31 Rsch. Pol'y 109, 122 (2002) (noting that as commercialization efforts increase "the criticisms of those who feel that universities have gone too far in commercialization activities may be increasing in relevance.").

[236] Part of Morriss' position as Dean of the School of Innovation was an analysis of how to improve commercialization efforts at Texas A&M. With colleagues, he visited twenty leading university operations, spoke with various industry leaders, and reviewed the literature to determine best practices. The next section draws on the results of this review and is under-footnoted but Morriss retains original notes.

[237] William H.A. Johnson, *Managing University Technology Development Using Organizational Control Theory*, 40 Rsch. Pol'y 842, 845 (2011).

[238] *Id*. at 846.

[239] Different universities organize this function in different ways. The most common is a centralized office for the entire university, but some have decentralized offices in particular units (e.g., a medical school), some use contractors, and some have separate foundations that handle technology transfer. *See generally* F. Brescia, G. Colombo & P. Landoni, *Organizational Structures of Knowledge Transfer Offices: An Analysis of the World's Top-Ranked Universities*, 41 J. Tech. Transfer 132 (2016); U.S. Gen. Acct. Off., GAO/RCED-98-126, Technology Transfer: Administration of the Bayh-Dole Act by Research Universities (1998).

context of a university's history, environment, capacity, and reputation."[240] Patents also reflect the "seizing of opportunities along a novel research trajectory."[241]

The next stage is an evaluation of the idea. In the best case, this involves analysis in three dimensions: intellectual property potential, business potential, and technology potential.[242]

- The IP evaluation focuses on if the idea can be protected by intellectual property (typically a patent). Among the questions asked is: Has the idea been disclosed (through a paper or presentation) in a way that precludes issuance of a patent?
- The business potential assessment involves examining potential demand (Are there customers? How much better is the product than its competition?) and the type of business likely needed to commercialize the idea (Is this something best licensed to an existing firm or developed through a start-up?).[243]
- The technology potential assessment asks if the technology is ready for commercialization. Because much of federal funding focuses on basic research, there is often a problem that the innovation is not mature enough for commercialization.[244]

Then the university decides whether to pursue commercialization. Who makes the decision differs across universities. At some, the central TTO or other entity does, while at others the decision is delegated to the unit where the researcher resides. Generally, decision-making follows the funding of patent applications. To some

[240] Owen-Smith & Powell, *supra* note 197, at 99-100. The reasons why faculty patent vary widely across disciplines. Owen-Smith and Powell quote a TLO director – "[p]hysical scientists patent for freedom of action, life scientists patent for strategic advantage" – as an illustration of their conclusion that "life science inventions have a larger potential to open new markets where gaining value from intellectual property will not be constrained by existing products or patents. In contrast, physical sciences inventions . . . often enter crowded markets where established products and intellectual property hamper organizations' abilities to gain revenue from IP." *Id*. at 105.

[241] Azoulay et al., *supra* note 198, at 619.

[242] Dagmara M. Weckowska, *Learning in University Technology Transfer Offices: Transactions-Focused and Relations-Focused Approaches to Commercialization of Academic Research*, 41-42 Technovation 62, 63 (2015) (providing a concise description of the analysis).

[243] As we note, most faculty have no expertise in commercialization of research, but self-interest leads to serious disputes between inventors, who want to keep control and want more of the revenue, and school administrators, who have to pay certain costs and want more revenue to come to the school in case of success.

[244] H.R. Tech & Innovation Hearing, *supra* note 14, at 43-44.

extent, this decision is based on cost, although the prestige of getting a patent at some universities or in some departments may spur some demand for non-economically viable patents to be pursued. Some universities emphasize particular disciplines for commercialization; others take a general approach.[245] The initial up-front cost to a university of a provisional patent is generally relatively low ($3,000 is a range often mentioned). Pursuing a full patent usually costs considerably more ($10,000 to $25,000, depending on the area of technology and the complexity of the invention).[246] Universities often seek to recapture these expenses from licensees.[247] There can be a conflict of goals at this stage, with inventors preferring to own and TTOs preferring to license.[248]

Once an idea has been protected, a decision is made whether to seek to license the IP to a firm or to form a spin-off to further develop the idea. One issue is if there is a sponsored research agreement with a funder that might provide a right of first refusal and how the technology fits within the market. It appears that the more an idea needs a Schumpeterian entrepreneur, the more likely the idea is to be licensed to a start-up or existing firm that focuses on the idea. The more the idea produces a small change in an existing technology or process, the more likely it is to be licensed to an existing firm.

Universities vary in the services provided to new ventures that license the results of faculty research. Some universities take equity stakes in new ventures in lieu of license payments, others want royalties from the start, and others have deferred payment "express" license packages that pay lump sums when the venture receives outside funding.[249] Some universities participate in incubators

[245] Joshua B. Powers & Patricia P. McDougall, *University Start-Up Formation and Technology Licensing with Firms that Go Public: A Resource-Based View of Academic Entrepreneurship*, 20 J. Bus. Venturing 291, 306 (2005) [hereinafter Powers & McDougall, *University Start-Up Formation*].

[246] Patent expenses are often recouped from licensees, but this can take time. *See* H.R. Tech & Innovation Hearing, *supra* note 14, at 25 (statement of Catherine Innes, Dir., Off. of Tech. Dev., Univ. of N.C. at Chapel Hill) (discussing the need for universities to carry patent expenses for longer than originally anticipated).

[247] *Id*.

[248] Johnson, *supra* note 237, at 847.

[249] The University of North Carolina pioneered an "express license" program with local law firms, which do not take a fee, for start-ups with a UNC connection and which submit a business plan for university review. This requires a 0.75% value payout in lieu of equity and royalty payments at the first liquidity event. *See* H.R. Tech & Innovation Hearing, *supra* note 14, at 25 (statement of Catherine Innes, Dir., Off. of Tech. Dev., Univ. of N.C. at Chapel Hill); *see also* Grimaldi et al., *supra* note 221, at 1049. Michigan created the "Research Advantage" program that bounds license terms even before an invention is created to cut transaction costs.

that help start-ups develop, some provide gap funding to develop ideas (often without requiring equity or repayment), and some do relatively little. Experienced businesspeople may be brought in as entrepreneurs or executives-in-residence to mentor university researchers who wish to start their own company. Some universities participate in the National Science Foundation's I-Corps program, which puts would-be researcher entrepreneurs through a multi-week start-up boot camp focused on learning the market for an idea. Federal funding through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs also provides early-stage financial assistance for some university start-ups.[250] Many states provide similar funds to supplement federal programs.[251] In addition, there are informal technology transfers, including coauthoring papers with industry personnel and faculty serving as consultants to outside firms.[252]

Some university efforts for start-ups focus on getting the researcher with an invention up to speed as an entrepreneur. "There is more than one route to the commercialization of university intellectual property (IP) but that, whatever the route, core to its success will be the role played by the creator of the IP, the individual scientist or engineer."[253] This requires considerable effort, and many researchers lack business acumen. The focus of these efforts is on access to funding and business skills.

See H.R. Tech & Innovation Hearing, *supra* note 14, at 56 (statement of Kent Nisbet, Exec. Dir., Univ. of Mich. Tech. Transfer). Maryland operates an "Innovation Initiative" that "mines" five universities' research. *See* H.R. Tech & Innovation Hearing, *Id*. at 40 (statement of Robert Rosenbaum, President & Exec. Dir., Md. Tech. Dev. Corp.).

[250] *See generally* Ronald S. Cooper, *Purpose and Performance of the Small Business Innovation Research (SBIR) Program*, 20 Small Bus. Econ. 137 (2003); David B. Audretsch, *Standing on the Shoulders of Midgets: The U.S. Small Business Innovation Research Program (SBIR)*, 20 Small Bus. Econ. 129 (2003); Henry Etzkowitz & Loet Leydesdorff, *The Dynamics of Innovation: From National Systems and "Mode 2" to a Triple Helix of University-Industry-Government Relations*, 29 Rsch. Pol'y 109, 110 (2000); Toole & Czarnitzki, *Biomedical Academic Entrepreneurship Through the SBIR Program*, *supra* note 165, at 717 (explaining that investments in early-stage technologies are characterized by high degrees of technical and market uncertainty, which makes other sources of funding difficult); Josh Lerner, *The Government as Venture Capitalist: The Long-Run Impact of the SBIR Program*, 72 J. Bus. 285 (1999); Powers & McDougall, *Policy Orientation*, *supra* note 178, at 1041.

[251] Lauren Lanahan & Maryann P. Feldman, *Multilevel Innovation Policy Mix: A Closer Look at State Policies that Augment the Federal SBIR Program*, 44 Rsch. Pol'y 1387 (2015).

[252] Albert N. Link, Donald S. Siegel & Barry Bozeman, *An Empirical Analysis of the Propensity of Academics to Engage in Informal University Technology Transfer*, 16 Indus. & Corp. Change 641 (2007).

[253] Mike Wright, Sue Birley & Simon Mosey, *Entrepreneurship and University Technology Transfer*, 29 J. Tech. Transfer 235, 235 (2004).

If Schumpeter's description of the role of the entrepreneur is accurate, such efforts are unlikely to be enough. It is not clear if Schumpeter thought that entrepreneurship could be taught or if it derived from some combination of personality traits and experiences.[254] There is some evidence that individual characteristics (which Clarysse, Tartari, and Salter say are "to a large extent genetically imprinted") of potential faculty entrepreneurs play the most significant role in the decision to become an entrepreneur.[255] Similarly, Haye and Pries found that "repeat commercializers" accounted for a disproportionate share of commercialization in their sample.[256] Despite the proliferation of university-based entrepreneurship courses in recent years, it is difficult to know whether the training universities provide is teaching what is needed to be an entrepreneur.

There are proposals to improve the track record of bringing university-developed ideas into the world. Some critics argue that many universities' focus on exclusive licensing rights is an obstacle to successful incorporation of ideas from into products; they contend that universities should prioritize non-exclusive licenses.[257] Others argue that control of commercialization should be shifted away from university administration and given to research faculty.[258] Conflicts between universities and faculty over ownership of ideas threaten to disrupt the core academic mission of universities.[259] Some proposals would fundamentally

[254] In *Creative Response*, Schumpeter referred to entrepreneurs as a distinct "sociological and psychological" type. Schumpeter, *Creative Response*, *supra* note 32, at 224. Elsewhere he noted "some distinct entrepreneurial ability in making decisions under uncertainty" might exist, suggesting that this led in the direction of Knight's theories. *See* Schumpeter, *Economic Theory and Entrepreneurial History*, *supra* note 32, at 257. Both these comments suggest teaching entrepreneurship would be difficult. However, he also talked about entrepreneurship as "to act outside the pale of routine" and "essentially…doing things that are not generally done in the ordinary course of business routine" and as part of the "wider aspect of leadership." *Id*. at 258, 260.

[255] Clarysse, Tartari & Salter, *supra* note 194, at 1092.

[256] Kate Hoye & Fred Pries, *'Repeat Commercializers,' The 'Habitual Entrepreneurs' of University-Industry Technology Transfer*, 29 Technovation 682, 687 (2009).

[257] Ian Ayres & Lisa Larrimore Ouellette,*A Market Test for Bayh-Dole Patents*, 102 Cornell L. Rev. 271, 298 (2017); Mark Lemley, *Are Universities Patent Trolls?*, 18 Fordham Intell. Prop. Media & Ent. L.J. 611, 616 (2008).

[258] Kanarfogel, *supra* note 214, at 549 ("As the ones closest to the actual ground of technological and scientific research, faculty members are more intimately aware of the states of the fields in which they work than most anyone else. They will have a sense . . . of what ideas promise expansive or revolutionary further work and which are already close to marketability.").

[259] Grimaldi et al., *supra* note 221, at 1050 ("[M]any TTOs have become increasingly aggressive in claiming their rights to any inventions by researchers affiliated with their university or unilaterally changing

change how universities conduct research and move ideas into the economy. Few are built around a coherent theory of the entrepreneur's role.

III
Entrepreneurship & Red Boxes

We know for-profit firms wish to earn profits from innovations. How innovations emerge and are translated into successes is largely, in economics, still a black box matter. Universities wish for innovations to generate revenue, but they are not-for-profit entities. How entrepreneurial exploitation can happen within such red box organizations is not well understood. If we use Schumpeter's and Kirzner's insights into the role of the entrepreneur, how might we restructure university efforts at moving inventions from the lab to market? This section offers four suggestions. Our argument does not simply suggest universities devote more resources to commercialization.[260] Rather, this is an argument for an approach that built on Schumpeter's and Kirzner's ideas about entrepreneurship and innovation.

A. Focus on the Entrepreneur

Schumpeter argued that the essential function of the entrepreneur is "the doing of new things or the doing of things that are already being done in a new way (innovation)."[261] He distinguished this function from invention, management, risk-bearing, and financing – all necessary functions but ones provided by others (inventors, managers, capitalists, etc.).[262] The entrepreneur adds something and is not, as Schumpeter put it in rebutting a simplistic idea of growth, "a sort of beast of prey who withhold the fruits of technological advance from the community and sabotage progress in their own interest."[263] Kirzner developed the idea of alertness further: "Entrepreneurial alertness means the ability to impose constraints

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the formulae for dividing any patent income. This has led not only to researcher discontent and internal administrative investigations, but also litigation initiated by universities against their employees, including prestigious faculty members.").

[260] One commentator on TTO operations concluded by calling for universities to evaluate "their own access to capital, staff adequacy and capabilities of their TTOs, and other intangibles that affect commercialization capabilities" to determine if they "possess the same resources as an MIT or Johns Hopkins" and, if they do not, then to "seek out alternative ways to get their invention out of their own hands and into the hands of those capable of doing so." Krumm, *supra* note 19, at 193.

[261] Schumpeter, *Creative Response*, *supra* note 32, at 223.

[262] *Id*. ("It is one thing to set up a concern embodying a new idea and another thing to head the administration of a going concern, however much the two may shade off into each other.").

[263] Schumpeter, *Economic Theory and Entrepreneurial History*, *supra* note 32, at 265.

on that freedom, so that the entrepreneur's vision of the future may indeed overlap, to some significant extent, with the future that he is attempting to see."[264] This is critical to economic advances that arise from inventions; otherwise firms are only determining "wandering terms of exchange" for existing goods.[265] The costly launching of innovative products requires conscious action by entrepreneurs, be they existing enterprises or new firms created for that purpose. Such expertise divorced from the invention process itself. "Entrepreneurship is. . . not something to be deliberately introduced into a potential production process: it is, instead, something primordial to the very idea of a potential production process awaiting possible implementation."[266]

Is the entrepreneurial function present in the university process described above? While it may be, it is rarely recognized or explicitly addressed and, if it is addressed, it is done so accidentally. As a result, red boxes underperform their potential to seed the economy with new ideas. Incorporating a Schumpeterian perspective would increase the success rate in moving ideas from research to the economy.

Inventors do not know if an invention, regardless of how highly it is regarded by the inventors, if pushed forward, will have sufficient market value to be deemed a success.[267] As Kirzner explains, this leads us into uncertainty or open-ended ignorance. The possibility of failure or success is not known. It is unlike risk, which is closed-ended ignorance—if you flip a coin, you do not know if it will come up heads or tails, but you know it will be one or the other and you know what the chances are so you can measure the risk.[268] New products

[264] Israel Kirzner, *Uncertainty, Discovery, and Human Action: A Study of the Entrepreneurial Profile in The Misesian System*, in Method, Process, and Austrian Economics: Essays in Honor of Ludwig von Mises 179 (1982) [hereinafter Kirzner, *Uncertainty, Discovery & Human Action*].

[265] Israel Kirzner, *Mises on Entrepreneurship*, in The Collected Works of Israel M Kirzner: Ludwig von Mises: The Man and His Economics 154 (Peter Boettke & Frederic Sautet, eds., 2019).

[266] Israel Kirzner, *The Primacy of Entrepreneurial Discovery*, in The Collected Works of Israel M. Kirzner: Reflection on Ethics, Freedom, Welfare Economics, Policy, and the Legacy of Austrian Economics 368 (Peter Boettke & Frédéric Sautet, eds., 2018).

[267] That does not mean that the work may not have value—it may help people understand something better that may lead to further productive work. But the work may not have specific value in the market. It is possible that the work may have market value but that no entrepreneur sees the opportunity.

[268] Israel Kirzner, *Discovery, Capitalism, and Distributive Justice*, in Discovery, Capitalism, and Distributive Justice: The Collected Works of Israel Kirzner 38-39 (Peter J. Boettke & Frederic Sautet, eds., 2016) [hereinafter Kirzner, *Discovery, Capitalism & Distributive Justice*]. Open-ended

are launched into an uncertain world of open-ended ignorance. Capitalists risk capital in such ventures. They put their money into a black box to generate the product for the market. University managers are not capitalists, and they should not be risking taxpayer or student tuition money in endeavors unrelated to the educational mission by actually launching products. While worthy inventions arise in red boxes, TTO managers offer inventions to entrepreneurs who may be interested in them. That way, information about the possible opportunities are made known and firms may bid to risk capital and pay for the chance to promote an invention.[269] The economy benefits from the progress generated by such "dynamic competition" from the introduction of new products.[270] In such instances, investors are entrepreneurs—they operate in uncertainty where the outcome cannot be known. Such "entrepreneurial activity expresses pure discovery."[271]

Unfortunately, the university process described above, which results from the Bayh-Dole framework, reflects a view of economic growth inconsistent with Schumpeter's and Kirzner's insights.[272] University TTOs evaluate disclosures from faculty to identify those meriting an investment in intellectual property protection and then determine whether to seek to license the invention to an existing firm or to support the creation of a new firm. The TTO can execute this function well or not, but the paradigm remains primarily a straightforward linear process from

uncertainty is, as Kirzner recognizes, often called Knightian uncertainty for Frank Knight, Risk, Uncertainty and Profit (1921).

[269] This is a real-world process that is not modeled in the black box view of the firm. But real people are making real decisions about real inventions that require real capital. Without that, there can be no discovery of new economic value. Kirzner, *Discovery, Capitalism & Distributive Justice*, *supra* note 268, at 40-41.

[270] *Id*. at 84. Without dynamic change caused by new inventions, firms are engaged in static competition—the same products competing against each other, which is the essence of pure competition as taught in basic economics.

[271] *Id*. at 87.

[272] This the "Smith-Mill-Marshall" theory of economic growth, which Schumpeter critiqued because it implied that "the economy grows like a tree." In this view, while sometimes the economy is "exposed to disturbances by external factors that are not economic, or not strictly so," the growth process itself "proceeds steadily and continuously" and "the individuals, whose acts combine to produce each situation, count individually for no more than do the individual cells of the tree." Joseph A. Schumpeter, *Theoretical Problems of Economic Growth*, in Essays on Entrepreneurs, Innovations, Business Cycles, and the Evolution of Capitalism 238 (Richard V. Clemence, ed., 2008) (1947).

idea to disclosure to product.[273] As discussed, this linear progression rarely reflects reality.[274]

Research teams often consist of faculty and, perhaps, some graduate or post-doctoral students.[275] The team experiments, theorizes, and develops results that reach the point at which team members are ready to share them through publications. If the idea appears to a team leader to be viable, they may file a disclosure with the TTO. From a practical point of view, this highlights the importance of the TTO staff regularly interacting with faculty. More conversations about researchers' work will prompt more disclosures. Conceptually, the entrepreneurial content is an accident of whether or not a team member

[273] Frieder Meyer-Krahmer & Ulrich Schmoch, *Science-based technologies: university-industry interactions in four fields*, 27 Rsch. Pol'y 835, 848 (1998) ("Although there is a broad consensus that the linear model of innovation is inadequate, the concept of the 'one-way bridge' from public research to industrial research is still widespread in the discussion on technology transfer."); *see also* Siegel et al., *supra* note 92, at 119 (describing theoretical linear model); *id*. at 138 (presenting non-linear alternative). There is also a literature on the linear model of innovation, from basic to applied research to development and commercialization, derived from Vannevar Bush's conceptualization after World War II. *See* Stokes, *supra* note 2, at 10; Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Links and Impacts: The Influence of Public Research on Industrial R&D*, 48 Mgt. Sci. 1 (2002). As Cohen, Nelson, and Walsh note, this too has been replaced with a more complex model. *Id*. Etzkowitz and Leydesdorff describe the Triple Helix nonlinear model of innovation, which a future draft will consider in more detail. Etzkowitz & Leydesdorff, *supra* note 250, at 114-115.

[274] Conceição et al., *supra* note 227, at 621-22 (finding need for "an integrated and interactive approach that blends scientific, technological, socio-economic and cultural aspects in rapidly moving environments"); Grigg, *supra* note 79, at 289 (arguing that a cyclic model of innovation better reflects the interaction between "market pull" and "science push"); Lee & Gaertner, *supra* note 169, at 389-90 ("technological innovation does not move sequentially; rather it is an iterative process that must respond to the dynamics of the competitive marketplace.... this process is absent in the traditional, industry-based innovation literature."); Frederic Nlevmvo Ndonzoau, Fabrice Pirnay & Bernard Surlemont, *A Stage Model of Academic Spin-Off Creation*, 22 Technovation 281, 282-283 (2002) ("The process [of creating a startup] is neither straightforward nor spontaneous. Instead, it is strewn with numerous obstacles, difficulties, impediments, hindrances, and other sources of resistance.").

[275] Andy Lockett, Mike Wright & Stephen Franklin, *Technology Transfer and Universities' Spin-Out Strategies*, 20 Sm. Bus. Econ. 185, 188 (2003) ("The academic inventor is assumed to be particularly knowledgeable about his/her area of research, which has resulted in the development of the new technology. However, although the academic may be highly knowledgeable about his/her field of research, he/she may not be able to recognize its commercial potential. The inability to recognize such opportunities is not necessarily the result of a lack of information. Rather, the mindset of the academic may mean that they are not necessarily motivated or interested in considering the potential commercial applications of their research."). Graduate students appear to play a critical role in start-ups. *See* Wai Fong Boh, Uzi De-Haan & Robert Strom, *University technology transfer through entrepreneurship: faculty and students in spinoffs*, 41 J. Tech. Transfer 661, 668 (2016).

or someone who learns about the research has something of a Schumpeterian entrepreneurial mindset.[276] In other words, is someone involved with the team thinking about the doing of new things?[277]

Although there is reason to believe (as discussed above) that universities have a comparative advantage in attracting creative people who can generate innovative ideas, there is no particular reason that faculty (or anyone else in a university) would be more likely than people in the general environment to have an entrepreneurial mindset unless universities set out to find such people. What we know about entrepreneurs in university start-ups is that we do not know much.[278] Roberts and Peters concluded from their survey of MIT faculty that although a large percentage of faculty at MIT were likely to generate ideas with commercial value, only a "smaller fraction…can be expected to do anything toward exploiting these ideas; even fewer to undertake strong commercially oriented actions."[279] Smilor, Gibson and Dietrich's study of the motivation of faculty entrepreneurs at the University of Texas at Austin found self-reported motivations for forming a start-up to include "recognition of a market opportunity, desire to try something new, desire to put theory into practice, the prospect of business contracts, the desire to start a company, and the desire to have fun with an entrepreneurial venture."[280] Another survey found that "engagement with industry may be fueled by an individual's desire to compete effectively in the academic profession."[281] None of this is particularly helpful in identifying entrepreneurial faculty.

[276] Wright, Birley & Mosey, *supra* note 253, at 241 ("We know little about the extent to which habitual entrepreneurs exist in universities. To the extent that these individuals do exist, there may also be implications here for the development of university processes regarding technology transfer.").

[277] People coming up with new ideas in research are, by definition, thinking of "doing of new things" or doing things "in a new way" but they may not be framing those ideas in commercial terms.

[278] Wright, Birley & Mosey, *supra* note 253, at 240 ("There remains little evidence on the nature of entrepreneurs and their behavior in university technology transfer.").

[279] Roberts & Peters, *supra* note 94, at 122. Rahm distinguished between "spanning" and "university-bound" faculty members in categorizing interactions with firms. Rahm, *supra* note 96, at 274-75. The former was more likely to patent than the latter, among other things. *Id*.

[280] Raymond W. Smilor, David V. Gibson & Glenn B. Dietrich, *University Spin-out Companies: Technology Start-ups from UT-Austin*, 5 J. Bus. Venturing 63, 69 (1990).

[281] Tartari et al., *supra* note 110, at 1201. Discussions between TTOs and faculty inventors about sharing costs of exploitation, so the inventors have a deeper stake in success is part of complex negotiations and contract structures.

One reason for the difficulty in finding entrepreneurs on campuses is that they aren't there. Many people with an entrepreneurial mindset are likely to have chosen career paths that enabled them to have the chance to become entrepreneurs without bearing the costs to acquire a Ph.D., get a job as a faculty member, and then develop their ideas.[282] In many respects the stereotypical entrepreneurs are those who leave universities (sometimes without degrees) when they have entrepreneurial ideas they want to pursue (e.g., Sergey Brin, Bill Gates, and Larry Page).

This does not mean entrepreneurship is absent on campus. Etzkowitz argues that academic scientists are willing to mingle research and product development, with a "transmutation of ambivalence…into consonance" and the integration of entrepreneurship and basic research into "a complementary relationship."[283] If so, universities may have interest in encouraging entrepreneurship among research faculty. There is evidence that universities where faculty have greater ownership of their intellectual property produce more spinoff companies.[284]

Taking a more Schumpeterian-Kirznerian approach to commercialization requires focusing attention on the entrepreneurial potential a team might develop to build a business around the invention. As Schumpeter notes, "It is in most cases only one man or a few men who see the new possibility and are able to cope with the resistances and difficulties which action always meets with outside of the ruts of established practice."[285] One implication would be that a focus for ideas being licensed to new ventures should be on identifying team members who have entrepreneurial skills rather than on training team members to become entrepreneurs.[286] (Because universities are not organized around other necessary functions for a business, matching start-ups with managerial and financing skills

[282] See Bok, *supra* note 81, at 62 ("the values that have traditionally inspired academic scientists have generally been strong enough to withstand the desire to grow rich."). Agarwal and Ohyama develop a sorting model for science careers. Rajshree Agarwal & Atsushi Ohyama, *Industry or Academia, Basic or Applied? Career Choices and Earnings Trajectories of Scientists*, 59 Mgt. Sci. 950 (2013).

[283] Etzkowitz, *Norms*, *supra* note 233, at 827.

[284] Martin Kenney & Donald Patton, *Does Inventor Ownership Encourage University Research-derived Entrepreneurship? A Six University Comparison*, 40 Rsch. Pol'y 1100, 1109 (2011).

[285] Schumpeter, *Creative Response*, *supra* note 32, at 224.

[286] There is some evidence that university-connected start-ups have under-developed management teams. Michael D. Ensley & Keith M. Hmieleski, *A Comparative Study of New Venture Top Management Team Composition, Dynamics and Performance between University-based and Independent Start-ups*, 34 Rsch. Pol'y 1091, 1102 (2005).

is also necessary.) For inventions being licensed, putting a priority on licensing to firms that demonstrate entrepreneurial skills would add an appropriate dimension to the criteria for evaluating potential licensees.

There are efforts to do some of this. The NSF initiated the "I-Corps" program to put faculty and graduate students who have NSF grants through start-up training focused on gaining knowledge of the potential market for inventions through interviews with potential customers. A common comment about I-Corps is that part of its value is that it disabuses some faculty inventors who think they are entrepreneurs of that notion by showing them what is involved, persuading them to focus on their strength in invention. Part of its value is in encouraging university-connected start-ups to find outside entrepreneurs to join them. Many universities and communities provide incubators and accelerators to support start-up businesses with physical space, equipment, support services, and mentoring.[287] Expanding the number of universities participating in I-Corps and with incubators would likely improve universities' overall success at commercialization.

However, the entrepreneurial function for ideas coming out of university research requires more than training programs for faculty in aspects of being an entrepreneur. Some faculty have ideas they would like to see marketed but are not personally interested in being entrepreneurs or, even if they are, lack the requisite skills.[288] Then, matching ideas to potential entrepreneurs from the outside is necessary. Entrepreneurial abilities are scarce resources generally, so increasing their availability is critical to the transformation of ideas into impact in the broader community. Unfortunately, one of Schumpeter's fundamental points was that competent entrepreneurs are harder to come by than money for entrepreneurs to use.[289]

Kirzner emphasizes that markets are filled with uncertainty. Were they not, things would be simple: "Without uncertainty…decision making would no longer call for any imaginative, creative determination of what the circumstances really are. Decision making would call merely for competent calculation. Its results could,

[287] Frank T. Rothaermel & Marie Thursby, *Incubator firm failure or graduation? The role of university linkages*, 34 Rsch. Pol'y 1076 (2005) (describing role of incubators).

[288] Etzkowitz, *Norms*, *supra* note 233, at 831.

[289] Schumpeter, *Creative Response*, *supra* note 32, at 223, n. 5 (it became "increasingly easier to obtain other people's money by methods other than the partnership" over 19th century).

in general, be predicted without doubt. Human judgment would have no scope."[290] Universities are not stocked with entrepreneurs, so managers emerging from red boxes likely have worse information about market opportunities than do black box managers. Red box managers, such as TTO directors, lack the experience of firms that, despite making errors, are more likely to come closer to what may be received in the market than are a team of inventors working within a university who have less information about what may be marketable. Red box managers generally know less about what is required to launch products and do not bear the costs of launching inventions. It is not a simple process. Part of the solution is to focus on university culture, which we turn to next.

B. Building an Entrepreneurial Culture

For entrepreneurs, there is no equivalent to Smith's invisible hand. Indeed, the reason efforts are inside a red (or black) box is because conscious coordination is needed. The frequency of the "creative response" that entrepreneurs have, which is key to being entrepreneurial, is connected "(a) with quality of the personnel available in a society, (b) with relative quality of personnel, that is, with quality available to a particular field of activity relative to quality available at the same time, to others, and (c) with individual decisions, actions, and patterns of behavior."[291] The quality available is something universities can do little about, but they can take steps to enhance the second and third contributing factors. Recruiting those who have a "creative response" to improve the pool of potential entrepreneurs within the university is possible.[292] Research into entrepreneurship may help understand how to identify potential entrepreneurs. Advertising a desire to have them and provision of programs can bring students and faculty with entrepreneurial talents to a university. Entrepreneur-in-Residence programs provide visits by successful entrepreneurs. Other programs, including project-based classes, mentoring programs, accelerators and incubators, business plan competitions, and business training may help.[293]

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[290] Kirzner, *Uncertainty, Discovery & Human Action*, *supra* note 264, at 166.

[291] Schumpeter, *Creative Response*, *supra* note 32, at 222.

[292] Clarysse, Tartari & Salter, *supra* note 194, at 1092 ("The university's potential for commercializing its research results through entrepreneurial ventures is liable to depend on its ability to attract and retain academics with high levels of entrepreneurial capacity."). Hiring people who do not "look like" traditional academics is a major challenge at many universities.

[293] Boh, De-Haan & Strom, *supra* note 275, at 665.

Doing well at commercialization—in a bit of a chicken-and-egg conundrum—can help.[294] For example, one particularly successful TTO administrator said that faculty candidates often ask to meet with the TTO staff to learn whether or not that university is successful at commercializing faculty inventions.[295] Being known in the academic community as a university that provides resources to help faculty entrepreneurs and values their efforts will increase the "relative quality of personnel." Etzkowitz points to the importance of the creation of a "penumbra" of firms around the university.[296] Patenting and licensing may be common only in a narrow swath of universities, making it unlikely those activities change the broader culture.[297]

Less attention has been paid to building student entrepreneurship, although Grimaldi *et al.* make a case for giving it attention.[298] Bergmann *et al.* show the importance of climate and culture for students, particularly those not predisposed to be interested in entrepreneurship.[299] The University of Utah's Lassonde Studio is a leading example of a student-focused entrepreneurship program. Incorporating a living-learning community of 400 students with broader programs for the general student body, the program brings in students who have an entrepreneurial mindset and fosters its development.

A common theme in campus discussions of commercialization is whether the campus culture includes entrepreneurial success as something to be valued.[300] This may be critical. Economic historian Deidre McCloskey argues that what set

[294] Owen-Smith & Powell, *supra* note 197, at 109 ("Differences in faculty perceptions of patent processes and infrastructures across the campuses" help explain inter-university differences in disclosure rates).

[295] H.R. Tech & Innovation Hearing, *supra* note 14, at 53 (statement of Kent Nisbet, Exec. Dir., Univ. of Mich. Tech. Transfer) (faculty recruits at Michigan looking at TTC capabilities); Owen-Smith & Powell, *supra* note 197, at 111 ("A strong culture of patenting attracts faculty interested in pursuing commercial endeavors and socializes new university members into that pursuit.").

[296] Etzkowitz, *Norms*, *supra* note 233, at 829.

[297] Mowery et al., *supra* note 85, at 3.

[298] Grimaldi et al., *supra* note 221, at 1047.

[299] Heiko Bergmann, Mario Geissler, Christian Hundt & Barbara Grave, *The Climate for Entrepreneurship at Higher Education Institutions*, 47 Rsch. Pol'y 700, 701 (2018).

[300] Louis, Blumenthal, Gluck & Soto, *supra* note 194, at 111 (discussing importance of local culture); Owen-Smith & Powell, *supra* note 197, at 111 ("The catch-all phrase 'entrepreneurial culture' is central in informants' explanations of [their university's] commercial success."); *see also* Lockett, Wright & Franklin, *supra* note 275, at 191 ("This is an interesting result that suggests that universities, although keen to transfer technology to the private sector in the case of V10 institutions, do not want the academic to pursue a role in the management of the spin-out.").

off the industrial revolution in Britain and Holland was not a particular confluence of capital, inventions, or markets in those countries. Those factors had been present in other places. What distinguished Britain and Holland were cultural features that were "stumbled upon." There was "a new dignity for the bourgeoisie in its dealings and a new liberty for the bourgeoisie to innovate in economic affairs. Both were necessary for the modern world. The two, when linked, appear even to have been sufficient, if you supply a few routine background conditions enjoyed already in many places, as for example somewhat large cities and extensive trade and reasonable security of property and cheap if slow riverine or coastal transport in a biggish country."[301]

Translating McCloskey's argument to universities, their culture must provide recognition for entrepreneurship by faculty, staff, and students, as well as for more conventional measures of academic success (publications, prizes, grades, etc.) to convey its stature. Owen-Scott and Powell found that an "entrepreneurial culture" was a key differentiator between the two universities they studied and concluded that such culture "is central to informants' explanations" of the more successful university's efforts: "A strong culture of patenting attracts faculty interested in pursuing commercial endeavors and socializes new university members into that pursuit."[302] As our data shows, such a culture exists at only a small fraction of U.S. universities. Similarly, Rasmussen, Mosey, and Wright found departmental level effects on spinoff success that suggest the importance of culture: "Small differences in the local department environment relating to the access

[301] Deirdre N. Mccloskey, Bourgeois Dignity: Why Economics Can't Explain the Modern World 393-95 (2010).

[302] Owen-Smith & Powell, *supra* note 197, at 111; *see also* Grigg, *supra* note 79, at 296 (noting "entrepreneurs and entrepreneurship is often viewed with skepticism or even open hostility" within academic culture); Rory P. O'Shea, Thomas J. Allen, Arnaud Chevalier & Frank Roche, *Entrepreneurial Orientation, Technology Transfer and Spinoff Performance of U.S. Universities*, 34 Rsch. Pol'y 994, 1006 (2005) ("public policy and university heads would be advised to intensify their activities to implement educational, research and resource programs to enable a culture of academic entrepreneurship to emerge within universities."). Interestingly, Mowery, Sampat, and Ziedonis concluded that 'learning to patent' by universities was most likely the result of a "diffuse learning process" rather than any change in research culture. David C. Mowery, Bhaven N. Sampat & Arvidis A. Ziedonis, *Learning to Patent: Institutional Experience, Learning, and the Characteristics of U.S. University Patents After the Bayh-Dole Act, 1981-1992*, 48 Mgt. Sci. 73, 87-88 (2002). Even more intriguingly, Marx and Hsu speculate that faculty more inclined to commercialize their research select into "prominent institutions or resource-rich geographies." Matt Marx & David H. Hsu, *Revisiting the Entrepreneurial Commercialization of Academic Science: Evidence from 'Twin' Discoveries*, Nat'l Bureau of Econ. Rsch., Working Paper No. 28203, 2020.

to commercial partners, legitimacy of venturing to the department management and availability of venturing and commercial experience had a disproportionate effect upon subsequent venture development."[303] Examining more than 6,000 life scientists, Ding and Choi found that differences in social networks and institutional support affected the likelihood of creating a start-up or joining a scientific advisory board.[304]

It is not just within the university that there needs to be an emphasis on the entrepreneurial climate. Friedman and Silberman found that the local entrepreneurial climate (as measured by the Milken Foundation Tech-Pole Index) had a statistically significant positive impact on TTO outputs.[305] This is consistent with Florida's insights on the role of a creative community. Powers and McDougall identify being located in an area containing greater venture capital resources with increasing start-ups.[306] Another illustration is in Kenney and Goe's comparative study of Stanford and Berkeley electrical engineering and computer science departments. They found that Stanford faculty believed the university's most important motivation for supporting entrepreneurship by faculty was to increase university prestige while Berkeley faculty ranked that sixth, and believed financial rewards were the most important university motivation.[307] Analyzing faculty relationships with businesses in those departments, Kenney and Goe found that more Stanford faculty had such affiliations; those produced more affiliations, reinforcing the culture.[308] They concluded that "the institutional history, culture,

[303] Einar Rasmussen, Simon Mosey & Mike Wright, *The Influence of University Departments on the Evolution of Entrepreneurial Competencies in Spin-off Ventures*, 43 Rsch. Pol'y 92, 105 (2014); Tartari et al., *supra* note 110, at 1200 (finding evidence of peer influence within departments).

[304] Waverly Ding & Emily Choi, *Divergent Paths to Commercial Science: A Comparison of Scientists' Founding and Advising Activities*, 40 Rsch. Pol'y 69, 79 (2011).

[305] Friedman & Silberman, *supra* note 226, at 29.

[306] Powers & McDougall, *University Start-up Formation*, *supra* note 245, at 307.

[307] Martin Kenney & W. Richard Goe, *The Role of Social Embeddedness in Professorial Entrepreneurship: A Comparison of Electrical Engineering and Computer Science at UC Berkeley and Stanford*, 33 Rsch. Pol'y 691, 701 (2004).

[308] *Id*. at 704. Murray makes a powerful argument that the social capital faculty inventors bring to firms is also a critical ingredient.

> Firstly academic inventors contribute social capital, in addition to human capital, that can be translated by firms into embeddedness within scientific networks. Secondly, scientific careers play a critical role in establishing social capital and thus mediate a firm's embeddedness within the scientific community. Taken together, these arguments suggest that scientific careers are a

and regulations of the broader university in which a faculty member is embedded influence professorial entrepreneurship and corporate involvement."[309] Creating that is not easy. As former Harvard President Derek Bok notes, "to commercialize a university is to engage in practices widely regarded in the academy as suspect, if not downright disreputable."[310] Some business people's experience leaves them unconvinced that university culture is amenable to entrepreneurial behavior.[311]

A university must also accomplish the second part of McCloskey's formula (which is also Ridley's key insight), allowing the university community the liberty to "innovate in economic affairs," at the least by not imposing too many restrictions. Bayh-Dole took one step toward creating this freedom by loosening some restrictions on entrepreneurial activity involving the results of federally funded research. Universities must also ensure their internal procedures do not squelch such activities.[312]

Universities can build cultures that value entrepreneurship by celebrating it in connection with commercialization.[313] Litan, Mitchell, and Reedy argue that "a university culture that is accepting of entrepreneurial activities is best built

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key factor shaping science-based firms because they mediate the local and cosmopolitan social capital through which entrepreneurial firms become embedded in the scientific community.

Fiona Murray, *The Role of Academic Inventors in Entrepreneurial Firms: Sharing the Laboratory Life*, 33 Rsch. Pol'y 643, 644 (2004) (A future draft will include more discussion of her analysis.).

[309] Kenney & Goe, *supra* note 307, at 704.

[310] Bok, *supra* note 81, at 18.

[311] H.R. Tech & Innovation Hearing, *supra* note 14, at 39 (statement of Robert Rosenbaum, President & Exec. Dir., Md. Tech. Dev. Corp.) ("I think it is fair to say that universities have a very distinct culture in and of themselves, and the researchers within those universities have a particular headset in and of themselves. Primarily speaking and historically speaking—although it is changing—researchers within universities are very risk-averse.") This may also help explain the otherwise puzzling finding by Markman et al. that more experienced TTOs were negatively correlated with faculty disclosures, which they suggested was driven by that more traditional TTO approaches were less creative in structuring deals and so inducing disclosures. Gideon Markman et al., *Entrepreneurship from the Ivory Tower: Do Incentive Systems Matter?*, 29 J. Tech. Transfer 353, 360 (2004). Powers and McDougall found that more established TTOs produced more start-ups, which they suggested could be due to greater development of the competencies necessary to facilitate the process. *See* Powers & McDougall, *University Start-up Formation*, *supra* note 245, at 306.

[312] Discouraging entrepreneurial activity may be inadvertent. While universities may want such activity, internal regulatory constraints may set up so many costly hoops researchers must jump through that few will try and experienced faculty will know to shy away from such institutions. Attempts at universities to "engineer entrepreneurship" often fail. *See* Lee & Gaertner, *supra* note 169, at 129.

[313] Gideon D. Markman et al., *Entrepreneurship and University-Based Technology Transfer*, 20 J. Bus. Venturing 241, 253-254 (2005) [hereinafter Markman et al., *Entrepreneurship*].

from the ground up by researchers who promote and connect other colleagues both inside and outside of academe."[314] Schools can recognize and reward those who demonstrate entrepreneurial success, in the same way they reward success in publication or teaching. Entrepreneurship can be formally recognized as contributing to tenure decisions[315] Bringing alumni and community entrepreneurs to campus can help build entrepreneurial culture by recognizing these individuals as worthy participants in the university community and being mentors for potential faculty, staff, and student entrepreneurs.

Boh, De-Haan, and Strom suggest that universities should "leverage all potential university resources for technology transfer" through courses and centers to send a strong message.[316] One possibility is that greater knowledge production by university researchers that leads to publication in papers translates into greater local commercial research. Hicks, et al. found a strong relationship between the location of paper authors and patentees. Scientific knowledge is easy to get from conferences and articles, so distance between the producer and users should not have much impact. Nonetheless, they found a strong relationship.[317]

Changing a university's culture is easier said than done, of course. However, finding ways to build an entrepreneurial culture on campus would be a critical part of a Schumpetarian-Kirznerian approach.

C. Reshaping the Pipeline

A well-functioning TTO is a crucial element of an entrepreneurial campus culture. Researchers disclosing ideas must feel valued and receive the service equivalent of a visit to Apple's Genius Bar, a Disney resort, or a Four Seasons hotel.[318] Rapid responses, transparent processes, and clear feedback are parts of such experience. Wu, Welch and Huang recommend that TTOs focus on identifying

[314] Litan et al., *supra* note 109, at 48.

[315] Thursby & Kemp, *supra* note 235, at 122 (noting greater specialization in basic research may explain lower commercialization 'efficiency' at higher prestige universities).

[316] Boh, De-Haan & Strom, *supra* note 275, at 667.

[317] Diana Hicks, Tony Breitzman, Dominic Olivastro & Kimberly Hamilton, *The Changing Composition of Innovative Activity in the US – A Portrait Based on Patent Analysis*, 30 Rsch. Pol'y 681, 690-691 (2000).

[318] Owen-Smith & Powell, *supra* note 197, at 112 ("inconvenient or frustrating experiences with TTOs may be enough to convince ambivalent inventors that the benefits of IP protection do not outweigh the costs.").

faculty likely to succeed at commercialization.[319] Complicating this is that roles change on campuses.[320] UK research suggests that TTO business development capabilities are important in the success of spinoffs.[321] Not surprisingly, there are significant learning components to TTOs; experience helps performance.[322] The TTO needs to be treated as more than a revenue creation tool because they generally are not revenue generators (as noted earlier), and treating them as such sends the wrong message to faculty considering filing disclosures. One computer science professor complained in an interview that his university "saw inventions as a way to augment the shrinking university budget" and so the tech transfer office was "overly aggressive in trying to make money," forgetting that for him "money wasn't the primary motivation" but that the goal was to get his ideas "into real-world situations."[323]

Developing relationships between TTO staff and researchers is critical. As Owen-Smith and Powell note, "Most TTOs lack the resources and competencies necessary to search a wide range of laboratories and research groups for commercially viable technologies. Thus, institutional success depends in part on faculty perceptions of the benefits of patenting, the quality of the TTO, and the institution as a collective enterprise."[324] Relationships depend on delivering the level of services that inspire confidence and trust.[325]

A broader role for the TTO can pay dividends. Etzkowitz points to the importance of improving information about the technologies produced at the

[319] Yonghon Wu, Eric W. Welch & Wan-Lin Huang, *Commercialization of University Inventions: Individual and Institutional Factors Affecting Licensing of University Patents*, 36-37 Technovation 12, 24 (2015).

[320] Gideon D. Markman et al., *Innovation Speed: Transferring University Technology to Market*, 34 Rsch. Pol'y 1058, 1062 (2005) [hereinafter Markman et al., *Innovation Speed*].

[321] Andy Lockett & Mike Wright, *Resources, Capabilities, Risk Capital and the Creation of University Spin-out Companies*, 34 Rsch. Pol'y 1043, 1054 (2005).

[322] Gerard George,*Learning to Be Capable: Patenting and Licensing at the Wisconsin Alumni Research Foundation*, 14 Indus. & Corp. Change 119, 141 (2005).

[323] Ed Silverman, *The Trouble with Tech Transfer: Fighting Tech Transfer—and Winning*, 21 Scientist 40, 43 (2007).

[324] Owen-Smith & Powell, *supra* note 197, at 99.

[325] Michael D. Santoro & Shanthi Gopalakrishnan, *Relationship Dynamics between University Research Centers and Industrial Firms: Their Impact on Technology Transfer Activities*, 26 J. Tech. Transfer 163, 168-69 (2001) (discussing the importance of trust in collaborations between industry and university).

university that helps firms reduce uncertainty.[326] Haeussler, Harhoff, and Mueller find that information generated during the patent process has value for venture capitalists independent of the patent itself.[327] Agarwal and Shah point out the importance of micro-level policies to aid start-ups, where providing "access to complementary assets and resources for fledgling academic- and user-founded firms in early stage industries might encourage more rapid commercial introduction of novel innovations."[328] Mowery and Ziedonis find greater "localization" of knowledge spillovers from universities via licenses than through citations of academic work, which they suggest may be due to greater "tacitness" of licensed knowledge demanding closeness for access to the scientist.[329]

In a similar vein, Jain and George refer to TTOs as "uniquely suited to play a significant and active role in building legitimacy for new technologies emerging from university laboratories," while the technology is "still wrapped in a fog of uncertainty that is technical, commercial, social and/or ethical in nature."[330] Examining a study of WARF's role in the human stem cell technology at Wisconsin, they conclude "the activities of a TTO can extend beyond traditional patenting and licensing to include building legitimacy for nascent technologies."[331] Jain and George argue that WARF played the roles of protecting ("insulating the nascent technology from the extant institutional environment in situations where it is hostile to the innovation"), propagating ("dissemination of a coherent group of understandings and beliefs related to the technology" and not just diffusion), and influencing ("coalition building, lobbying, and compromise tactics").[332] TTOs' efforts at these roles "are broadly applicable to other actors considering building

[326] Etzkowitz, *supra* note 20, at 118.

[327] Carolin Haeussler, Dietmar Harhoff & Elisabeth Mueller, *How Patenting Informs VC Investors – The Case of Biotechnology*, 43 Rsch. Pol'y 1286, 1296 (2014).

[328] Rajshree Agarwal & Sonali K. Shah, *Knowledge Sources of Entrepreneurship: Firm Formation by Academic, User, and Employee Indicators*, 43 Rsch. Pol'y 1109, 1129 (2014).

[329] David C. Mowery & Arvidis A. Ziedonis, *Markets versus Spillovers in Outflows of University Research*, 44 Rsch. Pol'y 50, 59-60 (2015).

[330] Sanjay Jain & Gerard George, *Technology Transfer Offices as Institutional Entrepreneurs: The Case of Wisconsin Alumni Research Foundation and Human Embryonic Stem Cells*, 16 Indus. & Corp. Change 535, 538 (2007).

[331] *Id*. at 555. In the stem cell case, they note "In its role as an institutional entrepreneur, WARF has been involved in implementing a host of political and socio-cognitive strategies that included lobbying, negotiating, litigating, self-regulating and educating other actors." *Id*.

[332] *Id*. at 557-58.

legitimacy for a nascent technology."[333] The unusually successful WARF differs from most TTOs in that it has "skin in the game" in commercialization.

Beyond competency of a TTO, the implicit linear pipeline of disclosure-patent-license underlying much of current commercialization policy needs to be replaced with a broader vision of academic culture. It is not enough to get a researcher to disclose an idea to the TTO; the idea must be market feasible to be commercialized. This often requires pre-patent development funding to enable a promising idea to reach the stage at which viability can be assessed. As one commentator notes, "the single most common feedback we get from potential licensees is that the technology is too early. So proof-of-principle, proof-of-concept funding is the gating factor to getting more technology to a go-or-no-go decision point."[334] A survey of TTOs finds that universities with higher rankings license a higher proportion of disclosures in the proof-of-concept stage,[335] suggesting that there may be some halo effect to overall reputation. (They may also have better TTOs.) TTOs can play a key role in designing contracts that solve the thorny incentive problems inherent in early-stage inventions. Dechaneaux, Thursby, and Thursby conclude from their survey that proper contract design plays a "critical role" in addressing incentive issues.[336] Universities can also develop mechanisms for involving entrepreneurs in this process, both smoothing the way for faculty to share the critical tacit knowledge they possess and facilitating investment in the often-costly development process.

When the speed of innovation – the time from discovery to commercialization – is critical, universities need faster processes internally. Inventors play a crucial role in speeding up or slowing down particular inventions.[337] Thursby and Thursby note that research shows that "faculty are often involved in the license process well

[333] *Id*. at 562.

[334] H.R. Tech. & Innovation Hearing, *supra* note 14, at 60 (statement of Todd T. Sherer, President, Ass'n of Univ. Tech. Managers).

[335] Jensen et al., *supra* note 80, at 1273; *see also* Wesley David Sine, Scott Shane & Dante Di Gregorio, *The Halo Effect and Technology Licensing: The Influence of Institutional Prestige on the Licensing of University Inventions*, 49 Mgt. Sci. 478, 491 (2003) (university prestige increases licensing rate).

[336] Emmanuel Dechenaux, *Inventor moral hazard in university licensing: The role of contracts*, 40 Rsch. Pol'y 94, 102 (2011).

[337] Markman et al., *Entrepreneurship*, *supra* note 313, at 1073.

beyond disclosure."[338] Jensen and Thursby conclude that active participation by the faculty is essential for commercialization.[339]

A broader task for TTOs is translating university research into real world impact. A narrow focus on commercialization as the primary path may miss important opportunities. Litan, Mitchell, and Reedy lament: "[r]ather than implementing broad innovation/commercialization strategies that recognize different and appropriate pathways of commercialization, as well as multiple programs and initiatives to support each path, many have channeled their innovation dissemination activities through a centralized technology transfer office (TTO)." Too often, this results in TTOs becoming "bottlenecks rather than facilitators of innovation dissemination."[340]

D. Supporting Spinoffs

Entrepreneurship is needed for firms to emerge from universities. Spinoffs require particular support. Indeed, "[a]cademic spinoffs, given their technology basis, combine both the traditional problems associated with the start-up of a new business and the difficulties associated with the development of new technologies."[341] They are, of course, capital and credit rationed.[342] Lerner points out that many candidates for start-ups are "characterized by uncertainty and informational gaps, which make it difficult for the investors to evaluate business plans or to oversee the entrepreneurs once the investments are made."[343] He argues that TTOs can play an important role in solving these problems in two dimensions: "reducing the uncertainty of academic entrepreneurs about the spin-out process and easing outside investors' and strategic partners' doubts about the new venture."[344] However Clarysse, Tartari, and Salter point out that, given that it is a desire to be an entrepreneur that drives faculty behavior, "the creation and efforts of

[338] Jerry G. Thursby & Marie C. Thursby, *Are Faculty Critical? Their Role in University-Industry Licensing*, 22 CONTEMP. ECON. POL'Y 162, 168 (2004).

[339] Jensen & Thursby, *supra* note 80, at 255.

[340] Litan et al., *supra* note 109, at 32.

[341] Ricardo Fini, Rosa Grimaldi, Simone Santoni & Maurizio Solernersalterbrero, *Complements or Substitutes? The Role of Universities and Local Context in Supporting the Creation of Academic Spin-offs*, 40 RSCH. POL'Y 1113, 1114 (2011).

[342] *Id*. at 1114.

[343] Lerner, *supra* note 250, at 50.

[344] *Id*. at 53.

TTOs is of modest or little use in itself unless such a creation is backed up by changes in the hiring and promotion practices of the university itself."[345] Creating a start-up may or may not be the most appropriate means of commercializing some university research.[346] Start-ups are not a priority for all TTOs or university administrations.[347] They have benefits for universities, but also have costs.[348]

> Communities surrounding universities want start-ups as an economic development tool.
>
> The key argument is that communities surrounding universities must have the capabilities to absorb and exploit the science and knowledge that universities generate. Even if new knowledge is generated in many places, it is only those regions that can absorb and apply ideas that are able to turn it into economic wealth. As a consequence, universities are a necessary but not sufficient condition for regional economic development.[349]

Students can also play this role.[350]

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[345] Clarysse, Tartari & Salter, *supra* note 194, at 1092.

[346] Brouwer, *supra* note 5, at 268 ("participating in startups constitutes the ideal technology transfer model for universities because it allows them to get the most from inventions, whose revenues are shrouded in uncertainty."). *But see* Grigg, *supra* note 79, at 294 (noting need for further development of university-derived technologies hinders use of start-ups). If a TTO invests in a failure, the loss is easy to identify and criticize. There is little criticism of deadwood faculty who deliver little value or staff members who do next to nothing, but specific expenditures on a venture that flops presents an opportunity to criticize wasteful efforts to cater to the market.

[347] Siegel et al., *supra* note 92, at 130.

[348] When a faculty-created invention is commercialized, the creator sometimes leaves academia. A study of MIT start-ups found that there was a significant "brain drain" from the university from this, as the faculty who left were more productive than their replacements. Andrew A. Toole & Dirk Czarniki, *Commercializing Science: Is there a University "Brain Drain" from Academic Entrepreneurship*, 56 Mgt. Sci. 1599, 1599 (2010).

[349] Fini, Grimaldi, Santoni & Sobrero, *supra* note 341, at 1116.

[350] A study of Swedish start-ups between 1994 and 2001 found that 528 came directly from universities but 8,663 came from businesses where university students had taken initial jobs and then later spun-out companies, suggesting universities' educational role is also a powerful source of new ventures. Similarly, U.S. data suggests the gross flow of start-ups from undergraduates with science and engineering degrees is considerably larger than the flow from faculty. Thomas Astebro, Navid Bazzazian & Serguey Braguinsky, *Startups by Recent University Graduates and their Faculty: Implications for University Entrepreneurship Policy*, 41 Rsch. Pol'y 663 (2012).

Spinning off a start-up may not be the right strategy. Evidence suggests this is often the case when the technology needs further development before it is ready for the market, as with many medical devices based on ideas from university researchers.[351] As a result, "many [university] inventions are so embryonic that they might remain in the lab without license agreements designed to induce collaboration between inventors and licensees."[352] This has consequences for license terms, which must be designed to induce collaboration.[353]

Not all technologies are equally likely to result in start-ups. University spin offs commercialize more innovative technologies than industry incumbents' spin offs.[354] This may be the result of an earlier stage of university-related spin off technology. There is evidence that start-ups with radical technologies and strong intellectual property in fragmented industries are more likely to survive.[355] As universities became more experienced with start-ups, they became more comfortable taking equity stakes rather than upfront license fees, which raised additional challenges for TTOs in structuring deals and monitoring

[351] Fontes suggested that "spin-offs tend to emerge as a response to system gaps regarding the exploitation of academic research. These gaps are related both to the nature of the knowledge, which may make its direct exploitation by existing companies less likely, thus calling for some previous transformation or translation conducted by other actors, familiar with that knowledge; and to the nature of the organizational setting where knowledge production takes place, namely the difficulties in conciliating in the same organizational context activities that have fundamentally different objectives and require different governance structures." Margarida Fontes, *The Process of Transformation of Scientific and Technological Knowledge into Economic Value Conducted by Biotechnology Spin-offs*, 25 TECHNOVATION 339, 341 (2005).

[352] Jensen & Thursby, *supra* note 80, at 241. At the same time, the uncertainties associated with embryonic technologies increase the risk of choosing the wrong licensee, suggesting flexibility in adapting as learning occurs is important. *See* Jeannette Colyvas et al., *How Do University Innovations Get into Practice?*, 48 MGT. SCI. 61, 66 (2002).

[353] *Id*. at 255.

[354] Henry Chesbrough, *The Governance and Performance of Xerox' Technology Spin-off Companies*, 32 RSCH. POL'Y 403, 403 (2003); Erwin Danneels, *Disruptive Technology Reconsidered: A Critic and Research Agenda*, 21 J. PROD. INNOVATION MGT. 246, 246-258 (2004).

[355] Atul Nerkar & Scott Shane, *When Do Start-ups that Exploit Patented Academic Knowledge Survive?*, 21 INT. J. IND. ORG. 1391, 1408 (2003); *see also* Scott Shane, *Technological Opportunities and New Firm Creation*, 47 MGT. SCI. 205 (2001) (using data on inventions at MIT, "[c]ontrolling for who invented the technology, the characteristics of the industry, the time period when the technological development took place, and the nature of the technology, more important inventions, more radical inventions, and inventions with a broader scope of patent protection were more likely to be commercialized through the creation of new firms.").

performance.[356] Taking equity stakes in lieu of royalties appears to promote the creation of start-ups.[357] Similarly, permitting part-time employment at start-ups is valuable.[358] However, Lerner catalogs a variety of dangers for university-related start-ups in obtaining financing and for universities in establishing their own venture funding.[359]

Creating a start-up company requires complex connections with entrepreneurial, managerial, and financial resources.[360] Zahara, Van de Velde and Larrañeta propose that "a key source of the potential performance differences" among spinoffs "lies in their 'knowledge conversion capability' (KCC) that refers to their capacity to transform research and scientific discoveries into successful products and goods that are efficiently and quickly commercialized to create value," although they concede that there is little knowledge of how spinoffs accomplish KCC.[361] They suggest three key components: (1) "conceptualization and visioning", which "means envisioning and conceiving potential uses and applications for the new technology;" (2) "configuration and design", which "centers on developing working and functional prototypes that transform this knowledge into new products that are easy to develop and manufacture;" and (3) "embodiment and integration" that "denotes a firm's ability to integrate and apply diverse knowledge from different sources and convert its technology to marketable products."[362] Surveying firms in five states, they find that corporate spin-offs have

[356] *See* Maryann Feldman, Irwin Feller, Janet Bercovitz & Richard Burton, *Equity and the Technology Transfer Strategies of American Research Universities*, 48 Mgt. Sci. 105, 106-107 (2002). Feldman, et al. describe TTOs' evolution from seeing equity as a last resort financing mechanism to seeing it as a useful tool in some instances. *Id*. at 109-110. In particular, equity stakes preserve the university's option value in the technology. *Id*. at 110.

[357] Dante Di Gregorio & Scott Shane, *Why Do Some Universities Generate More Start-ups Than Others?*, 32 Rsch. Pol'y 209, 224 (2003).

[358] Edward B. Roberts, *The Technological Base of the New Enterprise*, 20 Rsch. Pol'y 283, 297 (1991).

[359] Lerner, *supra* note 250, at 51-53.

[360] *See* Jean-Jacques Degroof & Edward B. Roberts, *Overcoming Weak Entrepreneurial Infrastructures for Academic Spin-off Ventures*, 29 J. Tech. Transfer 327, 340-341 (2004). One such complexity is that "the development of academic entrepreneurship abilities at the organizational level influences individual scientists and their perceptions." Grimaldi et al., *supra* note 221, at 1050.

[361] Shaker A. Zahra et al., *Knowledge Conversion Capability and the Performance of Corporate and University Spin-offs*, 16 Indus. & Corp. Change, 569, 570 (2007); *see also* Lockett, Wright & Franklin, *supra*, note 275, at 186-187.

[362] *Id*. at 574 (internal quotation marks omitted).

statistically significantly higher mean measures of all three KCC components.[363] They suggest this was because corporate spinoffs had better access to KCC-related skills (from their parent corporations) than university spinoffs.[364] A crucial step for universities is to bolster spinoffs' access to the KCC components.

University policies affect the likelihood of a start-up being a solution. Preferential treatment for those engaged in building start-ups, such as non-research leaves, temporary freezing of tenure clocks, and various recognition increase faculty willingness to take on such projects.[365]

University-related spinoffs can develop with one of the research team serving as CEO or an outsider with prior business experience taking on that role.[366] Relying on an academic entrepreneur rather than someone with business experience can bring more commitment to a new technology, but can mean the start-up lacks business knowledge and experience and may inappropriately focus the entrepreneur on the technology rather than the business aspects.[367] Some research suggests companies are more likely to grow substantially if the academic entrepreneur leaves the university.[368] Other research found that start-ups in a university incubator were slower to 'graduate' from the incubator if they had faculty members as part of senior management.[369] Franklin, Wright and Lockett surveyed universities with start-up experience and found that the more successful among them saw fewer disadvantages to having "surrogate entrepreneurs" manage the start-ups rather than the faculty member behind the technology.[370] The biggest challenge was locating appropriate surrogates.[371]

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[363] *Id*. at 589.

[364] *Id*. at 594.

[365] Fini, Grimaldi, Santoni & Sobrero, *supra* note 341, at 1115.

[366] There is some evidence that the location of the firm near the scientists involved is important in some circumstances. *See* David B. Audretsch & Paula E. Stephan, *Company-Scientist Locational Links: The Case of Biotechnology*, 86 Am. Econ. Rev. 641 (1996).

[367] Stephen J. Franklin et al., *Academic and Surrogate Entrepreneurs in University Spin-out Companies*, 26 J. Tech. Transfer 127, 128 (2001).

[368] *Id*. at 128 (citing Doutriaux)

[369] Rothaermel & Thursby, *Incubator firm failure or graduation? The role of university linkages*, *supra* note 287, at 1088.

[370] Franklin et al., *supra* note 367, at 138.

[371] *Id*. at 138; see also Lockett, Wright & Franklin, *supra* note 275, at 193.

As noted earlier, one approach to start-ups is to train the research team in entrepreneurial skills. "Academics are often highly dependent on others in their environment to supply the competencies needed to launch a new venture given the traditionally non-commercial environment in which they operate."[372] Some argue that training programs such as the NSF I-Corps do not adequately prepare researchers because they focus on starting a business "but don't necessarily teach them how to grow a business and manage a business."[373] One suggests that ten years of support would be needed, rather than just one year.[374]

Early-stage funding support makes a difference.[375] Support programs are complicated to design and administer. The earlier stage of much technology coming out of universities raises problems for securing financing because it causes an "information asymmetry [for investors] vis-à-vis the TTO and the investment manager. Valuation of patents or tacit knowledge at the early stage of product development is quite uncertain and poses particular problems for venture capital firms. This problem is exacerbated because there is typically little information about the acceptability of the product in the market or the size of the market."[376] At the same time, leveraging IP rights is increasingly important for emerging technology companies' funding strategies.[377] To fill the gap created by these difficulties, some European countries provide public funding for start-ups. One fear with such funding is that firms will be overfunded relative to their merits, leading to overvaluations that then hinder subsequent funding rounds from market sources.[378] A study of European university spinoffs found evidence to support this effect.[379]

Another support tactic is to increase entrepreneurial faculty opportunities to build social capital through pre-start-up connections with venture capitalists. Drawing on a dataset of MIT spinoffs, Shane and Stuart suggest that founders'

[372] Rasmussen, Mosey & Wright, *supra* note 303, at 94.

[373] H.R. Tech & Innovation Hearing, *supra* note 14, at 59 (statement of Robert Rosenbaum, President & Exec. Dir., Md. Tech. Dev. Corp.).

[374] *Id*.

[375] H.R. Tech & Innovation Hearing, *supra* note 14, at 60 (statement of Kent Nisbet, Exec. Dir., Univ. of Mich. Tech. Transfer).

[376] Clarysse et al., *supra* note 50, at 612.

[377] Charlotte H. Copperthite & Michael J. Lerner, *Leveraging Intellectual Property to Obtain Financing in a Global Arena*, 2 J. World Intell. Prop. 1015, 1016 (1999).

[378] Clarysse et al., *supra* note 50, at 613-14.

[379] *Id*. at 633.

social capital as measured by pre-formation connections with venture capitalists improved university start-ups' success at funding.[380] Aldritch and Audretsch find that academics' social capital (such as membership on a scientific advisory board or co-authoring with an industry scientist) is associated with higher propensity to become an entrepreneur.[381] Examining data from start-ups from two European universities, Soetanto and van Geehuizen find the university networks aid in securing financing.[382]

Creating conditions that nurture start-ups is a complex problem not solved by throwing money at firms (although they appreciate it), providing training in finance, management, or accounting (although this is useful), or asking researchers to read Schumpeter. Environments that help start-ups flourish are analogous to a coral reef: a diverse ecosystem.[383] The coral reef metaphor is apt because start-ups are not homogenous.[384]

Nelson concludes his case study of a Stanford-related innovation with mixed results in commercialization by pointing to the need for better "alignment" between universities and those who can make commercialization a success:

> Rather than suggesting that "firms are better at innovation than universities," "small firms are better at innovation than large firms," or "entrepreneurial innovation plays a more important role [than] structural innovation in universities," the present case points to the need to seek alignment between technological, organizational, institutional (and likely national) contexts – for it is in leveraging context and in

[380] Scott Shane & Toby Stuart, *Organizational Endowments and the Performance of University Start-ups*, 48 Mgt. Sci. 154, 168-169 (2002).

[381] Aldridge & Audretsch, *supra* note 230, at 1065-66.

[382] Danny Soetanto & Marina van Geenhuizen, *Getting the Right Balance: University Networks' Influence on Spin-offs' Attraction of Funding for Innovation*, 36-37 Technovation 26, 26 (2015).

[383] Gregory P. Pogue et al., *Building an Innovation Coral Reef: The Austin Technology Incubator Case Study*, *in* Open Innovation 203 (Arthur B. Markman, ed., 2016); Powers & McDougall, *Policy Orientation*, *supra* note 180, at 1039-1040 (discussing importance of local environment to success of spinoffs); Rory O'Shea et al., *Universities and Technology Transfer: A Review of the Academic Entrepreneurship Literature*, 25 Irish J. Mgt. 11, 19-20 (2004).

[384] Celine Druilhe & Elizabeth Garnsey, *Do Academic Spin-Outs Differ and Does it Matter?*, 29 J. Tech. Transfer 269, 269 (2004).

> recognizing where each context excels that we may hope to further both innovation and excellence in other university activities.[385]

This is a central issue for universities: how to harness resources to improve the flow of ideas from lab to market. It also highlights the central flaw in the Bayh-Dole approach of relying on universities to undertake a role for which they are ill-equipped.

Conclusion

To economists, the production of innovation by firms is still mostly a black box. How they generate research is not well understood. A few universities claim a significant role in innovation. There are touted successes: Gatorade (University of Florida) and the Moderna COVID-19 vaccine (MIT). These are not sufficient to allow us to know if universities play a major role in innovation; given the $50 billion spent by the NSF and NIH in 2021 alone, there should be many significant successes. Yet the data on university patents suggests that most universities are not engaged in this important preliminary step on the road to commercialization of research.

This Article provides insights into the red box innovation processes in non-profit universities that policymakers generally want to play a bigger role in successful research. Universities do offer an environment that businesses believe has advantages for at least certain types of research. Some of the most successful corporate laboratories mimicked university environments and those who have worked in them and studied them point to those features as critical to their successes. If we could do a better job of engaging universities in producing commercializable ideas – the first step toward which is more patenting of ideas from research – we might be able to unlock more of the benefits the proponents of Bayh-Dole promised the statute would deliver. However, universities are inherently conservative organizations, not prone to radical changes in structure. Nonetheless, from what we know of successful processes, some changes on the margins could improve university performance in commercialization.

Schumpeter put innovation in the center of his approach to economics, calling it a "third and logically distinct factor in economic change" (alongside the "non-

[385] Andrew J. Nelson, *From the ivory tower to the startup garage: Organizational context and commercialization processes*, 43 Rsch. Pol'y 1144, 1154 (2014).

cyclical element of growth" and "outside factors"), arguing that "If there be a purely economic cycle at all, it can only come from the way in which new things are, in the institutional conditions of capitalist society, inserted into the economic process and absorbed by it."[386] It drove the "incessant *creation* of new plant and equipment, embodying new technologies that revolutionize existing industrial structures"[387] producing "great surplus gains" from new industries and methods.[388]

As generators of ideas and of research likely to teach us how to "do new things" and "new ways of doing things," universities are a source of Schumpeterian innovation. But innovations have impact only if they reach the market. If we are to benefit more from investments of university researchers' effort, we need a better approach to moving ideas from lab to market. Approaching that problem with a Schumpeterian/Kirznerian view is one way. O'Kane *et al.* argue that TTOs struggle with contradictory identities, caught between a need for a scientific identity to connect with their faculty clients and a business identity to connect with university administration and potential licensees.[389] Having a clear framework for their mission could help accomplish that. Developing that framework requires universities to reject the anti-capitalist ideas so common in academia and encourage researchers to meet market tests of value. Another step may be to fill more positions with people with entrepreneurial experience. This would require universities to consider entrepreneurial skills and interests in hiring research faculty.

At a more mundane level, better data on university efforts at commercialization is needed.[390] We need to understand which technologies successfully move out of the university into the market, which faculty are more likely to be successful, and

[386] Joseph A. Schumpeter, *The Analysis of Economic Change*, *reprinted in* Essays on Entrepreneurs, Innovations, Business Cycles, and the Evolution of Capitalism 139 (Richard Clemence, ed., 2008) (1935) [hereinafter Schumpeter, *Economic Change*].

[387] Schumpeter, *Capitalism Essay*, *supra* note 32, at 198.

[388] Schumpeter, *Economic Theory and Entrepreneurial History*, *supra* note 32, at 258. Arguably, the most successful implementation of a Schumpeterian approach to economic growth came in the Asian Tiger economies, where there was "an extraordinary emphasis on saving and investment, a broad range of innovation across many industries, and a tremendous outburst of entrepreneurship in new companies …" McGraw, *supra* note 30, at 182.

[389] Conor O'Kane, Vincent Mangematin, Will Geoghegan & Ciara Fitzgerald, *University Technology Transfer Offices: The Search for Identity to Build Legitimacy*, 44 Rsch. Pol'y 421, 428-429, 432 (2015).

[390] Perkmann et al., *Academic Engagement & Commercialization*, *supra* note 111, at 430-31. We are working on an extension of this project with additional coauthors, seeking to map which areas universities are patenting in and how their success compares to patents from other sources.

which forms of commercialization work best for various technologies. Better data includes better measures of success as well as more data on efforts at innovation.

The editors of a special issue of the *Journal of Economic Behavior and Organization* looked at academic science's relationship with entrepreneurship. Its overarching theme was that there are tradeoffs, "including the opportunity cost of searching for (and negotiating with) industrial partners, the shift in the time horizon and direction of research, and the distortions induced by limiting the dissemination and future use of research findings," involved in commercialization efforts.[391] Broader recognition of these tradeoffs by universities is essential.

Schumpeter argued that innovations tended to "*cluster* at certain times" because "as soon as the various kinds of social resistance to something that is fundamentally new and untried have been overcome, it is much easier not only to do the same thing again but also to do *similar* things in different directions, so that a first success will always produce a cluster."[392] Universities support researchers from a range of disciplines. They are positioned to consider not just the technologies that produce these clusters but to analyze the development and impacts of these clusters. A focus on technologically driven clusters would likely yield more innovation, thereby enhancing the value of universities to society.

"Most innovations…especially the successful ones, result from a conscious, purposeful search for innovation opportunities."[393] Innovations rarely result from flashes of inspiration. Paul McCartney woke up one day with the melody for the song "Yesterday" in mind, but then worked to perfect it for two years. It was "hard grueling work," not "sudden creative genius,"[394] that produced the successful version. So, too, it is with researchers inside the red boxes. Long work based on expertise is required and results are not guaranteed. University researchers help develop innovations that spur the economy. If we could do better than Bayh-Dole has done at encouraging such efforts, society as a whole would benefit. The process that has arisen to try to sell inventions to the private sector, usually through TTOs,

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[391] Adam Jaffe, Josh Lerner, Scott Stern & Marie Thursby, *Academic Science and Entrepreneurship: Dual Engines of Growth?*, 63 J. Econ. Behav. & Org., 573, 575 (2007).

[392] Schumpeter, *Economic Change*, *supra* note 386, at 141-42.

[393] Peter Drucker, *The Discipline of Innovation*, Harv. Bus. Rev. 95, 96 (Aug. 2002).

[394] Allen Gannett, the Creative Curve: How to Develop the Right Idea, at the Right Time 8 (2018).

ultimately needs to incorporate the insights Schumpeter and Kirzner developed on entrepreneurship. If they do so, they will be more successful at the process of moving new things into the market. We should care about how the products of university research move from the lab to the economy because, as Kealey says, "technology *is* wealth."[395] More than forty years of Bayh-Dole's inadequate linear model of innovation is enough. It is time for a serious effort to rethink how universities can best foster innovation and so create economic growth.

[395] KEALEY, *supra* note 12, at 205. Kealey makes a persuasive case that governments need not fund even basic research, a separate question from that addressed in this Article. *Id*. at 216-234.

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DISCLOSURE REQUIREMENTS FOR INFLUENCER MARKETING IN THE U.S. AND GERMANY

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This article compares the requirements for influencer marketing in the U.S. and Germany with a particular focus on the disclosure of commercial intent and material connections to sponsors. By analyzing different scenarios, the article shows that in the U.S. and Germany essentially similar rules apply. However, under German law a more complex analysis is required if influencers promote products without receiving any consideration or if they not even promote products but rather themselves to increase the number of followers. For example, the influencer bears the burden of proof that no consideration has been received under German law. In addition, German law does require the disclosure of the concrete purpose (e.g., free product v. consideration received) while U.S. law is less specific in this regard. While the material rules applying might be similar, the enforcement regime is entirely different. The respective U.S. law is enforced by the FDA as a public authority; the German law by private parties. The article compares both approaches and discusses the advantages and disadvantages such as more specific guidance provided by the FDA or private enforcement not being limited by authority resources.

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Introduction

With the growing popularity of so-called influencers on social media platforms such as Instagram, legal issues regarding the disclosure of payments and other considerations for publishing social media posts have been raised in several countries such as Germany and the U.S. This is not only relevant for product endorsements but for anything posted on social media extending the network of the influencer's commercial account.

In Germany, starting with several cease and desist letters addressed to influencers a few years ago, there has been uncertainty for influencers about how and when to disclose payments, other considerations, and – more broadly – any commercial intent under unfair advertisement law and media law. After several judgements by German regional courts and higher regional courts, the German Federal Court (Bundesgerichtshof – BGH) finally clarified the disclosure requirements for commercial social media posts under German Law in four decisions. These clarifications are accompanied by modifications made by the German legislature to unfair advertisement law, in effect since May 28, 2022.

Competitors and private organizations are entitled to enforce these provisions. Under U.S. law, the disclosure requirements for commercial posts are found in Sections 5(a) and 12 of the FTC Act (15 U.S.C. §§ 45(a), 52) and are enforced by the Federal Trade Commission (FTC) as a public authority. The clarity of these requirements seem to be less of an issue. In this context, the (non-binding) Endorsement Guides of the FTC are particularly relevant. Non-compliance with the Guides might constitute a deceptive practice and thus may be governed by the FTC Act.

This article compares both German and U.S. approaches by applying each to different scenarios. The comparison not only sheds light on the actual disclosure requirements in two important jurisdictions but can also be seen as an example of different ways of enforcing the law while highlighting their respective advantages and disadvantages. The scenario of an endorsement by an influencer with and without receiving consideration is discussed (Scenario 1). This article also addresses the endorsement of an influencer's own products (Scenario 2) and the "endorsement" of the influencer's account, itself without featuring any particular (other) services or products (Scenario 3). After describing these three scenarios, the article first discusses the German (and European) approach to endorsements in social media (Section II). The article then analyzes the U.S. approach (Section III). Finally, both approaches are compared and significant differences and advantages are discussed (Conclusion).

The article identifies a broader scope of German law; while U.S. law focuses particularly on the disclosure of material connections, German law has a broader focus on any commerciality. In Scenarios 1 and 2, disclosure is generally required under U.S. and German law unless there has been no consideration paid in Scenario 1. Under German law, the burden of proof of having received no such consideration lies with the influencer. Under U.S. law, a product of a very low value given to the influencer might require no disclosure at all. In Scenario 3, under both German and U.S. law, no disclosure is required. However, this scenario is considered more complex under German law. If a disclosure is required, both jurisdictions have similar requirements, including a prominently placed and visibly designed disclosure notice. However, German law requires more details on the concrete purpose (compare the Scenarios and different kinds of consideration).

In addition, this article shows that both enforcement regimes provide an effective response to the challenges raised by influencer marketing. Enforcement by

the FTC as public authority allows for better guidelines and control but is naturally limited by the resources of a single authority. The FTC focused on advertisers rather than the influencers themselves. In contrast, enforcement by private parties under German law has been focused on the influencers, has rapidly sensitized influencers and produced a greater number of court decisions with important guidance.

I
Different Scenarios

Influencer marketing[1] through posts on social media, endorsing products or services, may be an endorsement from various perspectives and under different circumstances.[2] This article focuses on three different scenarios (described below) to illustrate disclosure obligations for endorsements in the field of influencer marketing. "Influencer" as used in this article refers to a self-employed[3] individual publishing posts including text, pictures, and videos on social media, some of which are paid by advertisers.

A. Scenario 1-A: Paid Endorsement Not Disclosed

Influencer A publishes on her verified Instagram account a post containing a picture that shows her with a healthy and innovative food product. The text below the picture states "For my perfect start into the day #health #powerfood #fitness https://promoted-powerfood-company.com/buy-powerfood." The picture contains a so-called tap tag covering the area where the food product is shown in the picture. When a user clicks on such a tag, the respective company's name is displayed and after a second click, the user is redirected to the company's Instagram profile. The post is not explicitly labeled as advertising. A has been paid a fixed amount for

[1] *See, e.g.*, Jan Trzaskowski, *Identifying the Commercial Nature of Influencer Marketing on the Internet*, 65 Scandinavian Stud. L. 81, 82-84 (2018); Catalina Goanta & Sofia Ranchordás, *The Regulation of Social Media Influencers: An Introduction*, Univ. Groningen Fac. L. Rsch. Paper Series, No. 41/2019, at 3-8, https://ssrn.com/abstract=3457197; Christine Riefa & Laura Clausen, *Towards Fairness in Digital Influencers' Marketing Practices*, 8 J. Of Eur Consumer Mkt. L. 64, 64-65 (2019); Rich Wilson, *Influencer Marketing: Standing out in Your Digital Communities*, 39 Legal Mgmt. 9 (2020); Eur. Comm'n, *Behavioural Study on Advertising and Marketing Practices in Online Social Media* 32-33 (2018), https://ec.europa.eu/info/sites/default/files/osm-final-report_en.pdf.

[2] *E.g.*, Goanta & Ranchordás, *supra* note 1, at 9 (discussing influencer marketing and different business models on social media).

[3] *See* Trzaskowski, *supra* note 1, at 86, 98 (distinguishing employed and self-employed influencers).

publishing this post after she agreed with the advertising company to promote the product in a post.

B. Scenario 1-B: Endorsement for Free Product

Other than in Scenario 1-A, A did not receive any payment, but instead, she received the endorsed product for free.

C. Scenario 1-C: Endorsement Without Any Consideration

Other than in Scenario 1-A, A received neither payments nor the product for free and did not conclude any contracts with an advertiser.

D. Scenario 2: Endorsement of Own Products

Other than in Scenario 1-A, A promotes products she sells on her own website.

E. Scenario 3: Endorsement of the Influencer Herself

Influencer A publishes a post on her verified Instagram account with a photo showing her in front of a mirror and in her non-branded training outfit. The photo is accompanied by the text "Shoutout to everyone who is training hard – every single day – to become better, stronger and healthier. Learn more about the positive effects of weight training on my website: https://influencer-website.com #mirrorselfie #fitnessselfie #weighttraining".[4] The post does not contain any tap tags or product endorsements. The website influencer-website.com does not show any advertisements or promotions of particular goods or services.

II
The German Approach

First, this article analyzes the German[5] approach based on several provisions of unfair advertisement law and unfair media law.

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[4] *Cf*. Bundesgerichtshof [BGH] [Federal Court of Justice], Sep. 9, 2021, I ZR 90/20, Neue Juristische Wochenschrift [NJW], Influencer I (Ger.), http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&Datum=2021-9&Seite=7&nr=122152&pos=237&anz=283 (however, significantly amended; the original post contains tap tags).

[5] *See* Rossana Ducato, *One hashtag to rule them all? Mandated disclosures and design duties in influencer marketing practices, in* The Regulation of Social Media Influencers 232, 245-52 (Catalina Goanta & Sofia Ranchordás eds., 2020) (discussing the Italian way in this regard); Sophie C. Boerman, Natali Helberger, Guda van Noort & Chris J. Hoofnagle, *Sponsored Blog Content: What do the Regulations Say? And what do Bloggers Say?*, 9 J. Intell. Prop. Info. Tech. & Elec. Com. L., 146, 148-51 (2018) (discussing the Dutch approach).

A. Background

German law follows an enforcement approach mostly based on private enforcement and litigation.[6] While several acts stipulate the different or similar obligations of providers, such as influencers, all of these obligations can be enforced by competitors and some private organizations under the Act on Unfair Competition (Gesetz gegen den unlauteren Wettbewerb – UWG).

Along with § 5a(4) UWG, § 6(1)(1) Telemedia Act (Telemediengesetz – TMG) and § 22(1)(1) Interstate Media Treaty (Medienstaatsvertrag – MStV) oblige (telemedia) providers including influencers to label advertising as such if the commerciality is not apparent from the circumstances.[7] In addition, specific provisions in § 3(3) UWG in connection with the Annex (so-called black list) prohibit (deceptive) advertorials (no. 11) and traders to create the impression that they are consumers (no. 22). Some of these provisions implement EU legislation, which has to be taken into account when interpreting them. Section 5a(4) UWG is in part based on Art. 7(2) Unfair Commercial Practices Directive 2005/29/EC (UCP Directive). Section 3(3) UWG in connection with Annex no. 11, 22 of the UWG are also based upon the UCP Directive and its Annex. Section 6(1)(1) TMG and § 22(1)(1) MStV[8] implement Art. 6(a) Directive 2000/31/EC (e-Commerce Directive).

Pursuant to § 1, the UWG aims to protect competitors, consumers, and other market participants against unfair commercial practices. The requirement under § 5a(4) UWG that the commercial intent of a commercial practice must be apparent is consistent with this aim. However, this particular provision implements the UCP Directive, and lays a focus on consumer protection as the UCP Directive does according to its Art. 1(1) ("The purpose of this Directive is to contribute to the

[6] The enforcement of media law is with specific public authorities under, for example, §§ 105, 106 MStV. In addition, other public authorities are competent with regard to violations with relevance for more than one EU member state. *Cf.* Commission Regulation 2017/2394, 2017 O.J. (L 345) 1 (EU).

[7] Additionally, § 22(1)(1) MStV requires a clear separation of advertising from other content. *See also* Hans-Jürgen Ahrens, *Influencer Marketing – Regulierungsrahmen und Konsequenzen seiner Anwendung (Teil 1)* [Influencer Marketing - Regulatory Framework and Consequences of its Application (Part 1)], 120 Gewerblicher Rechtsschutz und Urheberrecht [GRUR] 1211, 1218 (2018).

[8] Bundesgerichtshof [BGH] [Federal Court of Justice] Jan. 13, 2022, I ZR 35/21, Influencer III, ¶ 74, http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&Datum=2022-1&Seite=5&nr=126840&pos=172&anz=277.

proper functioning of the internal market and achieve a high level of consumer protection [. . .]"). All the named provisions of UWG, TMG, and MStV generally aim to protect consumers or recipients against deception about the commercial background[9] and to protect their autonomy.[10] Such protection against deception is relevant as consumers may face a noncommercial post more openly than they would an apparent commercial post.[11] However, the policy considerations differ in the details of the different acts. For example, § 22(1)(1) MStV might be considered as protecting in particular the independence of telemedia providers.[12]

B. Disclosure of a Commercial Intent Under UWG, TMG, and MStV

The UWG requires a commercial practice (§ 2(1)(2) UWG), extending the definition of Art. 2(d) UCP Directive.[13] Commercial practices whose commerciality is not apparent might violate § 6(1)(1) TMG and § 22(1) MStV. A commercial violation of these two provisions is relevant under §§ 3a, 3 UWG. A practice might also be a violation of Annex no. 11, 22 of § 3(3) UWG or § 5a(4) UWG and thus prohibited under § 3 UWG. However, to the extent provisions of TMG or MStV are exhaustive, Annex no. 11, 22 of § 3(3) UWG and § 5a(4) UWG

[9] BGH, I ZR 90/20, *supra* note 4, at ¶ 70 (discussing specifically § 5a(6) UWG, the predecessor of § 5a(4) UWG); Tristan Radtke & Fabian-Philipp Camen, *Des Wortlauts letzter Schluss? Für mehr Rechtssicherheit bei der Kennzeichnung kommerzieller Influencer-Beiträge* [The final interpretation? For more legal certainty in the labeling of commercial influencer posts], 66 Wettbewerb in Recht Praxis [WRP] 24, ¶¶ 4, 5 (2020); BGH, I ZR 35/21, *supra* note 8, at ¶ 74, http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&Datum=2022-1&Seite=5&nr=126840&pos=172&anz=277.

[10] Ducato, *supra* note 5, at 238.

[11] BGH, I ZR 90/20, *supra* note 4, at ¶ 70; Bundesgerichtshof [BGH] [Federal Court of Justice], Sep. 9, 2021, I ZR 125/20, ¶ 36, (Ger.) https://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bghArt=ennr=122155pos=0anz=; Radtke & Camen, *supra* note 9, at ¶ 4.

[12] *Cf.* Karl-Nikolaus Peifer, *Influencer Marketing – Rechtlicher Rahmen und Regulierungsbedürfnis (Teil 2)* [Influencer Marketing - Legal Framework and Need for Regulation (Part 2)], 120 GRUR 1218, 1224 (2018) (discussing editorial independence under German media law in general).

[13] Bundesgerichtshof [BGH] [Federal Court of Justice], Sep. 9, 2021, I ZR 126/20, ¶ 52, http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&Datum=2021-9&Seite=7&nr=122158&pos=236&anz=283; Case C-391/12, RLvS Verlagsgesellschaft mbH, ECLI:EU:C:2013:669, ¶¶ 37-39 (Oct. 17, 2013) (emphasizing that the UCP Directive requires the practice to be connected with the business of the trader oneself or, in case of the promotion of another company's business, that the trader has to act in the name or on behalf of the other company; if a practice is not covered by the UCP Directive broader national law might still apply).

do not apply (compare § 1(2) UWG and Art. 3(4) UCP Directive).[14] Any of these violations entitle market participants, such as direct competitors, to injunctions and – with less relevance in practice – damages (§§ 8-9 UWG).

1. Commercial Practice

First, a commercial practice is required. A commercial practice is–basically– any act or omission of a person in favor of his own[15] or another's company,[16] which has a direct and objective connection with the conclusion of a contract about goods or services (cf. § 2(1)(2) UWG and Art. 2(f) UCP Directive).[17] A relationship of the endorsing influencer to the company selling the promoted goods can indicate a commercial practice.[18] The requirement of a *direct* connection has been recently added to the UWG while being already included in the UCP Directive.[19] The German legislature explicitly added this language to clarify that the practice of an

[14] Gesetzentwurf [Bill], Deutscher Bundestag: Drucksache [BT] 19/27873, at 31-32, (Mar. 24, 2021), https://dserver.bundestag.de/btd/19/278/1927873.pdf (Ger.); BGH, I ZR 90/20, *supra* note 4, at ¶ 46, http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&nr=122152&pos=0&anz=1; BGH, I ZR 126/20, *supra* note 13, at ¶ 75. *Cf.* Trzaskowski, *supra* note 1, at 94.

[15] *See* Case C-105/17, Evellina Kamenova v. Okrazhna prokuratura - Varna, ECLI:EU:C:2018:808 (Oct. 4, 2018) (discussing the requirements for being considered a "trader," which is necessary for the UCP Directive and its transformation into national law to apply to the person).

[16] *See generally* Riefa & Clausen, *supra* note 1, at 66 (discussing the different relationships of influencers as potential traders with social media platforms and users); Ducato, *supra* note 5, at 234-37.

[17] The UCP-Directive is insofar more specific as it requires, under Art. 2(d) and Art. 3(1), a connection "with the promotion, sale or supply of a *product to consumers*" (emphasis added) and it covers practices in favor of another's business only narrowly and is therefore not likely to apply to Scenarios 1-A, -B and -C; *Cf.* Case C-391/12, RLvS Verlagsgesellschaft mbH v. Stuttgarter Wochenblatt GmbH, ECLI:EU:C:2013:669, ¶¶ 37-39 (Oct. 17, 2013). As a consequence, national law can apply irrespective of the UCP Directive.

[18] Bundesgerichtshof [BGH] [Federal Court of Justice], Nov. 5, 2020, I ZR 234/19, ¶ 25, (Ger.) http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&Datum=2020-11-5&nr=112970&pos=5&anz=8; BGH, I ZR 126/20, *supra* note 13, at ¶ 23, (Ger.) https://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&nr=122158&pos=0&anz=1.

[19] The language of the UCP Directive does not require a "direct *and objective* connection" (emphasis added) but only a direct connection. Art. 2(f) UCP Directive. However, the CJEU seems to require an objective perspective when interpreting the direct connection. *Cf.* RLvS Verlagsgesellschaft mbH, *supra* note 17, at ¶ 44; *See also* Recital 7 UCP Directive. Overall, to the extent the UWG transforms the UCP Directive into national law, the "direct and objective connection" has to be interpreted in accordance with the UCP Directive.

influencer promoting services or goods without receiving any consideration might not constitute a commercial practice.[20]

As in Scenario 1-A, an influencer might promote certain services or goods of another company for consideration. Such promotion might happen by so-called "tap tags," by referring directly to the company's website or by just mentioning the specific company or its brands in general. This act in favor of the company and the influencer herself[21] is directly and objectively connected to the performance of the contract between the advertiser and the influencer[22] as well as to the potential conclusion of a contract between the consumer and the advertiser. The same applies if the influencer receives other consideration instead, such as the product for free in Scenario 1-B.[23] This applies regardless of the value of the product[24] and also in cases where the granted product would only encourage the influencer to publish a post endorsing the product.[25] In general, it does not make a difference whether the influencer has drafted the post herself.[26]

If the influencer does not receive any consideration for promoting the good or service as in Scenario 1-C, a connection between the publishing of the post and the sale of goods or services is less evident.[27] However, depending on the totality of the circumstances, there might still be a connection within the meaning of the

[20] Gesetzentwurf, *supra* note 14, at 31-32. *See* Christian Alexander, *Transparenz beim Influencer-Marketing – BGH-Rechtsprechung und UWG-Neuregelungen* [Transparency in influencer marketing – BGH case law and UWG amendments], 66 Zeitschrift für Urheber- und Medienricht [ZUM] 77, 83 (2022) (criticizing this requirement and implying that the eCommerce-Directive requires already a direct connection). As such promotion of one's own business is covered under the prevailing UCP Directive, the amendment by the German legislature has to be interpreted in accordance with the UCP Directive.

[21] Alexander, *supra* note 20, at 79 (calls this a "Doppelförderung", i.e. a double promotion).

[22] BGH, I ZR 90/20, *supra* note 4, at ¶ 38.

[23] BGH, I ZR 35/21, *supra* note 8, at ¶¶ 43, 60.

[24] *Id.* at ¶¶ 66, 75-76.

[25] *Id.* at ¶ 65. *See also* Bernd Holznagel & Sarah Hartmann, *Teil 3 – Rundfunk und Telemedien, in* Handbuch Multimedia-Recht [Handbook Multimedia Law] ¶ 215 (Thomas Hoeren et al. eds., 57th ed. 2021) (arguing that products granted for free are to be treated the same under § 2(5)(b) TMG as a financial consideration).

[26] Trzaskowski, *supra* note 1, at 96.

[27] *See* Trzaskowski, *supra* note 1, at 96 (arguing in favor of a commercial nature of posts under European Law if a product has been sent to an influencer "without prior interaction").

UWG[28] if the post has a so-called "advertising surplus"[29] in favor of the company selling or manufacturing the promoted product. Enthusiastic praise of the product[30] and including links to the website of the promoted company[31] indicate such an advertising surplus. In Scenario 1-C, positive language in combination with the link and tap tag suffice to establish such an advertising surplus. Accordingly, there is a commercial practice in this scenario.

In Scenario 2, the influencer promotes products she sells on her own website. In such a case, the promotion encourages users to buy the products through her website. Publishing such a post directly and objectively connects to potential contracts between the influencer and customers about the sale of the influencer's products.[32] It constitutes so-called self-advertising (see also § 2(2)(7) MStV),[33] which is covered by § 2(1)(2) UWG.

Particularly interesting to assess is Scenario 3, in where the influencer seems to promote nothing. She just posts an update to keep her followers informed of her life and potentially gain new followers and website visitors. However, the interest of the influencer in getting more followers lead German courts to a different assessment: Each posting aims at generating more followers and thus makes the respective influencer a more promising candidate for future advertising deals with

[28] The UWG goes insofar as in the other scenarios discussed before beyond the scope of the UCP Directive. *Cf.* Deutscher Bundestag: Drucksachen [BT]19/27873 (Ger.), at 34-35; Case C-391/12, RLvS Verlagsgesellschaft mbH, ECLI:EU:C:2013:669, ¶¶ 39-44 (Oct. 17, 2013); BGH, I ZR 126/20, *supra* note 13 at ¶ 52; Alexander, *supra* note 20, at 82.

[29] This is not in conflict with the prevailing (*cf.* also § 1(2) UWG) eCommerce Directive, BGH, I ZR 90/20, *supra* note 4, at ¶ 48, (Ger.); BGH, I ZR 126/20, *supra* note 13, at ¶ 39. *See also* Alexander, *supra* note 20, at 83 (arguing that Art. 3(4) UGP-Directive which stipulates the priority of the eCommerce-Directive does not apply because there is no commercial practice; however, it is important to note that the eCommerce-Directive has still priority over national law in these cases). *See also* Die Medienanstalten [The Media Authorities], Leitfaden der Medienanstalten – Werbekennzeichnung bei Online-Medien [Guideline of the Media Authorities - Advertising Labeling in Online Media] 6 (June, 2021), https://www.die-medienanstalten.de/fileadmin/user_upload/die_medienanstalten/Service/Merkblaetter_Leitfaeden/ua_Leitfaden_Medienanstalten_Werbekennzeichnung_Online-Medien.pdf.

[30] BGH, I ZR 90/20, *supra* note 4, at ¶ 61.

[31] *Id.* at ¶ 67.

[32] Within the meaning of both the UWG and UCP Directive, Ducato, *supra* note 5, at 241.

[33] Martin Gerecke, *Kennzeichnung von werblichen Beiträgen im Online-Marketing* [Labeling of promotional contributions in online marketing], 120 GRUR 153, 155-56 (2018).

companies. [34] Accordingly, every posting is somehow connected to future contracts about goods and services in connection with the promotion of products by the influencer. While the post is objectively in connection with such later contracts, it requires several (uncertain) steps from publishing the post to obtaining such contracts (e.g., a non-endorsement post shared and liked by followers; connections of the followers see such post and might decide to follow the influencer; the influencer is in a better position for advertising deals; an advertising deal is concluded; an advertising post promotes a particular product available for sale to consumers) and therefore they are not *directly* promoted within the meaning of § 2(1)(2) UWG, Art. 2(f) UCP Directive.[35] Such assessment of this scenario is also in accordance with the intent of the German legislature as elaborated above. Even if publishing such a post would be considered a commercial practice contrary to the view taken here,[36] the commercial intent would be apparent and therefore no disclosure would be required.[37]

To sum up, only Scenarios 1-A to -C and Scenario 2 meet the first prong (§ 2(1)(2) UWG).

[34] *Cf.* BGH, I ZR 90/20, *supra* note 9, at ¶ 42 (with further references); LG München I [Munich Regional Court I], Apr. 29, 2019, 4 HK O 14312/18, Cathy Hummels, ¶¶ 39-40, https://www.gesetze-bayern.de/Content/Document/Y-300-Z-BECKRS-B-2019-N-7496?hl=true. Keine unzulässige Schleichwerbung in Posts von Influencern durch Verlinkung, Apr. 29, 2019 GBVl. Munich.

[35] *Cf.* Eur. Comm'n, Guidance on the Implementation of Directive 2005/29/EC on Unfair Commercial Practices 2.2 (May 25, 2016), https://www.gesetze-bayern.de/Content/Document/Y-300-Z-BECKRS-B-2019-N-7496?hl=true (emphasizing that a commercial practice must be directly linked to the promotion of a product to fall under the UCP Directive). *Contra* Alexander, *supra* note 20, at 83; Stefanie Will, *Werbung durch Influencer* [Advertisements by influencers], 85 Archiv für Medienrecht und Medienwissenschaft [UFITA] 137, 154-56 (2021) (Ger.) (criticizing the amendments in § 2 UWG by the legislature).

[36] Including "commercial communication" (Art. 2(f) eCommerce-Directive) as the pendant for a commercial practice under the eCommerce-Directive (and the TMG). *See also* BGH, I ZR 126/20, *supra* note 13, at ¶ 104, https://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&Datum=2021-9&Seite=7&nr=122158&pos=236&anz=283 (ruling that §§ 6(1)(1) TMG, 22(1)(1) MStV do not require a consideration in case of self-advertising); Gesetzentwurf [Bill], Deutscher Bundestag: Drucksachen [BT] 19/18789, at 34 (Ger.) (legislature's reasoning on amending § 2(1)(5)(b) TMG).

[37] *See* BGH, I ZR 125/20, *supra* note 11, at ¶¶ 37-39 (referring to a large sum of followers, verification of a profile, and professional pictures making the intent of the influencer to act in favor of its own business apparent); BGH, I ZR 126/20, *supra* note 13 at ¶¶ 69-74 (emphasizing in particular the knowledge of Instagram users about the business practices of influencers).

2. *Disclosure Obligations According to § 6(1)(1) TMG, § 22(1)(1) MStV, and the UWG*

In the second step, every commercial practice must comply with the requirements of the UWG and through § 3a UWG with provisions such as § 6(1)(1) TMG, § 22(1)(1) MStV. Generally, disclosure of the commerciality of a practice is not required if consumers are able to identify the commerciality "clearly and unambiguously at first sight".[38] The law distinguishes between the different commercial purposes by referring to "*the* commercial purpose" (emphasis added) in § 5a(4) UWG (e.g., whether in favor of one's own or another's company and whether the influencer receives a consideration).[39] However, Art. 7 UCP Directive—partly the basis for § 5a UWG—covers the omission of other material information as well. It could cover the non-disclosure of a material connection (as under U.S. law).[40]

In Scenarios 1-A and 1-B, there are no clear and visible indicators whatsoever for the commerciality of the practice in favor of the advertising company. An obligation to disclose the commerciality of the practice follows from § 5a(4)(1) UWG,[41] § 6(1)(1) TMG, and § 22(1)(1) MStV. The mere reference to a company via "@"-reference is likely insufficient.[42] The influencer could fulfill the disclosure obligation, for example, by including "paid product ad:"[43] at the beginning of the post.[44] A similar hashtag might also suffice[45] when it is not "hidden" among several other hashtags[46] and does not require a further click to be displayed. However, with regard to a tagged product, a disclosure within the picture's description is sufficient only if the disclosure is clearly referring to the tap tag and is sufficiently

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[38] BGH, I ZR 125/20, *supra* note 11, at ¶ 34.

[39] BGH, I ZR 90/20, *supra* note 4, at ¶¶ 54, 92; Radtke & Camen, *supra* note 9, at ¶ 22.

[40] Trzaskowski, *supra* note 1, at 97.

[41] *See generally* BGH, I ZR 90/20, *supra* note 4, at ¶¶ 74-77 (explaining the different views by scholars on whether the "commercial communication" purpose in § 5a(4) UWG requires more than the "commercial practice" under § 2(1)(2) UWG).

[42] *See also* Ducato, *supra* note 5, at 244.

[43] Radtke & Camen, *supra* note 9, ¶ 27 (arguing that "ad" might also be used in a German post as it is understood by German users of social networks).

[44] *E.g.*, Die Medienanstalten, *supra* note 30, at 3. *See also* Riefa & Clausen, *supra* note 1, at 69-71 (overview of what is considered sufficient in different EU member states).

[45] *But see* Riefa & Clausen, *supra* note 1, at 69-70.

[46] *See* Oberlandesgericht Celle [OLG Celle] [Higher Regional Court of Celle] June 8, 2017, 13 U 53/17, ¶¶ 11-12 (Ger.).

highlighted (e.g., special print of the letters or separate paragraph).[47] Scenario 1-B is a good example of how there might be several ways of disclosing commerciality. The influencer could include language in the first sentence of the post (e.g., "*Thanks to Y for providing the product X*"). In some cases, a post with a similar contractual background as in Scenarios 1-A and 1-B might constitute editorial content and might thus be prohibited as a deceptive advertorial under the stricter § 3(3) UWG in connection with Annex no. 11 of the UWG.[48]

With regard to Scenario 1-C, the TMG does explicitly consider the post non-commercial. The obligation under § 6(1)(1) TMG (and the e-Commerce Directive) is based on the term "commercial communication." This term is defined in § 2(1)(5) TMG, Art. 2(f) e-Commerce Directive and explicitly exempts "communications relating to the goods, services or image of the company, organisation or person compiled in an independent manner, particularly when this is without financial consideration." Such posts as in Scenario 1-C are still compiled independently, even though they are different from the typical case this provision should cover, i.e., independent tests by third parties.[49] Similarly, the MStV considers such posts not to be advertisements.[50] Pursuant to § 2(2)(7) MStV, advertisements in favor of another company require a consideration. Nevertheless, the more specific provision in § 5a(4) UWG as amended recently applies.[51] In general, a commercial intent has to be disclosed if the non-disclosure is likely to cause the average consumer to take a transactional decision that he would not have taken

[47] *See* BGH, I ZR 90/20, *supra* note 4, at ¶ 85.

[48] *Cf.* Helmut Köhler, *Anhang zu § 3 III* [*Annex to § 3 III*], *in* UWG, ¶ 11.2 (Helmut Köhler et al. eds., 40th ed. 2022). *See also* Trzaskowski, *supra* note 1 (discussing this in detail, including the implications on the applicability of the UCP Directive in general in such cases); Case C-391/12, RLvS Verlagsgesellschaft mbH v. Stuttgarter Wochenblatt GmbH, ECLI:EU:C:2013:669, ¶¶ 37-39 (Oct. 17, 2013) (discussing the trader requirements for the applicability of the UCP Directive). However, the requirement of "paid" content is interpreted broadly and includes benefits such as providing the product for free, Case C-371/20, Peek & Cloppenburg v. Peek Cloppenburg KG, ECLI:EU:C:2021:674, ¶ 42 (Sept. 2, 2021); *Cf.* Helmut Köhler, *Anhang zu § 3 III* [*Annex to § 3 III*] *in* UWG, ¶ 11.2 (Helmut Köhler et al. eds., 40th ed. 2022).

[49] Mario Martini, *§ 2 TMG, in* BeckOK Informations- und Medienrecht [BeckOK Information and Media Law], ¶ 29 (Hubertus Gersdorf Boris P. Paal eds., 34th ed. 2021).

[50] Nevertheless, surreptitious advertising under § 2(2)(9) MStV could be considered; *cf.* Gerecke, *supra* note 33, at 155. However, this likely applies only to broadcasting.

[51] *Cf.* BGH, I ZR 90/20, *supra* note 4 at ¶ 48 (discussing the priority of the TMG and MStV over the UWG); BGH, I ZR 126/20, *supra* note 13 at ¶¶ 75, 86-87. *See also* Will, *supra* note 35, at 156-59 (criticizing the amendments in § 5a UWG made by the legislature).

otherwise.[52] However, the provision requires no disclosure of a commercial intent if the influencer did not receive any consideration,[53] but imposes the burden of proof of the absence of a consideration on the influencer.[54] In Scenario 1-C, as the influencer can demonstrate that she did not receive any consideration, no disclosure of commerciality is required.

For a self-advertisement as in Scenario 2, all obligations under § 22(1)(1) MStV, § 6(1)(1) TMG, and § 5a(4)(1) UWG apply. Even the stricter § 3(3) UWG in connection with Annex no. 22 might be considered as it could be argued that the influencer is creating the impression that she is not "acting for purposes relating to [her] trade, business, craft or profession," or is falsely representing herself as a consumer.[55] Accordingly, a disclosure is required. The influencer could easily include the information that the product is her own product (e.g., "For a perfect start to the day, *try my new product*") to satisfy the disclosure requirement.

3. Obligations for Advertisers

Advertisers are in any case liable for violations of the disclosure requirements if they commission influencers to publish an advertising post.[56] The UWG itself does not explicitly provide for measures to avoid liability. Brtka and Witzmann recommend that advertisers contractually oblige "their" influencers to comply with the disclosure requirements, train them and implement a system to monitor their posts.[57]

III
The U.S. Approach

Second, this article analyzes the U.S. approach based upon the FTC Act and the agency's subsequent enforcement of the Act.

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[52] § 5a(4)(1) UWG.

[53] § 5a(4)(2) UWG.

[54] § 5a(4)(3) UWG.

[55] Riefa & Clausen, *supra* note 1, at 66.

[56] § 8(2) UWG; BGH, Oct. 7, 2009, I ZR 109/06, ¶¶ 22, 25 (Ger.); Hans-Wolfgang Micklitz Martin Schirmbacher, *§ 6 TMG, in* Recht der Elektronischen Medien [Law of Electronic Media], ¶ 52 (Gerald Spindler & Fabian Schuster eds., 4th ed. 2019); Roman Brtka & Markus Witzmann, *Der Einsatz von Influencer-Marketing in Social Media* [The use of influencer marketing in social media], 13 GRUR-PRAX 657, 660 (2021); Gerecke, *supra* note 33, at 159.

[57] Brtka Witzmann, *supra* note 56, at 660. *See also* Jens Matthes, *Comment on BGH, Oct. 7, 2009, I ZR 109/06*, 111 GRUR 1167, 1172 (2009).

A. Background

The enforcement of rules for unfair advertising practices is within the purview of the FTC as a(n) (independent)[58] federal agency. The FTC's "Guides Concerning the Use of Endorsements and Testimonials in Advertising" (16 CFR Part 255) (Endorsement Guides) are thus highly indicative of what the FTC might consider a deceptive or unfair advertising practice. Under Sections 5(a) and 12 of the FTC Act (15 U.S.C. §§ 45(a), 52), the FTC is empowered to prevent persons and corporations, such as advertisers and endorsers, from "unfair or deceptive acts or practices in or affecting commerce," which include the dissemination of false advertisements.[59]

Actors other than the FTC generally have no standing under federal law. Neither the FTC Act itself nor the Endorsement Guides grant individuals standing.[60] While violations of the FTC Act might also be actionable under § 43(a) of the Lanham Act,[61] extensive affirmative disclosure requirements cannot be established under this section of the Lanham Act in general,[62] notwithstanding any applicable state law.[63] This article will focus on the FTC Act. In recent years, the FTC published announcements and documents informing and reminding

[58] *See, e.g.*, Richard W. Murphy, *The DIY Unitary Executive*, 63 Ariz. L. Rev. 439 (2021) (discussing the current unitary executive debate).

[59] *See also* Tamany Vinson Bentz & Carolina Veltri, *The Indirect Regulation of Influencer Advertising*, 75 Food & Drug L.J. 185, 192 (2020) (discussing First Amendment protection of influencers).

[60] *E.g., Carlson v. Coca-Cola Co.*, 483 F.2d 279, 280 (9th Cir. 1973); *Naylor v. Case McGrath, Inc.*, 585 F.2d 557, 561 (2d Cir. 1978); Broadspring, Inc. v. Congoo, LLC, No. 13-CV-1866 (JMF), 2014 U.S. Dist. LEXIS 116070, at *36 (S.D.N.Y. Aug. 20, 2014); *Lokai Holdings, LLC v. Twin Tiger USA, LLC*, 306 F. Supp. 3d 629, 639 (S.D.N.Y. 2018). *But see*, Bentz & Veltri, *supra* note 59, at 193 (discussing several cases in which violations of the FTC Act have been considered, but which settled in the end).

[61] *E.g., Manning Int'l Inc. v. Home Shopping Network, Inc.*, 152 F. Supp. 2d 432, 437 (S.D.N.Y. 2001).

[62] *McNeilab, Inc. v. Am. Home Prods. Corp.*, 501 F. Supp. 517, 532 (S.D.N.Y. 1980); *Lokai Holdings, LLC v. Twin Tiger USA, LLC*, 306 F. Supp. 3d 629, 640 (S.D.N.Y. 2018). *Cf.* Clark Consulting, Inc. v. Fin. Sols. Partners, LLC., 05 Civ. 06296 (SAS),2005 U.S. Dist. LEXIS 28642, at *23 (S.D.N.Y. Nov. 17, 2005).

[63] *Cf.* Bentz & Veltri, *supra* note 59, at 194 (discussing several cases under state law in which influencers have not been held liable).

influencers about disclosure requirements.[64] The FTC's focus lies in preventing deceptive commercial practices and ensuring fair competition.[65]

B. Non-disclosure as Deceptive Practice

The starting point for any action by the FTC is either an unfair advertisement, which will be considered an unfair or deceptive practice,[66] or an otherwise unfair or deceptive practice.[67] The standard for establishing an unfair practice is found in 15 U.S.C. § 45(n), which requires deceptive practices be "[1] a representation, omission, or practice, that [2] is likely to mislead consumers acting reasonably under the circumstances, and [3], [that] the representation, omission, or practice is material."[68] The FTC often bases its actions on 15 U.S.C. §§ 45(a), 52 and considers the non-disclosure of material facts of an endorsement a deceptive practice.[69] The Endorsement Guides as well as the FTC's reasoning in previous cases (most often in the form of consent orders) provide helpful guidance for what is considered a deceptive practice.

1. Endorsement

The Endorsement Guides define an endorsement as "any advertising message [...] that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser, even if the views expressed by that party are identical to those of the sponsoring advertiser."[70]

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[64] Press Release, Fed. Trade Comm'n, FTC Staff Reminds Influencers and Brands to Clearly Disclose Relationship (Apr. 19, 2017), https://www.ftc.gov/news-events/press-releases/2017/04/ftc-staff-reminds-influencers-brands-clearly-disclose; Press Release, Fed. Trade Comm'n, FTC Releases Advertising Disclosures Guidance for Online Influencers (Nov. 5, 2019), https://www.ftc.gov/news-events/press-releases/2019/11/ftc-releases-advertising-disclosures-guidance-online-influencers. *See also* Bentz & Veltri, *supra* note 59, at 187-88.

[65] *Cf.* 15 U.S.C. § 45(a)(1).

[66] 15 U.S.C. § 52.

[67] 15 U.S.C. § 45(a).

[68] *Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 165 (1984); *FTC v. Verity Int'l, Ltd.*, 443 F.3d 48, 63 (2d Cir. 2006); *FTC v. LeadClick Media, LLC*, 838 F.3d 158, 168 (2d Cir. 2016) (numbers in brackets as cited by the court).

[69] *E.g.*, Complaint ¶¶ 47-48, FTC v. Genesis Today, Inc., Case No. 1:15-cv-62 (W.D. Tex. Jan. 26, 2015), https://www.ftc.gov/system/files/documents/cases/150126lindduncmpt.pdf. *See also*, Fed. Trade Comm'n, The FTC's Endorsement Guides: What People are Asking (2017) [hereinafter *Endorsement FAQ]* https://www.ftc.gov/tips-advice/business-center/guidance/ftcs-endorsement-guides-what-people-are-asking (under "What is the legal basis for the Guides?").

[70] 16 CFR § 255.0(b).

There is a strong focus on the honesty of *opinions*[71] rather than on the honest disclosure of *commercial intent* as under German law.[72] In addition, the provisions require there to be a "sponsoring advertiser."[73]

With that in mind, we first consider Scenario 1-A, in which the influencer is paid by a sponsoring advertiser for her social media post which promotes the product and does not disclose this fact. The consumers may likely believe that it is the influencer's unbiased opinion she expresses in her social media post even though such expressions may actually be influenced by the advertiser's payment. Such promotion might be carried out by referring to the brand in a description, in the picture or by using a tap tag.[74] In sum, there would be an endorsement in this scenario.[75]

In Scenario 1-B, the influencer receives the product for free from the sponsoring advertiser. Because of this consideration, her post meets the requirements of an advertising message and is also an endorsement.[76] When the product received is cheap, it is debatable whether influencers are still obliged to disclose this information. However, the fact that the influencer received a gift at all may be information whose omission is likely to mislead consumers.[77] Accordingly, the FTC recommends disclosing the receipt of even very small gifts or non-financial benefits in most circumstances.[78]

If, as in Scenario 1-C, the influencer is genuinely convinced of the product and writes a positive review without receiving any consideration from the advertiser,

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[71] Cf. 16 CFR § 255.1.

[72] *See supra* text in Section II.B.1.

[73] *See also, Endorsement FAQ, supra* note 69 ("The FTC Act covers only endorsements made on behalf of a sponsoring advertiser.").

[74] *Cf.* Complaint ¶ 5, Lord Taylor, LLC, FTC Docket No. C-4576, (May 23, 2016), https://www.ftc.gov/system/files/documents/cases/160523lordtaylorcmpt.pdf.

[75] *Cf. Lokai Holdings, LLC v. Twin Tiger USA, LLC*, 306 F. Supp. 3d 629, 639 (S.D.N.Y. 2018).

[76] *See also* third paragraph of Example 8 under 16 CFR § 255.0. *Cf.* Complaint ¶ 7, Lord Taylor, LLC, FTC Docket No. C-4576, (May 23, 2016). *See also* Complaint at 19, FTC v. Nobetes Corp., Case No. 2:18-cv-10068 (C.D. Cal. Dec. 3, 2018), https://www.ftc.gov/system/files/documents/cases/172_3119_nobetes_complaint.pdf.

[77] *Cf.* § 255.5 (Endorsement Guides).

[78] *Cf. Endorsement FAQ, supra* note 69 (under "When Does the FTC Act Apply to Endorsements?"; under "Do I need to list the details of everything I get from a company for reviewing the product?").

there is no *sponsoring* advertiser.[79] In this scenario, there is no endorsement, and accordingly, no related disclosure obligation.[80] This is significantly different from German law, under which extremely positive advertising messages may be seen as a commercial practice.[81]

The promotion of products sold by the influencer herself, as in Scenario 2, again conveys an advertising message. Depending on the circumstances, consumers might believe this reflects the opinions of the influencer as a consumer rather than as an advertiser. However, this implies that the endorsing party and the sponsoring advertiser can be the same party in different roles under the language of the Endorsement Guides. While this is not entirely clear under the Endorsement Guides, even though the FTC FAQ seems to suggest this,[82] non-disclosure might be deceptive under the three criteria described above when the consumers are likely to believe that the influencer is endorsing the products of another company.[83] For example, in the complaint of *FTC v. Genesis Today, Inc.*, the FTC highlighted the financial interest of an endorser who endorsed the products of a company which the endorser controlled.[84]

While there has been a discussion under German law about whether every post of a commercial influencer's account has *per se* commercial character,[85] the FTC will likely not consider such posts as in Scenario 3 to be endorsements. As in Scenario 2, there are doubts as to whether there is actually a sponsoring advertiser in this case. Furthermore, the post does not directly convey an advertising message, but rather contains opinions about the life and lifestyle of the influencer (instead of opinions about the influencer's account itself) which might convince users

[79] *See also* Example 8 under 16 CFR § 255.0(e); *Endorsement FAQ, supra* note 69 (from "Isn't it common knowledge [. . .]").

[80] *See also, Kramer v. Unitas*, 831 F.2d 994, 998 (11th Cir. 1987) (stating if one "merely introduced the company" this would not be considered as endorsement in context of common law fraud claims).

[81] *See supra* text in Section II.B.1.

[82] *Endorsement FAQ, supra* note 69 ("[. . .] you could simply say you were 'paid.' (That wouldn't be good enough, however, if you're an employee or co-owner.) [. . .]," emphasis added and quotation marks adapted).

[83] *Cf.* Complaint at 12, FTC v. Aura Labs, Case No. 8:16-cv-2147 (C.D. Cal. Dec. 2, 2016), https://www.ftc.gov/system/files/documents/cases/161212_aura_labs_complaint.pdf (discussing employees who did not disclose their material connections to their endorsed employer).

[84] Complaint ¶¶ 41-45, FTC v. Genesis Today, Inc., (W.D. Tex. Jan. 26, 2015), https://www.ftc.gov/system/files/documents/cases/150126lindduncmpt.pdf.

[85] *See supra* text in Section III.B.1.

to follow her.[86] The Endorsement Guides cover similar fact patterns but do not require disclosure in such scenarios; accordingly, the FTC will likely consider such practice as not deceptive. Thus, FTC requirements may be more straightforward and intuitive for influencers than requirements under German and EU law.

2. Disclosure

Scenarios 1-A and 1-B both feature endorsements and thus must be in compliance with the requirements of the Guides. For Scenario 2, similar disclosure requirements apply.

The Endorsement Guides require that endorsements "reflect the honest opinions [. . .] of the endorser."[87] Thus, "when the advertisement represents that the endorser uses the endorsed product, the endorser must have been a *bona fide* user."[88] Along with further requirements, material connections "between the endorser and the seller of the advertised product [. . .] must be fully disclosed."[89] In its FAQ, the FTC clarifies the disclosure requirement: the influencer does not need to disclose the exact amount of the consideration.[90] However, when the consideration consists of two elements, e.g., early access to a video game and additional payments, the substantial (monetary) compensation must be disclosed.[91]

The FTC recommends clear language such as "Company X gave me this product to try," "Ad," or "#ad."[92] Just referring to the advertiser with an "@" reference is not sufficient.[93] The influencer should position the language such that it is easy for users to notice the disclosure information.[94] For example, placing the

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[86] *See also, Endorsement FAQ, supra* note 69 (from "No. Some bloggers who mention products in their post [. . .]").

[87] § 255.1(a).

[88] § 255.1(c).

[89] § 255.5.

[90] *Endorsement FAQ, supra* note 69 (from "Do I need to list the details of everything I get [. . .]").

[91] *Cf.* Complaint ¶ 11, Warner Bros. Home Ent. Inc., FTC Docket No. C-4595 (Nov. 17, 2016), https://www.ftc.gov/system/files/documents/cases/161811warner_bros_complaint.pdf.

[92] *Endorsement FAQ, supra* note 69.

[93] *See, e.g.*, Complaint at 10-12, FTC v. Teami, LLC, Case No. 8:20-cv-518 (M.D. Fla. Mar. 5, 2020), https://www.ftc.gov/system/files/documents/cases/complaint_4.pdf; Complaint, Lord & Taylor, LLC, FTC Docket No. C-4576, (May 23, 2016); Complaint ¶ 14, Creaxion Corp., FTC Docket No. C-4668, (Feb. 8, 2019), https://www.ftc.gov/system/files/documents/cases/c-4668_172_3066_creaxion_complaint_cre-ip_compl_new_lineup_9-26-18.pdf.

[94] *Endorsement FAQ, supra* note 69.

language before the "more" link on Instagram,[95] not hiding the language in a long video description[96] and not placing it as a hashtag among several other hashtags.[97]

Accordingly, in Scenario 1-A, a description starting with "Ad:" or an easily visible "#ad" might suffice. In Scenario 1-B, the language might be included in the sentence (e.g., "*Thanks to Y for providing the product* – For my good start into the day #health #powerfood #fitness"). In Scenario 2, it might look like "*Check out my product X for a* good start into the day #health #powerfood #fitness." These requirements are in essence similar to those under German law, e.g., with respect to the clear visibility of the disclosure notice. However, German law requires a more specific disclosure of the commercial context.

Unlike the requirements under German law, there is no explicit exception to a disclosure when a material connection or paid consideration is evident from the circumstances. However, in such cases the fact has been arguably "disclosed" within the meaning of § 255.5.

3. Obligations for Advertisers

According to § 255.1(d) Endorsement Guides, "advertisers are subject to liability for false or unsubstantiated statements made through endorsements." The importance of this provision can be demonstrated by several cases. In *Lokai Holdings, LLC v. Twin Tiger USA, Inc.*, the plaintiff sued the *advertiser* for the influencers' endorsements.[98] In *FTC v. Teami, LLC*, the FTC pursued an injunction and equitable relief against the seller of an endorsed product when endorsers failed to sufficiently disclose the material connection.[99] In several other cases, advertisers have been targeted rather than influencers themselves when advertisers failed to sufficiently oblige influencers to disclose the material connection.[100] In *CSGOLotto, Inc.*, the parties agreed that the respondents have to implement a

[95] Complaint ¶ 16, FTC v. Teami, LLC, Case No. 8:20-cv-518 (M.D. Fla. Mar. 5, 2020), https://www.ftc.gov/system/files/documents/cases/complaint_4.pdf.

[96] Complaint ¶ 8-9, Warner Bros. Home Ent. Inc., FTC Docket No. C-4595, (Nov.17, 2016), https://www.ftc.gov/system/files/documents/cases/161811warner_bros_complaint.pdf.

[97] *Endorsement FAQ, supra* note 69.

[98] *Lokai Holdings, LLC v. Twin Tiger USA, LLC*, 306 F. Supp. 3d 629, 639-40 (S.D.N.Y. 2018).

[99] *E.g.*, Complaint at 10-12, FTC v. Teami, LLC, Case No. 8:20-cv-518 (M.D. Fla. Mar. 5, 2020), https://www.ftc.gov/system/files/documents/cases/complaint_4.pdf.

[100] *E.g.*, Complaint, Lord & Taylor, LLC, FTC Docket No. C-4576 (May 23, 2016), https://www.ftc.gov/system/files/documents/cases/160523lordtaylorcmpt.pdf (Complaint).

monitoring program of endorsers. As in several other cases,[101] the monitoring program includes:

- "Providing each such endorser with a clear statement of his or her responsibilities to disclose clearly and conspicuously, and in close proximity to the endorsement, [. . .] the endorser's unexpected material connection [. . .]";

- "Providing each such endorser with a clear statement of his or her responsibilities to disclose clearly and conspicuously, and in close proximity to the endorsement, [. . .] the endorser's unexpected material connection [. . .]";

- "Establishing, implementing, and thereafter maintaining a system to monitor and review the representations and disclosures of endorsers with material connections [. . .]";

- "Immediately terminating and ceasing payments to any endorser with a material connection" who fails to comply with its obligations (upon notice); and

- "creating reports [. . .]."[102]

Stipulation of a monitoring program demonstrates the important role of the advertiser when it comes to social media campaigns and endorsements. A mere contractual obligation for the influencer to "comply with the FTC guidelines on disclosures [. . .]" without reasonable monitoring is not sufficient.[103]

[101] *E.g.*, Decision and Order, Warner Bros. Home Ent. Inc., FTC Docket No. C-4595 (Nov. 17, 2016), https://www.ftc.gov/system/files/documents/cases/161811_c-4595_warner_bros_do.pdf; Decision and Order at 3-5, Machinima, Inc., FTC Docket No. C-4569 (Mar. 16, 2016), https://www.ftc.gov/system/files/documents/cases/160317machinimado.pdf; Decision and Order at 4-5, Creaxion Corp., FTC Docket No. C-4668 (Jan. 31, 2019), https://www.ftc.gov/system/files/documents/cases/c-4668_172_3066_creaxion_decision_and_order_2-8-19.pdf.

[102] Decision and Order at 4-5, CSGOLotto, Inc., FTC Docket No. C-4632 (Nov. 28, 2017), https://www.ftc.gov/system/files/documents/cases/1623184_c-_csgolotto_decision_and_order.pdf.

[103] *Cf.* Complaint ¶ 9, Legacy Learning Sys., Inc., FTC Docket No. C-4323, (June 10, 2011), https://www.ftc.gov/sites/default/files/documents/cases/2011/06/110610legacylearningcmpt.pdf.

The FTC's focus on advertisers is not unusual among government agencies. For example, the Food and Drug Administration (FDA) also has a particular focus on marketers when reviewing drug advertisements.[104]

Conclusion and Final Comparison of Both Approaches

The juxtaposition of the two approaches not only highlights the actual disclosure obligations in both countries, but also illuminates the relative advantages and disadvantages of enforcement either by a public authority or by competitors, and organizations.

A. Requirements for Influencer Marketing

When comparing the actual provisions across the different scenarios, there appear to be more similarities between U.S. and German law than differences. This is so even though German law focuses primarily on the disclosure of a commercial intent, while U.S. law concentrates on the disclosure of material connections. However, under German law, a material connection might indicate a commercial intent. Accordingly, German law has a broader scope, which explains why Scenarios 1-C and 3 may be assessed differently and require alternative reasoning than under U.S. law.

In Scenarios 1-A, 1-B and Scenario 2, both U.S. law and German law require the disclosure of material connections or of a commercial intent, respectively. For Scenario 1-B, there is no requirement of a minimum value of the product, but this might be relevant under U.S. Law. For Scenario 1-C, German law explicitly imposes the burden of proving no receipt of consideration on the influencer. Under U.S. law, influencers and advertising companies might be in any case required to provide certain information when the FTC requests it during an investigation. For Scenario 3, the details of how to assess this issue under German law are still not entirely clear and continue to be discussed by scholars. However, the result seems to be clear: in most scenarios, no disclosure is required. This is in line with the requirements under U.S. Law.

Disclosure requirements in both Germany and the U.S. are quite similar, e.g., regarding the wording of the disclosure notice and the position of such wording. The Endorsement Guides by the FTC are a helpful and concrete guideline lacking

[104] *Cf.* Bentz & Veltri, *supra* note 59, at 190.

a *sufficient* counterpart in Germany.[105] German law clearly requires a disclosure of the concrete advertising purpose and may be considered stricter when it comes to highlighting disclosure information within a post's description. A post which complies with U.S. law accordingly may require some modifications to comply with German law.

B. Enforcement by Private Parties Compared to Enforcement by a Public Authority

While the FTC is the primary enforcer of U.S. federal law regarding influencer marketing, the main[106] actors under German law are private parties.[107] Under German law, public media authorities may also enforce specific obligations. Additionally, the Consumer Protection Cooperation Regulation (EU) 2017/2394 provides for enforcement of intra-Union and widespread violations of consumer protection regulation including endorsement disclosure obligations by public authorities. The German approach is increasingly more of a hybrid.[108]

In the U.S., the FTC enforces the applicable law mostly against bigger companies and other relevant players – instead of the influencer themselves.[109] This means less enforcement in a quantitative sense, but not necessarily in a qualitative sense. The enforcement against advertisers might be more effective by covering practices conducted by several influencers at the same time.[110] Furthermore, the high number of settlements may effectively encourage respondents and other parties to comply with the requirements. The FTC is in a solid position to control its enforcement practice and focus on the most "important" cases. Nevertheless, it *has*

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[105] *See* Die Medienanstalten, *supra* note 29.

[106] *See, e.g.*, Boerman et al., *supra* note 5, ¶ 4 (discussing self-regulation in Europe and the U.S.); International Consumer Protection and Enforcement Network, Online Reviews Endorsements – ICPEN Guidelines for Digital Influencers (June 2016), https://icpen.org/sites/default/files/2017-06/ICPEN-ORE-Guidelines%20for%20Digital%20Influencers-JUN2016.pdf.

[107] *See* Leonid Guggenberger & Tristan Radtke, *Die Missbräuchlichkeitskontrolle von Unterlassungsansprüchen – Rechtsdurchsetzung unerwünscht?* [*The Abuse of Rights Control of Injunctive Relief – Legal Enforcement Undesirable?*], 77 Juristenzeitung [JZ] 338 (2022) (Ger.) (discussing advantages of different types of enforcement and criticizing the current German system of private law enforcement under the UWG).

[108] *See* European Commission, *supra* note 1, at 53 (emphasizing the advantages of combining different remedies).

[109] *See* Bentz & Veltri, *supra* note 59, at 187.

[110] Bentz & Veltri, *supra* note 59, at 189.

to focus on such important cases to make most effective use of its limited financial and personnel resources. In addition, it provides comparably well-designed guidelines that give influencers, and advertising companies, comprehensible materials to help them satisfy the legal requirements.[111]

In Germany, the competitors and competent organizations are free to enforce almost any violation which affects them.[112] This mostly covers, but is not limited to, economically relevant violations. Anyone can be subject to the claims of competitors and competent organizations, including influencers and small or big companies. While the FTC focuses particularly on advertisers, in Germany, often (and many) influencers are sued instead of the advertising companies. There have been at least eleven German district court cases[113] and probably many more settlements. As a consequence, it would seem the German influencer community has been sensitized rapidly. The applicable law is relatively concrete compared to U.S. law, yet there are no comparably comprehensive guidelines. Instead, influencers and advertising companies have to rely on the law as interpreted and concretized by the courts. This system may encourage parties other than large corporations to comply with requirements but may at the same time make compliance more difficult.

Overall, under both German and U.S. systems, influencer marketing and disclosure obligations have been addressed and "solved" in some way. Both approaches provide guidelines clarifying the obligations of influencers and advertisers over time. One could say that both approaches passed the challenge posed by this developing area of law, but in different ways.

[111] Take the extensive FAQ on exact disclosure requirements as one example and the guidance on monitoring programs by advertisers as another example.

[112] *See, e.g.*, Ducato, *supra* note 5, at 252 (emphasizing the high number of influencer cases registered by German courts).

[113] *Cf.* Radtke & Camen, *supra* note 9, ¶¶ 7-9.

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I WANT MY NFT!: HOW AN NFT CREATIVE COMMONS PARALLEL WOULD PROMOTE NFT VIABILITY AND DECREASE TRANSACTION COSTS IN NFT SALES

MOLLY MARIAS*

Non-fungible tokens ("NFTs") have ushered in a novel era of creative expression and ownership, but with their introduction comes an array of unprecedented legal issues. Neither traditional copyright nor property law conforms to NFT creator or purchaser expectations, and these conflicting expectations hamper the efficiency of NFT sales. Authors of original works may be unprotected from purchasers subsequently minting NFTs from those original works, and NFT purchasers will often be without remedy should an NFT creator mint multiple, substantially similar NFTs from the same underlying asset. NFT purchasers face an additional information hurdle that hampers their ability to negotiate efficiently. Namely, contrary to most mainstream media coverage, NFT ownership does not correlate to a proprietary interest in the NFT's underlying asset. Smart contracts are often touted as the preeminent solution to this efficiency quandary, but they do little to lower the transaction costs associated with the information asymmetry between NFT creator and purchaser. Further, while smart contracts are an efficient mechanism to implement the NFT's terms of sale, they are ill-equipped to equalize an unbalanced negotiating process.

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An NFT Creative Commons parallel ("NFT CC") is the solution to these issues. With an NFT CC, creators would be able to affix established NFT CC licenses to their NFTs, pre-sale. These licenses would define, and readily convey, the NFT creator's and purchaser's legal rights in the NFT and its underlying asset and would allow for a more informed and efficient negotiating process. The licenses could range from full copyright transfer, to no copyright transfer, to more moderate "reciprocal ongoing licensing transfers" ("ROLTs"), which would enable NFT creators and purchasers to share ongoing copyright interests in the NFT. The NFT CC licenses' transparency would fundamentally lower NFT transaction costs by remedying the negotiating parties' information asymmetry. Injecting clarity and predictability into NFT transactions would not only augment the NFT market but would also protect NFTs' viability as an emerging asset class worthy of investment in the long term.

INTRODUCTION

On March 10, 2021, Christie's sold the digital artist Beeple's collection of Non-fungible tokens ("NFTs"), "Everydays—The First 5000 Days," at auction for $69.3 million, in what critics dubbed a "historical inflection point" for the

art world.[1] Two months later, an NFT of the infamous viral video "Charlie Bit My Finger" sold for over $700,000.[2] Paris Hilton collaborated with the artist Blake Kathryn on a collection of NFTs, which sold for more than $1.1 million,[3] and she recently backed an NFT nonprofit worth $300 million.[4] Even Martha Stewart joined the cryptocurrency art space, minting NFTs from images of iconic Halloween costumes and selling them on her e-commerce site.[5] For better or worse, NFTs went from "cult to culture in 2021," and their stark rise in prominence makes defining the NFT legal space imperative in order to maintain long-term NFT viability.[6]

NFTs have ushered in a novel era of creative expression and ownership, but with their introduction comes an array of unprecedented legal issues.[7] Neither traditional copyright nor property law conforms to NFT creator or purchaser expectations, and these conflicting expectations hamper NFT sales' efficiency.[8] On the one hand, an author may be unprotected if a purchaser mints an NFT from the author's original work and subsequently sells it.[9]On the other hand, a purchaser may be disadvantaged and without remedy if they are unclear about the scope of

[1] Scott Reyburn, *JPG File Sells for $69 Million, as 'NFT Mania' Gathers Pace*, N.Y. Times (Mar. 25, 2021), https://www.nytimes.com/2021/03/11/arts/design/nft-auction-christies-beeple.html.

[2] Christina Morales, *'Charlie Bit My Finger' Is Leaving YouTube After $760,999 NFT Sale*, N.Y. Times (May 30, 2021), https://www.nytimes.com/2021/05/24/arts/charlie-bit-my-finger-nft-auction.html.

[3] Sarah Cascone, *Here Are the 14 Most Expensive NFTs Sold to Date, From Beeple to Mad Dog Jones and Beyond*, ArtNet (June 21, 2021), https://news.artnet.com/market/updated-most-expensive-nfts-1980942.

[4] Joanna Ossinger, *Paris Hilton and Bill Ackman Back $300 Million NFT Foundation*, Bloomberg (Nov. 23, 2021, 7:00 AM), https://www.bloomberg.com/news/articles/2021-11-23/paris-hilton-and-bill-ackman-back-300-million-nft-foundation.

[5] Nashia Baker, *Martha Launched a Halloween-Inspired Collection of NFTs That You Can Bid on Right Now*, Martha Stewart (Oct. 19, 2021), https://www.marthastewart.com/8170277/martha-stewart-nft-halloween-launch.

[6] Ryan Zurrer, *Why I Spent $29M on a Beeple*, CoinDesk (Jan. 21, 2022, 4:26 PM), https://www.coindesk.com/layer2/culture-week/2021/12/16/why-i-spent-29m-on-a-beeple/.

[7] Gregory J. Chinlund & Kelley S. Gordon, *What are the Copyright Implications of NFTs?*, Reuters (Oct. 29, 2021, 11:41 AM), https://www.reuters.com/legal/transactional/what-are-copyright-implications-nfts-2021-10-29/.

[8] Gary P. Kohn, *Feature: NFTs and The Law*, L.A. Law. 18, 18 (2021); *see generally* Warren J. Samuels, *The Coase Theorem and the Study of Law and Economics*, 14 Nat. Res. J. 1, 6 (1974) (discussing Coase's theorem on the economic significance of market rights, and the impact these market rights have on protected interests and subsequent bargaining efficiency).

[9] Lynne Lewis et al., *Non-Fungible Tokens (NFTs) and Copyright Law*, Bird & Bird (June 2, 2021), https://www.twobirds.com/en/news/articles/2021/australia/non-fungible-tokens-nfts-and-copyright-law.

their NFT ownership rights.[10] Because NFT ownership does not automatically vest the purchaser with a proprietary copyright interest, an NFT creator could mint additional NFTs from the same underlying asset, which may de-value the original purchaser's NFT.[11] This phenomenon runs counter to most mainstream media coverage—which suggests some form of purchaser proprietary interest—so NFT purchasers are often ill-informed, and this hampers their ability to negotiate effectively.[12]

As marketplaces work in real-time to facilitate transactions between NFT creators and purchasers, they are hobbled by information inequities and inefficient transaction infrastructures.[13] Early-stage NFT jurisprudence has coalesced around traditional principles of copyright law in order to establish NFT creator rights, and purchasers occasionally negotiate copyright transfer and licensing rights through private agreements.[14] However, these private contracts, coupled with the tensions between creator rights and purchaser expectations, are inefficient and raise NFT sales' transaction costs.[15] Smart contracts are typically touted as the preeminent solution to this efficiency quandary, but smart contracts between an NFT creator and purchaser are subject to the same asymmetrical information constraints that plague traditional private agreements.[16]Efficient implementation does not equate

[10] *Id.*

[11] *See generally* Mark A. Lemley, *IP in A World Without Scarcity*, 90 N.Y.U. L. Rev. 460, 482 (2015) (discussing traditional economic theory's relationship to scarcity and purchaser incentives, noting IP's role in artificially raising the cost of imitation to make imitation at least as costly as creation, and highlighting the need to protect purchaser investments in a digital age with limitless reproduction potential).

[12] Will Garton & Farah Mukaddam, *NFTs and Intellectual Property Rights*, Norton Rose Fulbright (Oct. 2021), https://www.nortonrosefulbright.com/en/knowledge/publications/1a1abb9f/nfts-and-intellectual-property-rights.

[13] Ali Dhanani & Chris Sabbagh, *How Nonfungible Tokens Could Disrupt the Legal Landscape*, Law360 (Mar. 22, 2021), https://plus.lexis.com/document?crid=d39383e7-199f-441f-9d18-74a4f30f675d&pddocfullpath=%2Fshared%2Fdocument%2Fanalytical-materials%2Furn%3AcontentItem%3A628F-B921-F81W-20BD-00000-00&pdsourcegroupingtype=&pdcontentcomponentid=122100&pdmfid=1530671&pdisurlapi=true.

[14] Lewis et al., *supra* note 9.

[15] Lennart Ante, *Non-Fungible Token (NFT) Markets on the Ethereum Blockchain: Temporal Development, Cointegration and Interrelations* 22 (Blockchain Research Lab Working Paper Series No. 22, 2021).

[16] Ling W. Cong & Zhiguo He, *Blockchain Disruption and Smart Contracts, available at* https://ssrn.com/abstract=2985764 (noting that while automatically self-executing smart contracts are an efficient tool to implement contractual terms based on the "decentralized consensus" (i.e., the universally accepted state of the world), establishing the "decentralized consensus" remains

to an efficient negotiating process.[17] Accordingly, while smart contracts are an efficient mechanism to implement the NFT's terms of sale, they are ill-equipped to equalize an unbalanced negotiating process because the parties must still define the smart contract's terms.[18] At present, the NFT market infrastructure remains murky.[19]

Ultimately, protecting NFTs as a unique asset and investment opportunity requires a new legal paradigm that both embraces the spectrum of alienable ownership rights and facilitates clear and efficient information exchange. Further, the paradigm should capitalize on emerging technologies and lend itself to default purchasing arrangements. An NFT Creative Commons parallel ("NFT CC") meets this high burden. With an NFT CC, creators would be able to affix established NFT CC licenses to their NFTs, pre-sale. These licenses would define and convey the NFT creator's and purchaser's legal rights in the NFT and its underlying asset, allowing for a more informed and efficient negotiating process. The licenses could range from full copyright transfer to no copyright transfer, to what this note dubs more moderate "reciprocal ongoing licensing transfers" ("ROLTs"), which would enable NFT creators and purchasers to share ongoing copyright interests in the NFT.

The transparency of NFT CC licenses would fundamentally lower NFT transaction costs by remedying the negotiating parties' information asymmetry; in doing so, it would also offer the necessary infrastructure on which to build

predicated on "record-keepers' observing and receiving greater amount[s] of information."). In other words, the smart contract's terms reflect agreed-upon reality, but that reality is defined by individuals acting on the information available to them—it is same reality reflected in traditional contractual ordering. *See id. See also* Stefaan G. Verhulst, *Information Asymmetries, Blockchain Technologies, and Social Change: Reflections on the Potential (and Challenges) of Distributed Ledgers for 'Market for Lemons' Conditions*, Medium (July 24, 2018), https://sverhulst.medium.com/information-asymmetries-blockchain-technologies-and-social-change-148459b5ab1a (highlighting that while smart contracts have the potential to reduce instances of information asymmetry associated with compliance and enforcement (by automating these processes), they may also "create new or reinforce existing information asymmetries instead of dismantling them…").

[17] *See* Benjamin F. Blair & Tracy R. Lewis, *Optimal Retail Contracts with Asymmetric Information and Moral Hazard*, 25 RAND J. Econ. 284, 284–85 (1994) (discussing information asymmetries that arise when one party has private information).

[18] *See id.*

[19] *See generally* Ante, *supra* note 15, at 15 (observing that "many…legal and technical issues of NFTs remain open…and the legal rights to NFTs are insufficiently clarified.").

a sustainable, reliable, and efficient NFT marketplace.[20] Injecting clarity and predictability into NFT transactions would not only augment the NFT market but would also protect NFTs' viability as an emerging asset class worthy of investment in the long term.[21] In order to appreciate an NFT CC's utility and advantages, Part I of this note will review foundational NFT technology and transaction practices in order to contextualize NFT legal issues. Part II will then discuss NFT copyright implications, and Part III will highlight core NFT legal tensions. Part IV will examine an NFT CC's conceptual framework and discuss potential NFT CC default licenses—licenses which could exist on a spectrum of full copyright transfer from creator to purchaser to no copyright transfer at all. Part IV will also proffer the unique NFT CC licensing options that would enable the aforementioned reciprocal ongoing licensing transfers ("ROLTs"). Finally, before concluding, Part V will address pertinent NFT policy implications and discuss an NFT CC's sociocultural significance.

I
NFT Background & Transaction Mechanisms

Virtually any original work of authorship ("original work")—be it a digital or physical work of art, piece of music, written work, etc.—can be an NFT, and that original work is referred to as the NFT's "underlying asset."[22]The individual who creates an NFT is distinguishable from the individual who makes, and/or retains a copyright interest in, the original work.[23] Authors of original works may create NFTs from those works—and thus become NFT creators—but the NFT creator

[20] *See* Samuels, *supra* note 8.

[21] *See id.*

[22] In fact, even this Note is an NFT. It is listed here: https://opensea.io/collection/i-want-my-nft. *See* Copyright Act of 1976, 17 U.S.C. § 101 (1978) (referring to "original works of authorship" in the "definitions" section); *see also* Jones Day Commentaries, *NFTs: Key U.S. Legal Considerations for an Emerging Asset Class*, Jones Day (Apr. 2021), https://www.jonesday.com/en/insights/2021/04/nfts-key-us-legal-considerations-for-an-emerging-asset-class (using the term "underlying asset" when referring to the original work from which the creator minted the NFT).

[23] *See* 17 U.S.C. § 201(b) (1978) (discussing "works made for hire"); *see also* Scott K. Zesch, *Application of "Works for Hire" Doctrine Under Copyright Act of 1976 (17 §§ 101 et. seq.)*, 132 A.L.R. Fed. 301 (1996) (noting that generally the party who actually creates the work is the work's author (see 17 U.S.C. § 102) and that copyright ownership initially vests in that author (see 17 U.S.C. § 201(a)), but that under 17 U.S.C. § 201(b), if a work is made for hire, the employer or other person for whom the work was prepared is considered the author and copyright holder).

may also be a different individual from the author entirely.[24] This note will refer to the person who creates the NFT as the "creator" and the author of an original work as the "author" in order to highlight the difference between creating an NFT and making the original work on which the NFT is based.

A. NFT Basics & Blockchain

NFTs are assets created using blockchain technology.[25] Once a creator decides to create an NFT, the creator will first need to "mint" that work.[26] Minting is the process of validating the original work's information by scanning it with the appropriate software so that it may be recorded as a unique coded transaction on the blockchain.[27] The "chain" of the blockchain is akin to a public ledger, and each "block" represents a specific transaction.[28] On the blockchain, the NFT may represent ownership of both tangible and intangible items.[29] Unlike fungible currencies, whose values are comparable to each other, NFT values are unique, individualized, and cannot be interchanged.[30] To ensure individualization, each NFT has a "hash" associated with it—a string of numbers and letters that serve as the NFT's unique digital fingerprint.[31] Through NFTs, these hashes enable creators to transform digital works of art and other collectibles into one-of-a-kind, verifiable goods which may be bought, sold, and traded.[32] Though the scanning technology that tokenizes original works and uploads them to the blockchain to create NFTs is not itself novel, NFTs have only recently entered the mainstream art world and cultural conversation in a meaningful way.[33]

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[24] *See* Jones Day Commentaries, *supra* note 22.

[25] Mitchell Clark, *How to Create an NFT—and Why You May Not Want To*, Verge (June 6, 2022, 8:00 AM), https://www.theverge.com/22809090/nft-create-opensea-rarible-cryptocurrency-ethereum-collectibles-how-to.

[26] *Id.*

[27] Clark, *supra* note 25; *see generally* Polygon, https://mintnft.today/ (last visited Feb. 27, 2022) (an example of NFT minting software).

[28] *Id.*

[29] *Id.*

[30] Chinlund & Gordon, *supra* note 7.

[31] Lyle Daly, *What is Proof of Work (PoW) in Crypto?*, Motley Fool (Dec. 3, 2021, 12:16 PM), https://www.fool.com/investing/stock-market/market-sectors/financials/cryptocurrency-stocks/proof-of-work/.

[32] *See id.*

[33] *See* Clark, *supra* note 25; *see also* Marco Iansiti & Karim R. Lakhani, *The Truth About Blockchain*, Harv. Bus. Rev. 120, Jan.-Feb. 2017.

B. NFT Marketplace Sales

Typically, once minted, creators must choose whether to sell their NFTs on an online marketplace or privately via smart contracts.[34] The creators who select marketplaces typically choose those compatible with the Ethereum blockchain.[35] The Ethereum blockchain employs the "Proof of Work" system, which uses each NFT's unique cryptographic fingerprint as a marker to verify all blockchain transactions.[36] As an initial investment, creators usually compensate the "crypto miners" who write the creator's newly minted NFT onto the blockchain with the cryptocurrency specific to the blockchain on which they are working.[37]

To list an NFT on an established marketplace, creators first upload the file they wish to mint as the NFT and then fill-in additional information about the NFT's properties and statistics.[38] These statistics may include basic descriptive information, like the work's medium and date, or may extend to private "unlockable content" available to only the NFT purchaser.[39] Unlockable content may include coded maps for the purchaser to follow and find additional pieces of artwork, opportunities for the NFT creator to tell the purchaser a story, or a link to an additional certificate of authenticity.[40] Once the creator enters this descriptive information and clicks "Create," the NFT officially exists on the blockchain.[41] The creator can then list and sell the NFT for whatever price they choose.[42]

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[34] Iansiti & Lakhani, *supra* note 33, at 126.

[35] *See* Clark, *supra* note 25.

[36] *See* Jeffrey Craig, *Crypto Minting vs. Mining: What's the Difference?*, Phemex (Aug. 7, 2021), https://phemex.com/blogs/crypto-minting-vs-crypto-mining.

[37] Clark, *supra* note 25 ("…every transaction on the Ethereum blockchains costs fees that are paid to the miners. These fees are called 'gas,' and the amount of gas [needed] for a transaction can vary significantly."). While NFT payment systems and cryptocurrency are fascinating, these payment systems and their associated legal issues are complex and beyond this paper's scope. Suffice it to say, NFT creators typically set up "wallets," which are applications that store cryptocurrencies as well as minted or purchased NFTs. *Id.* These wallets are accessible via a browser extension, and once a creator sets up a wallet and downloads the extension, the creator will be able to access marketplaces compatible with the wallet. *Id.*

[38] *Id.*

[39] *Id.*

[40] *Unlockable content in NFTs: What is it?*, Mintable, https://editorial.mintable.app/2021/09/05/unlockable-content-in-nfts-what-is-it/ (last visited Feb. 27, 2022).

[41] *See* Clark, *supra* note 25.

[42] *Id.*

C. NFT Smart Contract Sales

In contrast to marketplace sales, where the newly minted NFT itself is added to the blockchain, creators may also embed their NFTs in decentralized smart contracts.[43] A smart contract is a digital contract where the agreement between the parties is written in code that can be programmed to self-execute when the parties meet pre-defined, "triggering" conditions.[44] Creators generally upload their newly minted NFT to the smart contract, write the code for the triggering conditions, and then upload that smart contract to the platform of their choosing.[45] Then, when the NFT purchaser meets the smart contract's triggering conditions—the most common condition being the purchase price—the smart contract automatically distributes the NFT to the purchaser, encodes the transaction on the blockchain, and thus completes the transaction.[46]

II
NFT Copyright Implications

Under 17 U.S.C § 106, copyright owners have the right to reproduce, prepare derivative works, distribute copies, and publicly display or perform their works.[47] NFTs are most akin to reproductions or derivative works: works based on one or more preexisting work(s) that may be recast, transformed, or adapted.[48] Consequently, tensions often arise when the NFT creator and the original work's author are not the same person. This is because the author, as the presumed copyright holder, has the inherent authority to transform the original work into an NFT.[49] Any NFT minted from an original work without the copyright

[43] Kohn, *supra* note 8, at 22; *see* Shaan Ray, *NFTs and Smart Contracts*, Medium (May 18, 2021), https://medium.com/lansaar/nfts-and-smart-contracts-6c4c5516d5a0.

[44] Ray, *supra* note 43.

[45] *Id.*

[46] *See generally id.*

[47] 17 U.S.C. § 106 (2002).

[48] *See* 17 U.S.C. § 101 (2010) (for a definition of "derivative work"); Daniel Dubin & H. James Abe, *'Pulp Fiction' NFT Lawsuit Presents New IP Battleground*, Law360 (Dec. 20, 2021), https://www.law360.com/articles/1450002.

[49] 17 U.S.C. § 102 (1978); *see also* 1 Melville B. Nimmer & David Nimmer, Nimmer On Copyright § 2.03 (2022) ("There is but a single work of authorship, no matter how numerous and diverse the copies. . . the 'author' is the originator of the intangible material (e.g., the novel), rather than the individual who fixes it into particular copies (e.g., the stenographer)."); Carly Kessler, *Copyright Concerns for NFT Buyers, Sellers in Music Industry*, Law360 (Apr. 20, 2021, 4:48 PM), https://www.law360.com/articles/1377035.

holder's explicit permission is therefore fraudulent and amounts to a copyright infringement.[50]

Purchasers also retain no default copyright interest in the NFT's underlying asset.[51] The purchaser can prove ownership of the NFT itself, but the purchaser has no intellectual or tangible property rights associated with the underlying asset, absent specific contractual provisions in the NFT's terms of sale.[52] This outcome runs counter to most mainstream media coverage, which suggests that NFT ownership correlates to some form of proprietary interest in the NFT's underlying asset.[53]

To illustrate, Jack Dorsey, co-founder and former CEO of Twitter, auctioned and sold an NFT of his first tweet, "just setting up my twttr" for $2.9 million.[54] The sale's terms made it clear that the purchase transferred no copyright to the purchaser, and that the NFT was analogous to no more than a "virtual autograph" "signed and verified by the creator."[55] As such, the purchaser owns an NFT of the tweet but is unable to use the tweet—by copying it onto merchandise, for example—without Jack Dorsey's express authorization as the tweet's copyright holder.[56] A major source of purchaser misunderstanding, therefore, is that NFT ownership does not automatically vest an ownership interest in the NFT's underlying asset.[57]

To summarize, NFT creators do not have the inherent authority to mint an NFT from an original work without the copyright holder's express permission—lest they commit copyright infringement—and purchasers have no ownership interest in the NFT's underlying asset, absent special contractual provisions in the NFT's terms of sale.[58] While traditional copyright principles afford insight into protecting authors of original works and NFT creators, these

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[50] 17 U.S.C. § 102.

[51] Garton Mukaddam, *supra* note 12.

[52] *Id.*

[53] *Id.*

[54] Taylor Locke, *Jack Dorsey Sells His First Tweet Ever as an NFT for Over $2.9 Million*, CNBC (Mar. 22, 2021, 3:07 PM), https://www.cnbc.com/2021/03/22/jack-dorsey-sells-his-first-tweet-ever-as-an-nft-for-over-2point9-million.html.

[55] *Id.*

[56] Garton & Mukaddam, *supra* note 12.

[57] *See* Dubin & Abe, *supra* note 48.

[58] *See* 1 Nimmer, *supra* note 49.

principles do little to protect purchasers, whose expectations often conflict with the realities of NFT ownership.[59] In short, both NFT creators and purchasers must tread cautiously before, during, and after an NFT's sale.

III
NFT Legal Tensions & Current Inadequacies in NFT Sales

Copyright law and traditional property law often work symbiotically; however, the distinction between copyright ownership and "ownership of a copy" is exceedingly relevant and may raise problems when expectations associated with tangible property ownership conflict with intangible intellectual property rights.[60] NFT creation, sales, and ownership aptly exemplify these tensions and create novel issues for both the NFT creator and purchaser, most of which stem from the nature of NFTs themselves.[61] More specifically, the often unclear "bundle of rights" to which NFT creators and purchasers are entitled after an NFT sale place copyright law and property law in stark conflict.[62]

A. Creator & Purchaser Expectations Conflict in NFT Sales

To illustrate, consider two scenarios: (1) an author sells a work of art to a purchaser, and the purchaser then mints an NFT from that work of art and sells it without compensating the author, and (2) an NFT creator sells an NFT to a purchaser and then mints multiple new NFTs from the same, or a substantially similar, underlying asset, which devalues the first purchaser's NFT because that NFT is no longer functionally scarce.

Both scenarios have parallels in the non-NFT world. After all, a creator minting an author's original work as an NFT without authorization is, on a basic level, an infringing reproduction—the same sort of infringing reproduction that constitutes a copyright infringement, regardless of the reproduction's medium.[63]

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[59] *See* Kessler, *supra* note 49.

[60] *See* U.S. Copyright Off., https://www.copyright.gov/help/faq/faq-fairuse.html (last visited Mar. 4, 2022) (ownership of a "copy"…the tangible embodiment of the "work"…is distinct from the "work" itself—the intellectual property."); *see also* 1 Nimmer, *supra* note 49 ("Ownership of tangible materials is distinct from ownership of intangible rights under copyright.").

[61] *See* Kohn, *supra* note 8, at 22.

[62] Will Gottsegen, *NFT Forgeries Aren't Going Away*, CoinDesk (Dec. 20, 2021, 11:34 AM), https://www.coindesk.com/layer2/2021/12/20/nft-forgeries-arent-going-away/.

[63] Jason Mazzone, *Copyfraud*, 81 N.Y.U. L. Rev 1026, 1029 (2006).

And purchasers often find themselves in situations where their initial investments are devalued based on volatile extraneous market circumstances.[64] However, NFTs represent unique challenges to creators and purchasers because the existing copyright and property frameworks are ill-equipped to accommodate ambiguous, and often complex, NFT ownership interests.[65] Creators often do not consider that, without the copyright holder's express permission, minting an NFT from the author's original work constitutes a copyright infringement, and most purchasers do not understand the limited reality of their initial NFT investment's associated copyright.[66]

B. VARA & the Resale Right as Suggested Solutions

The small body of NFT literature that addresses these tensions largely proposes solutions rooted in copyright, and while these solutions may shield NFT creators, they do little to protect purchasers who do not understand the rights associated with their NFTs.[67] These copyright solutions suggest enshrining the NFT creator's moral rights by either (1) expanding the scope of the Visual Artists Rights Act of 1990 ("VARA") or (2) mandating a de facto resale right in all NFT sales.[68] Moral rights are the rights afforded to authors by virtue of the author's role as the maker of the original work.[69] In addition to the economic rights associated with copyright, which control access to creative works and compensation for their exploitation and utilization, moral rights give authors control over how others may use their works in non-economic ways.[70]

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[64] *See generally* Paul G. Haskell, *The Prudent Person Rule for Trustee Investment and Modern Portfolio Theory*, 69 N.C. L. Rev. 87, 103 (1990) ("The 'laws' of economics are different from the laws of nature. . . .What happened yesterday in nature is an excellent predictor of what will happen tomorrow. . . .[This] assurance does not exist with respect to past economic experience. . . .It is uncertain that the future will be consistent with the immediate past. . . .The economic tomorrow may vary. . . based on. . . [new] information.").

[65] *See* Jones Day Commentaries, *supra* note 22 ("The existing regulatory and legal environment was not designed to accommodate digital assets, including NFTs. Nonetheless, there are some key issues that have emerged while investors. . . explore this space.").

[66] *See* Kessler, *supra* note 49 ("It is important for buyers and sellers to be careful when transacting in this new [NFT] marketplace. Sellers should be aware of what intellectual property rights they own. . . before offering it for sale as an NFT, and buyers should be aware of what they are actually purchasing.").

[67] *See* Lewis et al., *supra* note 9 ("The minting and sale of NFTs are susceptible to 'copyfraud' and infringement of copyright in the underlying work as well as the infringement of the moral rights of the author of the original work," but buyers remain unprotected in the NFT market).

[68] *See id.*

[69] *See* 3 Melville B. Nimmer & David Nimmer, Nimmer on Copyright § 8D.02 (2022).

[70] *Id.* at § 8D.06.

Generally speaking, the United States maintains a strictly neutral stance with respect to moral rights in intellectual property and does not afford them much protection.[71] However, under VARA, the United States recognizes artists' moral rights of attribution and integrity under extremely specific and limited circumstances.[72] The right of attribution includes the right to (1) claim authorship, (2) prevent others from using the artist's name to promote visual works of art that the artist did not create, and (3) prevent others from affixing the artist's name to a work that the artist did create but that has been distorted or otherwise modified in a way that harms the artist's reputation.[73] The right of artistic integrity grants artists the right to prevent (1) any intentional modifications of their works and (2) others from attaching the artist's name to works that the artist did not create.[74] In theory, VARA's moral rights' protections could extend to NFT creators if Congress expanded the statutory definition of a "work of visual art."[75] Under VARA, "works of visual art" currently include only paintings, drawings, prints, or sculptures.[76]

The "resale right" solution is based on the principle that authors, especially authors of graphic or plastic works, should have the ability to reap additional economic benefits if their works are later re-sold or displayed for profit.[77] In contrast to the United States' historically steadfast commitment to neutrality regarding moral rights, international copyright laws often grant resale rights to artists, and these royalties apply to all "works of graphic or plastic art such as pictures, collages, paintings, drawings, engravings . . . made by the artist himself."[78] To date, more than fifty countries have implemented some form of

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[71] *Id.*

[72] *See id.*

[73] *Id.*

[74] 3 Melville B. Nimmer & David Nimmer, *supra* note 69 at 8D.06; *see also* Information Sheet, Sharon Forscher, Philadelphia Volunteer Laws. Arts, The Visual Artists Rights Act of 1990 (on file with the City of Albuquerque), https://www.cabq.gov/artsculture/public-art/documents/visualartistsrightsact_philadelphiavolunteerlawyersarts.pdf.

[75] 3 Nimmer, *supra* note 69, at § 8D.06.

[76] 17 U.S.C. § 101 (1978) (defining "work of visual art."); *see also* 3 Nimmer, *supra* note 69, at § 8D.06.

[77] Elisa D. Doll, Note, *The Equity for Visual Artists Act of 2011 (EVAA): Crafting an Effective Resale Royalty Scheme for the United States Through Comparative Mediation*, 24 Ind. Int'l & Comp. L. Rev. 461, 466 (2014).

[78] Doll, *supra* note 77 at 467; *see generally* 3 Nimmer, *supra* note 69, at § 8D.06 (discussing the United States' commitment to neutrality regarding moral rights).

resale royalty legislation.[79] These resale royalties are economic in nature but stem from the "special relationship" that exists between authors and their works.[80] Resale royalty legislation finds its purpose in equity and brings about equitable results through economic measures.[81] The legislation seeks to address the power imbalance between poor artists and dealers who flip paintings for additional profit and/or exploit the artist's creative efforts.[82] Certain scholars maintain that encoding a de facto resale right into an NFT's terms of sale would protect NFT creators from exploitation on the secondary art market and authors of original works from having NFTs minted from their works without their express authorization.[83]

C. Flaws in the Suggested & Current Solutions

The suggested VARA and resale right solutions are inadequate. Though these solutions would likely benefit original works' authors by protecting their right of artistic integrity and allowing them to collect revenue from purchasers subsequently minting NFTs from the authors' original works, these copyright solutions do little to protect an NFT purchaser's investment if the NFT creator mints subsequent NFTs from the same underlying asset.[84]

There is no default copyright transfer from NFT creator to purchaser, so the copyright solutions that protect NFT creators are unavailable to protect purchasers; moreover, proponents of the VARA and resale royalty right solutions do not allege that these solutions *should* protect NFT purchasers.[85] The creator retains a full copyright interest, and the purchaser owns only their isolated NFT, which

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[79] Doll, *supra* note 77, at 461.

[80] *Id.*

[81] *Id.* at 465.

[82] *Id.*

[83] *See* Collin Starkweather et al., *How Intellectual Property Rights Can Complicate NFT Market*, Law360 (Aug. 17, 2021, 5:26 PM), https://www.law360.com/articles/1412858/how-intellectual-property-rights-can-complicate-nft-market; *see generally* Ingram Yuzek Gainen Carroll & Bertolotti, LLP, *Buying Selling NFTs: Navigating the Legal Landscape*, JD Supra (Nov. 30, 2021), https://www.jdsupra.com/legalnews/buying-selling-nfts-navigating-the-2284166/ (noting that coded resale royalties "may be configured to pay a percentage…from the secondary sale of the NFT as a royalty payment to the artist upon each resale…" and that "[a] groundbreaking feature of NFTs is the ability of the rights owner or original seller to capture revenue from the secondary market, or the resale marketplace.").

[84] *See id.*

[85] *See* Zhao Zhao, *Fulfilling the Right to Follow: Using Blockchain to Enforce the Artist's Resale Right*, 39 Cardozo Arts Ent. L.J. 239, 251 (2021) ("As artists advocate for the resale right to become mandatory, it is just as crucial to consider innovative ways to achieve effective enforcement.… [G]overnments should

ultimately grants the purchaser no copyright interest or default licensing claim in the underlying asset.[86] There is also no analogous resale right available to purchasers that would similarly allow purchasers to collect revenue from NFT creators who sell substantially similar NFTs to new buyers after the initial purchaser's NFT investment.[87]

The proposed resale right solution is particularly non-viable, given the United States' clear hesitancy to adopt any federal resale royalty legislation. In 1992, the U.S. Copyright Office issued an extensive report with findings regarding how a potential resale royalty right, or "droit de suite," may operate in the United States.[88] The 1992 report recognized that many countries, particularly those in the European Union, do more to encourage the social and economic well-being of visual artists than the United States, and that adopting a federal resale royalty right may be a viable mechanism to support struggling artists.[89] Yet, the report also recognized that a resale royalty may violate the first sale doctrine and run counter to long-held principles of property's free alienability post-sale—a hallmark of Anglo-American jurisprudence.[90] Notably, the report expressed additional concerns that integrating a resale royalty into a free market system would depress the art market, as buyers would not be willing to pay as much for works bound by subsequent royalties.[91]

In 2013, the Copyright Office issued a follow-up to the 1992 report which addressed the 1992 report's concerns and examined countries who had, in the interim between the two reports, adopted a resale royalty right in some form.[92] The report noted that in 2013, more than seventy countries—including the European Union—had enacted some form of a resale royalty provision, and that the 1992

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also consider… blockchain as a means of enforcing resale royalty rights for visual artists who create physical artwork.").

[86] Lewis et al., *supra* note 9 ("Acquiring ownership of an NFT representing a work in which copyright subsists does not, without more, grant the new owner of the NFT copyright in the underlying work.").

[87] *See id.*

[88] U.S. Copyright Office, Droit de Suite: The Artist's Resale Royalty (1992).

[89] *Id.* at 60, 133.

[90] *Id.* at 134 n.43 (highlighting that the "concept of individual purchaser[s] having to share ownership with other [purchasers is] inconsistent with U.S. property law); *see also* 17 U.S.C. § 109(a) (1978) (codifying the first sale doctrine which grants an IP holder and copyrighted work's owner the right to sell, lend, and share copies of the copyrighted work without having to obtain permission or compensate the work's original author).

[91] *See id.* at 139.

[92] *See* U.S. Copyright Office, Resale Royalties: An Updated Analysis (2013).

report's assumptions that a resale royalty would substantially reduce primary art market prices proved to be without merit.[93] In stark terms, the Copyright Office expressed that there were no clear impediments to implementing a resale royalty right in the United States, and that the United States should consider the right as one remedy to address disparities between visual artists—who are disadvantaged due to the nature of their work—and other authors under copyright law.[94] The report additionally outlined precise legislative recommendations for Congress to consider should it wish to adopt a resale royalty right.[95]

Yet, despite the Copyright Office's go-ahead, the United States has yet to adopt any federal resale royalty legislation. Perhaps this stems from the 2013 report's cautioning that a resale royalty right should be considered as only one potential option, and that Congress must deliberate further to determine if it is the best option.[96] It is also possible that Congress deliberated and concluded that principles of property's free-alienability and the first sale doctrine take precedence over protecting visual artists.[97] Either way, the lack of federal resale royalty legislation suggests that Congress would be similarly hesitant to recognize a uniform NFT resale right.

While the suggested VARA and resale right solutions are clearly inadequate, the current solution—to mitigate the tensions between creator and purchaser through private negotiation and contractual arrangements—is no better because it is inefficient.[98] NFT ownership is often in conflict with the purchaser's traditional

[93] *Id.* at 2 (acknowledging that the 1992 report's arguments may have been "overblown.").

[94] *Id.* at 3 (observing that visual artists are at a practical disadvantage when compared with other authors due to "certain factors endemic to the creation of works…produced in singular form (or in very limited copies) and are valued for their scarcity.").

[95] *Id.* (recommending that the legislation: (1) "[a]pply to sales of works of visual art by auction houses, galleries private dealers, and other[s]…engaged in the business of selling visual art," (2) "[e]stablish a royalty rate of 3 percent to 5 percent of the work's gross resale price," (3) "[r]equire copyright registration as a prerequisite to receiving royalties," etc.).

[96] *Id.*

[97] *See* U.S. Copyright Office, *supra* note 88.

[98] U.S. Copyright Office, *supra* note 88; *see also* Sean M. Sullivan & Lance Koonce, *What You Don't Know About NFTs Could Hurt You: Non-Fungible Tokens and the Truth About Digital Asset Ownership*, Davis Wright Tremaine LLP (Mar. 24, 2021), https://www.dwt.com/insights/2021/03/what-are-non-fungible-tokens ("The purchase of a token *may* include, as a matter of contract, other associated rights…even…transfer of possession of a digital file of the digital asset, but that depends entirely on the terms of sale for any particular NFT. The range of rights that *could* flow…are virtually unlimited.").

property expectations, so the purchaser is not in an efficient negotiating position.[99] An efficient party is an informed party, and the less informed the party, the more onerous and futile the negotiating process.[100] In short, information asymmetry makes NFT transactions inefficient.[101]

Proponents of private negotiation, especially those who also support encoding a de facto resale right, often point to smart contracts as the most viable and efficient transaction instrument.[102] Yet the smart contract's efficiency wanes when contextualized in light of the negotiating parties' conflicting expectations and the purchaser's dearth of information.[103] In other words, smart contracts may be an efficient *mechanism* to enforce private agreements for an NFT's sale—because smart contracts automatically enforce themselves when the parties meet the contract's encoded triggering conditions—but they do little in the way of lowering the negotiation and transaction costs necessary to establish those conditions in the first place.[104]

Within the NFT realm, all contractual solutions—traditional and smart—are also inefficient due to their potential for non-enforcement.[105] Smart contracts are touted as an efficient sales mechanism because they "cut out the middle man," but

[99] *See* Inés Macho-Stadler & J. David Pérez-Castrillo, An Introduction to the Economics of Information 54, (2d ed. 2001) ("The existence of…hidden information introduces important inefficiencies into the contract….").

[100] *Id.*

[101] *See id.*

[102] Ingram Yuzek Gainen Carroll & Bertolotti, LLP, *Buying & Selling NFTs: Navigating the Legal Landscape*, JDSupra (Nov. 30, 2021), https://www.jdsupra.com/legalnews/buying-selling-nfts-navigating-the-2284166/ ("the first sale doctrine appears to have no place in the universe of NFTs. NFTs are coded with smart contracts, which may be configured to pay a…royalty payment to the artist."); *see also* Kei Teshirogi, *Mechanism of NFT and Legal Issues Related to NFT Transactions*, 51 Oh-Ebashi Intell. Prop. Newsl. (Feb. 17, 2022), *available at* https://www.ohebashi.com/jp/feature/2022NFT_features.php (discussing how NFT creators can code something similar to a resale right as one of the smart contract's terms at the time of the NFT's issuance in order to receive a portion of the transaction amount if the purchaser resells the NFT to a third party).

[103] *See generally* Blair & Lewis, *supra* note 17 at 285 (discussing information asymmetries that arise when one party has private information).

[104] *See id.*

[105] As an initial matter, courts recognize smart contracts' validity. *See Rensel v. Centra Tech, Inc.*, No. 17-24500-CIV, 2021 WL 4134984 (S.D. Fla. Sept. 10, 2021); *see also* Sullivan & Koonce, *supra* note 98 (noting that while courts recognize smart contracts as viable instruments, "the NFT smart contract itself cannot *enforce* . . . provision[s]—a seller would have to resort to traditional methods of enforcement (e.g., demand letters, litigation).").

if the creator or purchaser breaches the NFT's terms of sale, the smart contract's enforcement mechanism still rests in traditional legal actions.[106] Moreover, if the purchaser is ill-informed of the NFT's terms of sale or does not understand the practical effects of those terms, then the purchaser could bring an action against the NFT creator for fraudulent misrepresentation, breach of contract, or seek a rescission of the contract in its entirety.[107]

These copyright and property tensions, coupled with the inadequacy of the proposed and current mitigation measures, highlight the overemphasis on NFT creator protection at the expense of NFT purchasers.[108] In fact, the asymmetric bargaining power inherent in the proposed and current solutions may ultimately constitute a "moral hazard," where the purchaser bears the economic risk of a volatile investment while the NFT creator can capitalize on the lack of legal restraints in subsequent NFT minting.[109] In the same way that private negotiation exacerbates information asymmetry, expanding VARA and the resale right similarly place the NFT creator and purchaser on unequal footing because the purchaser has neither a copyright claim in the original work nor a remedy against a creator for minting and selling substantially similar NFTs to other purchasers.[110] When NFT creators sell multiple, substantially similar NFTs—NFTs which are *functionally* identical to each other, despite each having their own unique hash on the blockchain—the initial NFT purchaser ends up assuming the majority of the transaction risk.[111] Initial purchasers may purchase NFTs at high prices, which do not reflect the creator's ability to sell additional NFTs from the same underlying asset, and the value of the initial purchaser's NFT may then depreciate because it is no longer functionally unique.[112] Without adequate purchaser protections, the

[106] *See* Sullivan & Koonce, *supra* note 98.

[107] *Id.*; *see also* Luca Anderlini et al., *Should Courts Always Enforce What Contracting Parties Write?*, 7 Rev. L. & Econ. 15, 16 (2011) ("The potential benefit of a court's voiding explicit contractual clauses stems from asymmetry of information between the parties at the time they contract. Because of asymmetric information, when the court does not intervene, inefficient trades may take place.").

[108] *Id.*

[109] *See* CFI Team, *Moral Hazard*, Corp. Fin. Inst. (May 18, 2020), https://corporatefinanceinstitute.com/resources/knowledge/other/moral-hazard.

[110] *See id.*

[111] *See id.*

[112] *See* Luke Dormehl, *NFTs and the Explosive Rebirth of Artificial Scarcity, Digit. Trends* (Mar. 22, 2021), https://www.digitaltrends.com/features/nfts-artificial-scarcity ("[NFT's] digital scarcity does not refer to the artwork [itself]…the digital scarcity refers to…the receipt for the artwork…the ownership of the artwork

precise attribute that makes NFTs valuable—their scarcity—may be nothing more than a fallacy.[113]

IV
Novel Solution: An NFT Creative Commons Parallel ("NFT CC")

Clearly, the challenges posed to the integrity of the NFT purchase and the ultimate viability of NFTs as a unique asset and investment opportunity necessitate a novel solution. This solution must draw from copyright law, address traditional property expectations, capitalize on emerging technologies, and lend itself to default purchasing arrangements. Such a hybrid solution would (1) permit the NFT creator and purchaser to know precisely what rights they are entitled to in the NFT and (2) decrease transaction costs and make NFT sales more efficient by mitigating information asymmetry. An NFT Creative Commons parallel ("NFT CC") meets this high standard.

A. Creative Commons Overview

Creative Commons ("CC") works in tandem with The Copyright Act's "all rights reserved" setting and affords authors the ability to grant specific licenses and copyright permissions for others to use their original works.[114] The Creative Commons seeks to build "a layer of reasonable, flexible copyright in the face of increasingly restrictive default rules."[115] All CC licenses allow authors to retain a full copyright interest while still allowing others to distribute, reproduce, create derivative works, and otherwise make use of authors' original works in ways defined by the licenses the authors choose.[116] Because these licenses are premised on copyright, they last as long as the copyright interest exists.[117]

CC licenses employ a "three-layer" design that renders the licenses legally legitimate, accessible to laypeople, and conducive to creative works that employ

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[is] scarce, *not* the artwork itself. All you really own…[with] an NFT is an entry in a database on the blockchain…that *entry* is scarce.").

[113] *Id.*

[114] *See About CC Licenses*, Creative Commons, https://creativecommons.org/about/cclicenses (last visited Nov. 24, 2022).

[115] Lydia Pallas Loren, *Building a Reliable Semicommons of Creative Works: Enforcement of Creative Commons Licenses and Limited Abandonment of Copyright*, 14 Geo. Mason L. Rev. 271, 273 (2007).

[116] *About CC Licenses*, *supra* note 114.

[117] *Id.*

technology.[118] The first "Legal Code" layer utilizes copyright licenses' traditional language and text.[119] The second "Commons Deed" layer serves as a reference that summarizes and expresses the licenses' salient terms for creators, educators, and others who wish to license their creative works but are ill-versed in the legal field.[120] The third and final "Machine Readable" layer of the license encodes the license's terms so that they are recognizable through software.[121] Simply put, the three layers of CC licenses protect licensors and licensees by observing legal formalities while simultaneously ensuring layperson and software accessibility.

There are currently six CC licenses, and each license permits and restricts certain licensee actions; the multitude of licenses gives authors a flexible range of options when sharing their works with the public.[122] Each license has a specific name and graphic associated with it that both designates the type of license it is and conveys the ways in which licensees may legally make use of the licensor's work.[123] For example, the "Attribution-NoDerivs" ("CC BY-ND") license permits licensees to reuse the licensor's work for any purpose, but restricts licensees' abilities to share the work in an adapted form; the license also requires the licensee to credit the licensor.[124] Once an author chooses the CC license that best reflects the ways in which they intend for licensees to use their works, the author then affixes the license to their work, either through a link, graphic, piece of text, or embedded HTML code, along with a link explaining the chosen license's terms.[125]

B. NFT CC's Logistics

An NFT CC, with an analogous three-layer license design that would define how the NFT creator and purchaser may utilize the NFT and its underlying asset post-sale, would lower NFT transaction costs by increasing the reliability and efficiency of NFT sales. Affixing an NFT CC license to an NFT prior to its sale would place purchasers on notice of precisely how they may utilize their NFT.

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[118] *See About the Licenses*, Creative Commons, https://creativecommons.org/licenses (last visited Nov. 24, 2022).
[119] *Id.*
[120] *Id.*
[121] *Id.*
[122] *Id.*
[123] *Id.*
[124] *Id.*
[125] *See About CC Licenses*, *supra* note 114.

Crucially, these licenses would also alert the purchaser to whether the NFT creator retains the right to mint additional, substantially similar NFTs from the same underlying asset. With this information in mind, purchasers would then be able to negotiate prices that adequately convey the NFT's true market value.

Although the possibilities for potential NFT CC licenses are abundant, this note offers six examples to demonstrate their utility.[126] The first two license examples represent extreme options: (1) full copyright transfer from NFT creator to purchaser in the NFT's underlying asset and (2) no copyright transfer at all. The four middle license examples represent a more moderate approach, with what this note terms "reciprocal ongoing licensing transfers" ("ROLTs"). These ROLTs would enable purchasers and creators to share licensing rights and revenues when either meets the licenses' pre-defined conditions. For example, drawing from established resale royalty logistics, which compensate authors based on a percentage of the work's sale price, these ROLTs could include licenses that: (3) permit authors of original works to receive a percentage of the revenue from a purchaser who mints an NFT from the original work, (4) prohibit NFT creators from minting additional NFTs from the same underlying asset, but permit creators to mint NFTs from the underlying asset's derivative works, (5) prohibit authors from creating substantially similar derivative works from the underlying asset and then minting additional NFTs from those derivative works, and (6) permit NFT creators to mint and sell subsequent NFTs from the same underlying asset as the initial purchaser's, but also permit the initial purchaser to claim a percentage of the subsequent NFTs' revenue.

The NFT CC solution is, in essence, a spectrum of licensing arrangements where in certain scenarios the purchaser is entitled to a greater claim on the NFT and its underlying asset, and in other scenarios the NFT creator and/or original author retains more control. The key element of this solution's viability is that the licenses' terms would be easily communicable to purchasers, readily digestible due to their three-layer structure, and reliable because of the licenses' codified and pre-defined conditions. Together, these factors ensure transaction efficiency

[126] It is for a future project to determine the "who" and "how" of NFT CC licenses, but it is the author's opinion that a consortium comprised of stakeholders with diverse interests in the NFT market should design the NFT CC licenses. The 1992 U.S. Copyright Office's report is informative; in discussing a proposed resale royalty right, the report references testimony from "artists, representatives of museums, art galleries, auction houses, and legal experts…" U.S. Copyright Office *supra* note 88, at 99. The NFT CC license consortium should similarly take these diverse perspectives into account when designing the licenses.

by decreasing information asymmetry. Through the licenses, NFT creators would be able to signal to purchasers precisely what the sale affords both parties, and the informed purchaser would be in a better negotiating position as a result.

C. NFT CC's Proposed Benefits

Utilizing NFT CC licenses would increase the overall efficiency of NFT sales by clarifying the rights and responsibilities of creators and purchasers from the transaction's inception.[127] From a free market perspective, an NFT's price would reflect its licensing terms, and a potential purchaser dissatisfied with an NFT's post-sale rights may choose not to purchase it.[128] In this way, because the NFT's price would be impacted by its attached NFT CC license, the NFT's price would more accurately convey its true market value.[129] The NFT CC licensing structure internalizes transaction costs by shifting the majority of the risk to NFT creators, who are the parties best-equipped to determine the NFT's worth and choose the appropriate license to attach to it.[130]

The NFT CC solution is also economically efficient because it ensures that the party with the greater interest in the NFT's digital scarcity pays more.[131] This

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[127] *See* Timothy Vollmer, *Do Open Educational Resources Increase Efficiency?*, CREATIVE COMMONS (Sept. 9, 2010), https://creativecommons.org/2010/09/09/do-open-educational-resources-increase-efficiency.

[128] *See* James G. Gatto, *NFT License Breakdown: Exploring Different Marketplaces and Associated License Issues*, NAT'L L. REV. (Sept. 21, 2021), https://www.natlawreview.com/article/nft-license-breakdown-exploring-different-marketplaces-and-associated-license-issues (discussing how a seller's representations of rarity impact the NFT's price).

[129] *But see* Kate Rooney, *Crypto Investors See Looming NFT Bubble but Tout Staying Power of the Underlying Tech*, CNBC (Dec. 3, 2021, 10:42 PM), https://www.cnbc.com/2021/12/03/crypto-investors-see-an-nft-bubble-but-tout-power-of-underlying-tech.html (highlighting the demand for NFTs, but noting that only the quality projects will have staying power in the long-term). *See generally* International Trade Administration, *Export Pricing Strategy*, INT'L TRADE ADMIN., https://www.trade.gov/pricing-strategy (discussing traditional factors to include in price calculation e.g., market demand and competition).

[130] *See generally* Samuels, *supra* note 8, at 6 (discussing Coase's theorem on the economic significance of market rights, and the impact these market rights have on protected interests and subsequent bargaining efficiency).

[131] *See* David Z. Morris, *Art in the Age of Digital Scarcity: Why NFTs Enchant Us*, COINDESK (Oct. 19, 2021, 5:04 PM), https://www.coindesk.com/business/2021/08/30/art-in-the-age-of-digital-scarcity-why-nfts-enchant-us ("NFTs are valuable in themselves…because they give digital objects a claim on the sense of presence, history, and authenticity previously reserved for physical objects."); *see also* Robyn Conti & John Schmidt, *What You Need to Know About Non-Fungible Tokens*

scarcity stems from either owning the right to mint subsequent NFTs (creator scarcity), or owning an NFT from which a creator may never mint a subsequent NFT from the same or a substantially similar work (purchaser scarcity). For example, NFT creators who retain the right to mint subsequent NFTs would "pay more" for this creator scarcity by listing the NFT for a lower price. Conversely, purchasers who own an NFT with a license that prohibits the creator from minting subsequent NFTs from the same underlying asset would pay more for this purchaser scarcity because the NFT would be valued at a higher price.

An NFT CC would also protect the value of the NFT purchaser's investment by stabilizing the lower threshold of the NFT's price.[132] Though the NFT creator would choose which license to attach to their work, the purchaser would have an equal power to choose which NFT, with its corresponding license, they would be willing to purchase, or even negotiate with the creator over the affixed license itself. Purchasers may choose not to purchase NFTs that are subject to licenses that limit what the purchaser may do with either the NFT or its underlying asset, or licenses that limit purchaser claims if the creator retains the right to mint subsequent NFTs. NFT CC licenses are also advantageous from a contractual standpoint. In the event of a breach, courts would be more likely to enforce an NFT sales contract with the weight of an NFT CC license behind it than a traditional NFT sales contract that supplies terms that clearly demonstrate the parties' information asymmetry.[133]

Put simply, NFT sales in their current state are inefficient because the purchaser is ill-informed.[134] The current practice is to bargain the NFT's terms of sale through private negotiation, but private negotiation does little to remedy the

(NFTs), Forbes (Apr. 8, 2022, 8:36 AM), https://www.forbes.com/advisor/investing/nft-non-fungible-token (noting that NFTs create digital scarcity); Steven L. Jones & Jeffry M. Netter, *Efficient Capital Markets*, Econlib, https://www.econlib.org/library/Enc/EfficientCapitalMarkets.html (last visited Nov. 24, 2022) (discussing the ways in which price reflects consumer expectations); *see generally* Jaya Klara Brekke & Aron Fischer, *Digital Scarcity*, 10 Internet Pol'y Rev. 2, 2 (2021) (defining digital scarcity).

[132] *See* Lawrence M. Ausubel et al., *Bargaining with Incomplete Information, in* 3 Handbook of Game Theory (Robert J. Aumann & Sergiu Hart eds., 2002) (discussing buyer/seller equilibrium in terms of information access through a game theory analysis).

[133] Amit Elazari Bar On, *Unconscionability 2.0 and the IP Boilerplate: A Revised Doctrine of Unconscionability for the Information Age*, 34 Berkeley Tech. L.J. 567, 567 (2019) ("Private [contractual] ordering is expanding its governing role in IP, creating new problems and undermining the rights…[of] creators and users.").

[134] *See generally* Samuels, *supra* note 8.

stark information asymmetry between NFT creators and purchasers.[135] An NFT CC is an elegant solution to these problems. The licenses would not only serve a signaling purpose to purchasers but would also put the most salient terms of the NFT's sale in accessible language so that the purchaser would know exactly what rights they, and the creator, are entitled to post-sale.

V
NFT CC's Significance & Policy Implications

NFTs have revolutionized the modern art and media worlds and also the broader technology culture. The national and international NFT markets support novel artistic contributions and have opened new pathways for unprecedented purchaser access to art and media ownership.[136] An NFT CC would contribute to this valuable innovation—and would particularly bolster the international market—by streamlining the NFT sales process. Moreover, an NFT CC would afford auction houses the stability necessary for long-term NFT viability in art transactions.[137] Generally speaking, NFTs have added to the growing mainstream awareness of "digital scarcity" and continue to fundamentally alter what it means to "own" a digital asset.[138] Consequently, any legal solution, including an NFT CC, that protects NFT investments will impact, be implicated in, and inform all forthcoming digitally-scarce spaces writ large.

A. An NFT CC Would Bolster Efficiency in the International IP Market

Compared with a federal statutory scheme, an NFT CC is almost certainly the more effective way to implement NFT licenses and effectuate copyright law's longstanding goal to promote scientific and artistic innovation.[139] As IP markets become increasingly global, "traditional IP norms and private ordering regimes have failed to keep pace with changing market realities."[140] Private international IP

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[135] *See* Ausubel et al., *supra* note 132.

[136] *See* Sonia Baldia, *The Transaction Cost Problem in International Intellectual Property Exchange and Innovation Markets*, 34 Nw. J. Int'l L. & Bus. 1, 31 (2013).

[137] *See generally* Partha Dasgupta & Eric Maskin, *Efficient Auctions*, 115 Q.J. Econ. 341, 342 (2000) (discussing the market inefficiency that results when buyers attach values to goods independent of information to which other buyers may have access).

[138] *See What is Digital Scarcity?*, NBX, https://nbx.com/crypto101/what-is-digital-scarcity (last visited Nov. 24, 2022).

[139] *See* U.S. Const. art. I, § 8, cl. 8.

[140] Baldia, *supra* note 136, at 31.

rules vary based on jurisdiction, and the exclusive rights a jurisdiction grants to its IP holders can be exercised only within the borders of that specific jurisdiction.[141] Consequently, federal NFT licensing statutes would be effective within only the United States and would likely complicate international NFT transactions because IP rights granted or denied in the United States would not obligate any other jurisdiction to recognize those rights within its borders.[142]

In contrast to federal licenses, the Creative Commons, on which an NFT CC would be based, is an internationally-recognized phenomenon that has been translated and adapted for the legal rules of over thirty-four countries.[143] Drawing from the collaborative copyright model, the Creative Commons is engaged in the International Commons Project, which posts and translates licenses to myriad legal jurisdictions.[144] Moreover, in recent years, the scientific and academic communities have generated Creative Commons spin-offs, with successful implementation both domestically and abroad.[145] Analogous to these spin-offs, an NFT CC would similarly be able to work within the existing international Creative Commons framework.[146]

From a Coasean market efficiency perspective, international NFT sales are subject to additional layers of transaction costs, which domestic NFT sales do not face, and these additional costs further impede NFT transactions and contribute to inefficient economic behavior.[147] Not only is there information asymmetry

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[141] *See id.* at 25–26.

[142] *See id.* at 26–27 (noting that (1) legal diversity is "deeply rooted in the principles of territoriality and independence of rights enshrined in the public international IP law," (2) these "independence of rights" principles imply that "an IP right granted or denied to an IP right holder by one jurisdiction does not obligate any other jurisdiction to do so within its borders," and (3) "[t]he nature and scope of IP rights in different countries can…modulate depending on…jurisprudential, social, political, and economic factors.").

[143] Loren, *supra* note 115, at 287.

[144] § 4. Atypical Developments and Other Legal Issues, Int'l Ency. Cyber L. (Wolters Kluwer 2022) (last updated Oct. 2022), at ¶¶ 394-95 (discussing iCommons and Creative Commons' international recognition).

[145] Ashley West, *Little Victories: Promoting Artistic Progress Through the Enforcement of Creative Commons Attribution and Share-Alike Licenses*, 36 Fla. St. U. L. Rev. 903, 904–05 (2009) ("…Creative Commons has stimulated several recent spin-offs, such as the Science Commons and CCLearn, which are similar licensing regimes for the scientific and academic communities.").

[146] *See id.*

[147] *See* Baldia, *supra* note 136, at 23–25 (noting that parties bargaining internationally "…may incur high transaction costs, knowingly or unknowingly, ex ante in search and bargaining costs, or ex post in enforcement costs, or both…" and transaction costs which are "too high relative to the transaction value…can

inherent in the NFT sale itself—the same asymmetry currently present in *all* NFT sales with which this note is primarily concerned—but from the international vantage, there are also transaction costs associated with negotiating and navigating multi-jurisdictional IP rights that may or may not transcend territorial bounds.[148] Implementing an NFT CC would not only alleviate the information asymmetry in the NFT sale, for the reasons stated above, but an NFT CC could also potentially mitigate tension-inducing discrepancies between jurisdictions by working within the existing Creative Commons architecture.[149]

More generally, the importance of increasing and facilitating international IP exchange cannot be overstated.[150] An efficient international IP network not only enhances global problem solving, but also promotes best-use knowledge sourcing and idea-generation.[151] An NFT CC would encourage open innovation by streamlining multi-jurisdictional NFT transactions with its internationally-accepted, recognizable, and transparent licensing system. An NFT CC would significantly decrease the transaction costs associated with international NFT sales and would ultimately ensure that the NFT market allocates NFT IP rights to those who value them most.[152]

B. An NFT CC Would Support Auction Houses & NFT Market Access

An NFT CC would benefit auction houses by facilitating NFT sales' ease and predictability.[153] Recent economic trends speak to consumers' growing awareness that art should be treated as an investment first and consumption good second.[154] This understanding of art as an investment underscores the necessity of stable price-setting processes that promote sophisticated, streamlined efficiency throughout

impede transactions…resulting in inefficient economic behavior…" Under the Coase theorem, "the higher the transaction cost, the less likely the IP exchange transaction will be made.").

[148] *Id.* at 27.

[149] *See* West, *supra* note 145.

[150] *See* Baldia, *supra* note 136, at 3.

[151] *Id.* at 15.

[152] *See id.* at 25 ("Viewed through a Coasean prism, high transaction costs can be a threat to the ability of the market to allocate IP to those participants that value it the most.").

[153] *See* Dasgupta & Maskin, *Efficient Auctions*, 115 Q.J. Econ. 341, 342 (2000) (discussing the market inefficiency that results when buyers attach values to goods independent of information to which other buyers may have access).

[154] M.A. Louargand & J.R. McDaniel, *Price Efficiency in the Art Auction Market*, 15 J. Cult. Econ. 53, 53 (1991).

the auction process from acquisition to sale.[155] Works of art are quasi-financial instruments, so in order for the art market to run efficiently, it must meet the same standards established for financial markets.[156] An efficient market is one in which "prices which prevail at any time are found to be an unbiased representation of *all currently available information.*"[157] A competitive, efficient, and "fair game" auction house market is one in which a work's price at auction closely approaches what the purchaser realistically expected to pay.[158] Consequently, because "[c]ollectors typically specialize in one or more categories of art,"[159] auction houses with experts in those categories will be better equipped to accurately estimate efficient selling-price ranges.[160]

With these efficiency benefits in mind, the necessity of an NFT CC for large auction houses becomes apparent. Not only would an NFT CC promote the unbiased representation of "all currently available information," but it would also afford NFT collectors and sale experts the opportunity to immerse themselves in the NFT CC's non-volatile framework where each license brings with it clear, established, and unbiased conditions of ownership. This NFT CC infrastructure would enable NFT creators and purchasers to approach the auction process with the assumption that they are entering a "fair game" market with symmetrical information.[161] Establishing realistic market expectations around NFT sales would also allow for collector and curator specialization, contribute to NFT's stability and versatility as an emerging asset class, and make auction houses more likely to participate in the NFT art market.[162]

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[155] *Id.*

[156] *Id.* at 53–54.

[157] *Id.* at 54 (emphasis added).

[158] *Id.* at 57.

[159] *Id.* at 58.

[160] *See* William Z. Hodges, Capstone, *The Value of Estimating the Price of Art: A Lesson for Auction Houses*, WRLC (Fall 2011/Spring 2012), *available at* https://islandora.wrlc.org/islandora/object/1112capstones%3A217/datastream/PDF/view (noting that auction house experts set estimation ranges that "[signal] to buyers the experts' confidence in a work's value," and suggesting that "[b]y publishing an estimation window, an auction house asserts…that the [work's] true value is within that window.").

[161] *See id.* at 57.

[162] *See generally* Rocco Puno, *The Democratization of Fine Art: How Much for 0.02% of That Picasso?*, Harv. Bus. Sch. Digit. Initiative (Oct. 17, 2019), https://digital.hbs.edu/platform-digit/submission/the-democratization-of-fine-art-how-much-for-0-02-of-that-picasso/.

C. An NFT CC Would Protect Digital Scarcity

NFTs introduced digital scarcity into the market and starkly shifted the conversation around allocative efficiency and copyright.[163] At its core, digital scarcity is the notion that a digital asset may be coded to have a permanently limited supply.[164] This concept of a limited digital asset runs contrary to the traditional understanding of digital assets as being subject to potentially limitless replication and copies.[165] NFT's utilization of blockchain technology to credibly maintain the asset's uniqueness transformed the modern conception of what may be an "original" source where artistic provenance is concerned.[166] Though NFTs introduced and reified digital scarcity's prominence and legitimacy, they are but one example of how blockchain technology may be leveraged to both enable unique digital property ownership and establish the necessary infrastructure for other blockchain-based relationships.[167] As such, any copyright solution that affects NFT viability, sales, distribution, and use, will likely also influence future legal frameworks surrounding novel examples of digital scarcity.[168]

D. An NFT CC Would Encourage & Protect Innovation

Perhaps most compelling, an NFT CC would support exploration of NFT's untapped potential uses, particularly in the generative art space. Generative art is, in essence, a form of digital art that continually updates itself based on the artist's set parameters and algorithms.[169] In this way, generative art conceptualizes an

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[163] *See* Neil Weinstock Netanel, *Copyright and a Democratic Civil Society*, 106 YALE L.J. 283, 319 (1996) ("[Traditionally], private entitlements . . . best promote allocative efficiency when would-be users must pay the price agreed upon by the *entitlement holder* in a voluntary exchange.") (emphasis added).

[164] *What is Digital Scarcity?*, NBX https://nbx.com/crypto101/what-is-digital-scarcity#:~:text=Digital%20scarcity%20is%20the%20idea,million%20bitcoins%20in%20its%20code (last visited Nov. 24, 2022).

[165] *See id.*

[166] Jaya Klara Brekke & Aron Fischer, *Digital Scarcity*, 10 INTERNET POL'Y REV. 2, 5 (2021) ("The rise of NFTs has led to experiments with new types of digital property where 'the broader intention does not appear to be to reduce the circulation and reproduction of the work . . . .' This . . . implies producing a digital 'original' where its source and provenance is considered important enough to be able to acquire value as a 'unique' digital object . . . .").

[167] *Id.*

[168] *See generally id.* ("As more advanced and general-purpose blockchain networks [appear], the scope for scarce ledger entries [grows].").

[169] *See* AI Artists, *Generative Art Guide: Examples, Software and Tools to Make Algorithm Art*, AI ARTISTS, https://aiartists.org/generative-art-design (last visited Mar. 10, 2022).

artistic work as a "living system," capable of responding to code.[170] There has been a long tradition of generative art since the 1940s,[171] but the introduction of NFTs has allowed artists to put the code for these generative works entirely on the blockchain and implement blockchain transactions as part of the generative work's algorithm.[172] For example, pieces of generative art minted as NFTs may alter their appearance as purchasers buy and sell these generative works on the blockchain.[173] Minting generative art NFTs adds a level of previously unobtainable uniqueness and scarcity to digital works, which many digital artists view as a welcome paradigm shift in a digital art world otherwise plagued by the possibility of limitless reproduction.[174] In fact, the NFT platform Art Blocks is dedicated entirely to generative art NFTs.[175] On this platform, generative artists are able to upload algorithms from which purchasers may subsequently mint NFTs.[176] With the generative art NFT ecosystem in mind, it is clear that generative artists would benefit from the ability to include specific NFT CC licenses within their works' initial parameters, and both purchasers and subsequent NFT creators would also be able to take advantage of the NFT CC's established licensing boundaries.

In the modern art world, bolstering art NFTs' accessibility, supporting art NFTs' novel uses, and promoting art NFTs' transaction efficiency is paramount

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[170] Brian Droitcour, *Generative Art and NFTs*, Art News (Mar. 11, 2021, 4:12 PM), https://www.artnews.com/list/art-in-america/features/generative-art-and-nfts-1234586572/.

[171] *See* David Z. Morris, *How NFTs Put Generative Artists on the Map*, CoinDesk (Dec. 17, 2021), https://www.coindesk.com/layer2/culture-week/2021/12/17/how-nfts-put-generative-artists-on-the-map/ (noting that in the 1940s, prominent creatives began to explore "ideas of procedure and randomness." For example, composer John Cage and choreographer Merce Cunningham used "chance operations such as flipping a coin to determine the length of a note.").

[172] *Id.*

[173] *Id.*

[174] *See* Leeor Shimron, *The NFT Generative Art Movement is Challenging How We Think About Value*, Forbes (Sept. 8, 2021), https://www.forbes.com/sites/leeorshimron/2021/09/08/the-nft-generative-art-movement-is-challenging-how-we-think-about-value/?sh=1ddfddc478ae ("[G]enerative art projects often programmatically enforce a supply cap on the total amount of pieces that can be produced, which typically has been ∼10,000 unique NFTs per collection. . . creators may [also] include specific attributes. . . [which] imbu[e] additional scarcity and value to NFTs that have those rare traits.").

[175] Morris, *supra* note 131.

[176] Morris, *supra* note 131; *see Latest Curated Release*, Art Blocks, https://www.artblocks.io/ (last visited Mar. 10, 2022).

to ensuring continued purchaser engagement and societal recognition.[177] In November of 2021, Beeple sold *Human One*, a generative NFT kinetic hybrid sculpture, for $29 million.[178] The work portrays a video sculpture with a corresponding dynamic NFT component and is designed to continuously evolve over time.[179] Beeple, through the NFT aspect, retains remote access to the artwork and has creative control over its content forever.[180] *Human One* dabbles with the physical realm and is a seven-foot-tall, box-like sculpture with four LED screens that project video images of an astronaut walking through various dystopian environments.[181] The displays featured on the screens are stored on the Ethereum blockchain and change randomly every twenty-four hours.[182] Beeple plans to add new designs to the blockchain—a feat made possible through a more flexible interpretation of the work's corresponding NFT—meaning that as Beeple evolves, so too will the work.[183] In an interview with Christies, Beeple called *Human One* a "lifelong project, . . . [one where] people can continue to come back . . . and find new meaning in [it]."[184] Beeple additionally contemplated generative art's paradigm-shifting capacity, noting that "[while] traditional . . . art is more akin to a finite statement, frozen in time . . . [Human One's] ability to be updated makes it . . . an ongoing conversation."[185] An NFT CC would protect and embolden innovative NFT interpretations, like Beeple's generative kinetic sculpture, by establishing clear licensing terms for continuous artistic revisions and other forms of innovative NFT uses.

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[177] *See* Shimron, *supra* note 174 ("…early stewards of the [generative art NFT] movement believe it is ushering in a new digital renaissance enabling artists to reach a global audience and experiment with a new medium that is engaging collectors on a deeply emotional level.").

[178] *Beeple's 'Human One' Generative NFT Sculpture Sells for $29 Million USD*, HypeBeast (Nov. 11, 2021), https://hypebeast.com/2021/11/beeple-human-one-nft-29-million-christies-auction.

[179] *Id.*

[180] *Id.*

[181] Ryan Waddoups, *Beeple's First-Ever Physical Sculpture Evolves Over Time*, SurfaceMag (Nov. 02, 2021), https://www.surfacemag.com/articles/beeple-human-one-christies/.

[182] *Id.*

[183] *Id.*

[184] *Beeple Gets Real*, Christie's, https://www.christies.com/features/Beeple-gets-real-with-human-one-11940-7.aspx.(last visited Nov. 24, 2022) (interview by Noah Davis, Head of Digital Art, Christie's, with Mike Winkelmann aka Beeple).

[185] Waddoups, *supra* note 181.

Conclusion

NFTs have ushered in a novel era of creative expression and ownership, but with this phenomenon comes an array of unprecedented legal issues. Neither traditional copyright nor property law conforms to creator or purchaser expectations, and these conflicting expectations hamper NFT sales' efficiency.[186] On the one hand, authors of original works are unprotected when purchasers mint NFTs from those original works.[187] On the other hand, NFT purchasers often do not understand that they own no proprietary copyright interest in the NFT, and that NFT creators may mint subsequent, additional NFTs from the same underlying asset.[188] The suggested copyright solutions, like expanding VARA to include NFTs or coding a de facto resale right into an NFT's terms of sale, may protect NFT creators, but these solutions are not expansive enough to include uninformed NFT purchasers, whose NFT investments may be devalued if creators mint subsequent NFTs from the same, or substantially similar, underlying assets. The lack of transparency surrounding NFT sales results in information asymmetry, particularly from the purchaser's perspective, which makes the current mitigation measures insufficient.[189] Smart contracts, though an efficient implementation mechanism, do little in the way of lowering the transaction costs associated with brokering a sale between an NFT creator and ill-informed NFT purchaser.[190]

The NFT market needs a solution that would (1) permit NFT creators and purchasers to know precisely what rights they are entitled to post-sale and (2) make NFT sales more efficient by mitigating information asymmetry and decreasing the

[186] Kohn, *supra* note 8, at 8; *see generally* Samuels, *supra* note 8.

[187] Lewis et al., *supra* note 9.

[188] *Id.*

[189] Joshua A.T. Fairfield, *Tokenized: The Law of Non-Fungible Tokens and Unique Digital Property*, 97 Ind. L.J. 1261, 1303 (2022) (recognizing that NFT purchasers face a particular information hurdle in NFT sales and proposing that a warranty (which would be similar to, but narrower in scope than, an NFT CC) "would. . . act as an important counterbalance to power and information asymmetry in the NFT market. Those who know and make a living from the sale of NFTs would be held to the standard of the warranty, while those who merely purchase the assets and sell them occasionally to someone else would not.").

[190] Cong & He, *supra* note 16 (an ill-informed purchaser would not be able to reach a "decentralized consensus" with a knowledgeable NFT creator without additional information, and the smart contract cannot bridge that information divide. Smart contracts automatically execute "contingencies reached based on [the] decentralized consensus." Consequently, when one of the contracting parties is ill-informed, the smart contract—despite being efficient from an implementation perspective—remains inefficient because its terms reflect contingencies based on a non-consensus).

transaction costs associated with uninformed negotiation. To wit, it needs an NFT CC. An NFT CC, by employing a design like the traditional three-layer Creative Commons structure, would both define how the NFT creator and purchaser may utilize the NFT and its underlying asset post-sale and also lower NFT transaction costs by increasing NFT sales' efficiency and reliability. Affixing an NFT CC license to an NFT prior to its sale would remedy the stark information asymmetry that currently plagues the NFT transaction framework. These licenses would put purchasers on notice of precisely how they may utilize their NFT and, crucially, alert the purchaser to whether the NFT creator retains the right to mint additional NFTs that are substantially similar to the initial purchaser's. An NFT CC would also promote public policy by its ability to bolster the international IP market, stabilize the price-setting processes for auction houses, and contribute to the broader legal discussion around unique digital asset ownership and blockchain-based relationships.

At their core, NFTs are a fresh, contemporary medium in a long journey of human artistic expression. It is therefore unsurprising, given the historically well-established interplay between art and investment, that both NFT creators and purchasers enter transactions hoping to exploit NFTs' investment potential.[191] Current marketplaces are working in real-time to facilitate this exchange of value; yet, because these marketplaces are hobbled by information inequities and inefficient transaction mechanisms, they often fail to convey each parties' copyright interests post-sale.[192] The current contractual solutions that cannibalize copyright and traditional property theories of ownership are unsurprisingly proving insufficient to meet the contemporary and seemingly limitless forms of expression and investment opportunities that NFTs enable.[193] NFTs warrant a novel licensing

[191] Louargand & McDaniel, *supra* note 154.

[192] *See* Dasgupta & Maskin, *supra* note 137.

[193] *See* Jeremy M. Evans, *Practice Tips: A Primer on Digitalizing Sports Collectibles*, L.A. Law. 10, 12 (2021) ("The copyright, contract, privacy, security law, and money issues created by NFTs are substantial…"); *see also* Rebecca Carroll, *NFTs: The Latest Technology Challenging Copyright Law's Relevant Within a Decentralized System*, 32 Fordham Intell. Prop. Media Ent. L.J. 979, 984–85, 994–95 (2022) (highlighting that NFTs' non-fungibility can be challenging to comprehend because "[o]ne person's use of the intangible image…does not interfere with the NFT owner's use of their tangible asset," and that although copyright owners who wish to "voluntarily transfer all or certain specific rights…may do so by way of a contract," the contractual solution has proved complicated in practice, and that copyright infringement "run[s] rampant in the NFT space.").

approach—one that draws from the Creative Commons framework in order to embrace digital scarcity and effectively convey reliable information—on which both NFT creators and purchasers can act. An NFT CC, with its focus on clarity, transparency, and flexibility, would establish the necessary infrastructure on which to build a sustainable, reliable, and efficient NFT marketplace.