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Statement of Purpose

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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A nonpartisan periodical, the Journal is committed to presenting diverse views on intellectual property and entertainment law. Accordingly, the opinions and affiliations of the authors presented herein do not necessarily reflect those of the Journal members.

The Journal is also available on WESTLAW, LEXIS-NEXIS and HeinOnline.

PREFACE

Our Spring 2020 issue, Volume 9, Issue 2, is comprised of five individual pieces that explore significant, current themes in intellectual property and entertainment law, ranging from providing guidance from practice and experience, to questioning the very underlying legal framework of trademark law. In fact, each piece in this issue is focused on one of the fundamental areas of intellectual property law—trademark, copyright, and patent—but each intersects vitally with other disciplines from both inside and outside the world of IP, ranging from the music and entertainment industries, to history, to antitrust, to regulatory law.

In their essay, Justin F. McNaughton, Ryan Kairalla, Leslie José Zigel, and Armando Christian Perez (known professionally as Pitbull) illustrate their efforts in obtaining a sound trademark in Pitbull's famed yell, also known as a *grito*, for use in live and recorded musical performances. This effort illustrates the first time the United States Patent and Trademark Office (USPTO) has issued a trademark in the principal register for musical sound recordings. McNaughton, Kairalla, Zigel, and Perez illustrate the important impacts that obtaining this trademark will likely have both on the music industry and the entertainment industry more broadly.

Charles Duan provides an insightful and probing historical analysis of copyrights in the text of the law. In his article, Duan argues that States are incorrect in claiming a copyright interest in their official published codes of law. This article, and the argument contained therein, is particularly timely and important: in late April 2020, the United States Supreme Court ruled in *Georgia v. Public.Resource.Org, Inc.* that non-binding legal materials, such as annotations to state statutes, are not copyrightable. Duan models his article on an amicus brief he authored and submitted as part of the litigation, and it provides an in-depth, and often overlooked, historical analysis of practices in this area.

Moving to the student notes in Volume 9, Issue 2, Daniel Lifton's first analyzes the current state of trademark law, particularly with regards to the "Likelihood of Confusion" standard for trademark infringement liability. Lifton explains why this approach does not work across all types of confusion (such as post-sale confusion) and advocates the introduction of a "trademark rule of reason," similar to that found in antitrust law, to cover infringement liability where appropriate. In doing this, Lifton highlights trademark law as a species

of competition policy and carefully and completely addresses why the introduction of a rule of reason standard would better advance the goals and aims, broadly speaking, of trademark law.

Next, Sarah Sue Landau's note explores the vital intersection between copyright law and trademark law, deftly analyzing the history of Mickey Mouse and the famous character's impending expiring copyright. In particular, Landau looks at challenges surrounding overlapping protection—that is, when something receives both copyright and trademark protection—and works to provide a clear set of recommendations for ameliorating the current dilemma. Landau's analysis illustrates the broad set of options that courts, legislatures, and copyright- and trademark-holders have in navigating this complex legal landscape.

Finally, I present my own note, which discusses the intersection of patent term extension (PTE) and the FDA regulatory approval process for pharmaceutical products. PTE is a statutorily-granted extension in patent term meant to compensate for the time that it takes for a pharmaceutical product to go through the regulatory approval process. In particular, I look at the current challenges of applying patent term extension provisions to current, novel therapeutics. I aim to establish a new path forward, proposing a way for the law to catch up more quickly and efficiently with the rapid developments in the world of clinical therapeutics.

I hope that you enjoy this issue. On behalf of the 2019–2020 *JIPEL* editorial board, I thank all of you for following our work through the past year and Volume, and I hope that you will continue to read Volume 10 and beyond.

Sincerely,

Nicholas G. Vincent, PhD
Editor-in-Chief
NYU Journal of Intellectual Property & Entertainment Law

NEW YORK UNIVERSITY

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VOLUME 9 SPRING 2020 NUMBER 2

ESSAY

EEEEEEEYOOOOOO!: REFLECTIONS ON PROTECTING PITBULL'S FAMOUS *GRITO*

JUSTIN F. MCNAUGHTON, ESQ., RYAN KAIRALLA, ESQ., LESLIE JOSÉ ZIGEL, ESQ., AND ARMANDO CHRISTIAN PEREZ*

> *"I've worked so hard on crafting my sound and my brand over the years, and I am so pleased that the United States Patent and Trademark Office has awarded me trademark registrations in my original "Eyo" chant for musical sound recordings and live performances. ¡Dale!"*
>
> *-Pitbull*

PROLOGUE

Immediate recognition is the epitome of success for musical artists. Few artists attain the level of success at which fans easily identify their sound from a mere snippet of a track, joining the ranks of artists like Frank Sinatra, Dolly Parton, The Grateful Dead, Bob Dylan, and Ella Fitzgerald. Their unique sounds are almost immediately recognizable and easily distinguished from other artists in their genres. In the modern rap and pop world, Pitbull has attained this level of notoriety. Audiences easily recognize his raspy voice and his approach to rap, but it is his *grito* (yell), "EEEEEEEYOOOOOO!" that clinches it. This trademark yell—pun intended—sets him apart from all other artists, giving him a distinctive sound that is part of virtually every song that he performs and serves as a musical transition when he begins to rap. The U.S. Patent and Trademark Office ("USPTO") recently awarded trademark registrations to him for this yell for both sound recordings and for live performances. The registration of a sound trademark in the principal register for musical sound recordings is, to our knowledge, the first for the USPTO. This essay will offer some reflections and background on these registrations from Pitbull and the trademark attorneys who worked on the filings.

I
BACKGROUND

When listening to his music, Pitbull fans know to expect catchy and danceable hip hop beats, the acclaimed rapper referring to himself as "Mr. Worldwide" and "Mr. 305" on the track, and exclamations of "¡*Dale*!" (pronounced "DAH-lay," which literally means 'Hit it!' but in context means "'Let's Go!" Or "Let's Do This!"). His fans also know to expect a fantastically identifiable *grito* that he developed during his early club days. With a quick "EEEEEEEYOOOOOO!," listeners around the world know a Pitbull track when they hear it, regardless of their language or the musical genre.

In June 2017, Colombian singer J Balvin and French producer Willy William released the song "Mi Gente."[1] The track was a massive hit that *Pitchfork* dubbed "a certified banger from the moment it dropped."[2] Almost immediately after its release,

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[1] J Balvin, *J Balvin, Willy William—Mi Gente (Official Video)*, YOUTUBE (June 29, 2017), https://www.youtube.com/watch?v=wnJ6LuUFpMo.

[2] Matthew Ismael Ruiz, *J Balvin/Willy William "Mi Gente" [ft. Beyonce] (Remix)*, PITCHFORK (Sept. 29, 2017), https://pitchfork.com/reviews/tracks/j-balvin-and-willy-williams-mi-gente-ft-beyonce-remix/.

Pitbull began to receive praise for his guest appearance on the track.[3] As a frequent collaborator on songs with other fellow superstar artists, Pitbull's work on "Mi Gente" appeared to be just the latest in a long string of well-received team-ups for the Grammy-winning artist.

There was just one small wrinkle: Pitbull was not in "Mi Gente."

So why did people think that he was? We'll talk more about the impact that hearing Pitbull's *grito* in that song had on audiences around the world later in this essay.

II
EVOLUTION OF A *GRITO*

Pitbull's *grito* has become iconic. It allows fans instantly to recognize a Pitbull song or performance, whether in a live performance or in a musical recording, and serves as a distinctive call sign. This is intentional. At least as early as 2002, Pitbull began consistently using this *grito* to identify his performances, and over the years, it has been carefully curated.

As a young man coming up in Miami's nightclub scene, Pitbull's *grito* evolved as a way to communicate with friends that he was in trouble (and he'll be the first to tell you he's a lover not a fighter). He initially used his *grito* as a distinctive signal to alert friends that a situation was escalating: "Hey, I'm in trouble here. Hurry over!"[4]

Over time, Pitbull's iconic *grito* has become emblematic of his presence on a stage or in a song. It puts his stamp of ownership on a song even though the sound, style, and even the language of the track may be unfamiliar to the listener.

It's also a sly tip of the hat to the Cuban-American rapper's Mexican-American fans—likely one of the largest segments of his fanbase in the US. Pitbull's yell finds its inspiration from the traditional Mexican *grito*, a loud shout of joy or excitement that is commonly associated with Mexican culture.[5] As part of that

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[3] Personal Interview with Armando Christian "Pitbull" Perez (Feb. 1, 2020); Personal Interview with Bill Teck (Feb. 1, 2020).

[4] Perez Interview, *supra* note 3; Teck Interview, *supra* note 3.

[5] Brenda Salinas, *In Mariachi Music, A Distinctive Yell Speaks To The Soul*, NPR (Aug. 23, 2016, 4:34 AM), https://www.npr.org/sections/codeswitch/2016/08/23/488502412/in-mariachi-music-a-distinctive-yell-speaks-to-the-soul.

tradition, it is not uncommon for each person in a family to have his or her own distinctive *grito*.[6] That concept is not lost on Pitbull—his *grito* is unique.

Alt.Latino host Felix Conteras echoed this sentiment in a 2016 NPR interview: "I am pretty sure I could identify my *tíos* and *tías* [uncles and aunts] by their *grito*s, and many Mexican-American children begin finding their own *grito* voice early."[7] The tradition of Mexican "signature *grito*s" makes for one of the best moments in the 2016 film *Coco*, when Anthony Gonzalez's Miguel is asked for his best *grito* by Gael García Bernal's Hector as he's coaching him to go on stage.[8] And a quick YouTube search for "Mexican *grito*" will lead you down a rabbit hole of hours of proud moms and dads helping their children develop their own signature yells.

III
GRITO SCIENCE

Why is Pitbull's scream so effective? In short, researchers have made a case for the personalized nature of yells like Pitbull's *grito.* In a study entitled *Human Screams Occupy a Privileged Niche in the Communication Soundscape*, researchers studying brain patterns of humans reacting to screams found that "acoustic roughness [in yells] engages subcortical structures critical to rapidly appraise danger . . . [and] occupy a privileged acoustic niche that, being separated from other communication signals, ensures their biological and ultimately social efficiency."[9] The researchers concluded that screams and yells are "particularly difficult to predict and ignore."[10] It is almost impossible to ignore Pitbull's signature *grito*—in a club or in a song.

Pitbull's creation of a unique yell to alert friends in a loud nightclub setting was a highly effective tactic for getting their attention in the early days of his career. Today, his *grito* has evolved, serving a new purpose: to let people know that they are listening to a Pitbull song. The Pitbull *grito* is as much a part of Pitbull's brand as his "¡*Dale*!" catchphrase or even Pitbull's stage name itself.

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[6] *Id.*

[7] *Id.*

[8] COCO (Walt Disney Pictures 2017).

[9] Luc H. Arnal et al., *Human Screams Occupy a Privileged Niche in the Communication Soundscape*, 25 CURRENT BIOLOGY 2051, 2051 (Aug. 3, 2015).

[10] *Id.*

IV
IMPORTANCE OF PITBULL'S *GRITO* IN PERFORMANCES

Pitbull uses his *grito* as a sort of sonic signature. It is a critical component of his branding. Use of this distinctive *grito* is one of the hallmarks of Pitbull's style that separates him from other artists.

Bill Teck is a journalist who has been creating a recorded history of Pitbull and has known Pitbull since the early days of the artist's career. Teck reflects that he "first met Pitbull back when he was a teenager in 2000. I've watched [Pitbull's] career blossom and spent plenty of time thinking about his music beyond the irresistible hooks and pop craftsmanship. And one constant element I've identified across nearly all of his songs is his trademark yell, 'EEEEEEEYOOOOOO.'"[11]

Musicians face a challenge when they stray from their core genre. Fans may altogether miss an artist in a song if it sounds unfamiliar to what they're accustomed to hearing. Pitbull uses his *grito* as an innovative way to circumvent this problem. His *grito* announces that a song is a "Pitbull" song, even though the sound, style, and the language of the track may be unfamiliar to the listener. It is featured in songs where he is the lead artist, and it is also featured on tracks where he makes a guest appearance.[12] For the recordings in the latter group, Pitbull's *grito* frequently serves as a signal to listeners that "Mr. Worldwide" is about to rap a verse on another artist's track. The yell allows him to weave a common thread through the disparate song styles of his biggest hits. For example, "Timber" is country pop, while other songs of his are hip hop, Latin pop, or Middle Eastern pop; they all are connected by his *grito*. Even when dabbling in rock songs such as 2017's "Bad Man," the *grito* is there, announcing to everyone, "This is a Pitbull track!"

Pitbull's fans celebrate his iconic *grito* with memes and videos. One fan created a 3:31 minute video of back-to-back sound clips of Pitbull's *grito* from dozens of his tracks.[13] In another particularly clever video, with over 500,000 views,

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[11] Teck Interview, *supra* note 3.

[12] *See, e.g.*, PITBULL, I KNOW YOU WANT ME (CALLE OCHO) (Sony Music 2009) (1:10); PITBULL, FIREBALL (FEAT. JOHN RYAN) (Sony Music 2014) (0:45); PITBULL, TIMBER (FEAT. KESHA) (Sony Music 2013) (0:36); JENNIFER LOPEZ, ON THE FLOOR (FEAT. PITBULL) (Island 2011) (3:18); ENRIQUE IGLESIAS, I LIKE IT (feat. Pitbull) (Universal Republic 2010) (0:06); PRIYANKA CHOPRA, EXOTIC (FEAT. PITBULL) (Interscope 2011) (0:31).

[13] ExtremeenterpriseV2, *Pitbull Yell Compilation*, YOUTUBE (Sept. 22, 2014), https://www.youtube.com/watch?v=lCkEHBNLtO4.

a fan overlaid audio from 25 of Pitbull's songs, and what begins as a cacophony culminates in Pitbull's *grito* playing simultaneously across all of the tracks.[14]

V
THE LAW OF SOUND TRADEMARKS

The Lanham Act defines the term "trademark" to include "any word, name, symbol, or device, or any combination thereof . . . used by a person . . . to identify and distinguish his or her goods, including a unique product, from those manufactured or sold by others and to indicate the source of the goods, even if that source is unknown."[15] The Second Circuit has stated that, "[i]n expanding the universe of symbols and devices eligible for trademark protection, the Supreme Court has identified other attributes that are capable of conveying meaning to a consumer, for example, the shape of a product, its scent, a particular sound, and color. These attributes are entitled to protection under the Lanham Act."[16]

Trademarks provide valuable benefits to producers and consumers alike. "A [trade]mark's source distinguishing ability allows it to serve those basic purposes that gave birth to trademark law in the first place; that is, to ensure that a product's maker reaps the rewards of the reputation it has built, and to enable consumers to recognize and repurchase goods with which they have previously been satisfied."[17]

Sound trademarks belong to a special group of trademarks referred to as "sensory" trademarks that are not capable of a visual representation, such as sounds, colors, and smells. Comparatively few sensory trademarks ever attain registration. The first sound trademark was filed by The National Broadcast Company in 1947 to protect its famous chime sequence.[18]

Years later, the Trademark Trial and Appeal Board of the USPTO (the "Board") held:

> a sound mark depends upon aural perception of the listener which may be as fleeting as the sound itself unless, of course, the sound is so inherently different or distinctive that it attaches to the subliminal mind of the listener to be awakened when heard and to be associated with the

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[14] Oisín Quinn, *Every Pitbull song*, YOUTUBE (June 15, 2017), https://www.youtube.com/watch?v=bxRzsgtvakY.

[15] 15 U.S.C. § 1127 (2018).

[16] EMI Catalogue P'ship v. Hill, Holliday, Connors, Cosmopulos Inc., 228 F.3d 56, 62 (2d Cir. 2000) (citing Qualitex Co. v. Jacobson Prods. Co., 514 U.S. 159, 162 (1995)).

[17] *Id*.

[18] Registration No. 523,616 (NBC Chimes—*i.e.*, the musical notes G, E, C played on chimes).

> source or event with which it is struck. Thus, a distinction must be made between unique, different, or distinctive sounds and those that resemble or imitate 'commonplace' sounds or those to which listeners have been exposed under different circumstances.[19]

In other words, the Board confirmed that sounds can be trademarks.[20] However, the Board made a distinction between sounds that are uncommon and sounds that are familiar or even commonplace.[21] In its holding, the Board required a showing of acquired distinctiveness as a prerequisite to obtaining a trademark registration for sounds that can be considered familiar or of a common type.[22] Said in a different way, people yell all the time, so in order for a particular yell to become a trademark, it must acquire distinctiveness so that people recognize that it identifies a source rather than simply being a random yell.

Whenever a sound is familiar to most people, evidence must be provided that the trademark is, in fact, recognized by people to identify the source of a particular product or service.[23] This can be shown by evidence of "1) the length and manner of [its] use, 2) the nature and extent of advertising and promotion, and 3) other efforts at creating a conscious connection in the public's mind between the designation and the service."[24]

For example, one of the most famous sound trademark cases involved a duck call.[25] The case involved two amphibious boat tour operators (yes, those unsafe-looking WWII boats with Jeep tires on them).[26] In that case, one of the boat operators had obtained a federal trademark registration for blowing a duck call during a tour.[27] The particular services registered were "tour guide services over land and water by amphibious vehicles."[28] In that case, the court held that the sound of quacking was

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[19] In re Gen. Elect. Broad. Co., 199 U.S.P.Q. (BNA) 560, 563 (Trademark Tr. & App. Bd. 1978).

[20] *Id.*

[21] *Id.*

[22] *Id.* (stating that familiar or common sounds "must be supported by evidence to show that purchasers, prospective purchasers and listeners do recognize and associate the sound with services offered and/or rendered exclusively with a single, albeit anonymous, source").

[23] Am. Diabetes Ass'n, Inc. v. Nat'l Diabetes Ass'n, 533 F. Supp. 16, 19 (E.D. Pa. 1981).

[24] *Id.*

[25] Ride the Ducks, LLC v. Duck Boat Tours, Inc., 75 U.S.P.Q.2d 1269 (E.D. Pa. 2005).

[26] John Eligon et al., *Missouri Duck Boat Accident Kills 17, Including 9 From Same Family*, N.Y. TIMES (July 20, 2018), https://www.nytimes.com/2018/07/20/us/duck-boat-branson-accident.html.

[27] *Ride the Ducks*, 75 U.S.P.Q.2d at 1271.

[28] *Id.*

too familiar a noise to qualify as being inherently distinctive. Additionally the court held that the trademark owner did not submit evidence that customers actually associated the sound of a duck call with the services offered by the tour company (*i.e.*, "that a person apprehending a quacking noise on the streets of Philadelphia would reflexively think of the services provided by [plaintiffs]").[29] As quipped by Gilson on Trademarks, "[o]ne can only envision with wonderment a consumer survey interviewer stopping Philadelphia citizens on Broad Street and inquiring of their quacking noise association, if any."[30]

Like duck calls, people hear yelling commonly. In order for a yell to acquire secondary meaning, significant effort must be made to make the public recognize that yell as a unique call sign for a unique purpose. As a result, while sound trademarks themselves are rare, sound trademarks for common or familiar sounds like yells are even more unusual.

For context, as of the date of this publication, there are more than 2.6 million active trademark registrations in the United States.[31] Of those, there are only about 250 active sensory trademark registrations in the United States (as of February 27, 2020).[32] Of those, about 234 are sound trademarks.[33] Of those sound trademarks, about 36 are of familiar sounds (without words accompanying the sound).[34] These sound trademarks have acquired distinctiveness and have become trademarks in the United States because the owners have used them so that people associate them with a particular good or service.

For additional context, examples of sound trademarks that are unusual and that did *not* require any showing of acquired distinctiveness include NBC's chime,[35] MGM's lion roar,[36] Lucas Film's THX sound,[37] and the NY Stock Exchange Bell.[38]

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[29] *Id*. at 1276.

[30] Jerome Gilson & Anne Gilson LaLonde, *Cinnamon Buns, Marching Ducks and Cherry Scented Racecar Exhaust: Protecting Nontraditional Trademarks*, 95 THE TRADEMARK REP. 773, 804 (2005).

[31] *Trademark Electronic Search System Database (TESS)*, UNITED STATES PATENT AND TRADEMARK OFFICE, https://www.uspto.gov/trademarks-application-process/search-trademark-database (last visited, Apr. 14, 2020). The data in this paragraph were collected, compiled, and analyzed by the authors of this paper.

[32] *Id.*

[33] *Id.*

[34] *Id.*

[35] The mark comprises the musical notes G, E, C played on chimes, Registration No. 916,522.

[36] Registration No. 1,395,550.

[37] Registration No. 1,872,866.

[38] Registration No. 2,741,129.

Examples of sound trademarks for familiar sounds that required a showing of distinctiveness include the sound of a Zippo lighter opening, igniting, and closing, [39] Apple's two successive C# tones that a person hears when calling upon their Siri virtual assistant,[40] and the clacking of typewriters for CBS Radio.[41] Many readers will instantly recognize these sounds, which is an indication that these sounds have acquired distinctiveness and now function as trademarks.

Another interesting attribute of Pitbull's *grito* trademark is the fact that consumers experience the mark in the course of experiencing the product itself. In most contexts, sound trademarks serve the function of a "jingle" for a product or service: they are a brand identifier of a product or service but are spatially and/or temporally disconnected in some way from the product or service itself. For example, Nationwide Insurance's popular "Na-tion-wide-is-on-your-side" jingle is a registered trademark for the company's financial and insurance services, but the mark itself is mainly featured in the company's advertisements and is typically not heard by consumers in the course of the services provided by Nationwide.[42] Similarly, Twentieth Century Fox's orchestral fanfare is a registered sound trademark for its motion pictures, but the sound itself appears in the opening logo branding that precedes their films, rather than in the films themselves.[43]

Not all sound marks are separated from their respective goods or services in this way. A smaller class of sound marks features sounds that are emitted by the actual product or service itself. At least one commentator has referred to these marks as "sound products."[44] The Federal Signal Corporation has such a "sound product" in the form of its registration in the sound that its siren makes.[45] Another example is TiVo's trademark for the unique popping noise a user hears when clicking through the Digital Video Recorder's menus.[46] "Consumers are much more predisposed to

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[39] Registration No. 5,527,388.

[40] Registration No. 4,689,365.

[41] Registration No. 5,635,561.

[42] Registration No. 5,394,152; *see, e.g.*, Mark Nave, *Nationwide Light Switch humor garage door*, YOUTUBE (May 19, 2006), https://www.youtube.com/watch?v=QBDrRl7d5ZA.

[43] The mark consists of nine bars of primarily musical chords in the key of B flat; the chords consisting of four, eighth and sixteenth notes, Registration No. 2,000,732; *see, e.g.*, Izzat Fr, *20th Century Fox Intro [HD]*, YOUTUBE (Nov. 14, 2012), https://www.youtube.com/watch?v=YXWFYPk11GM.

[44] Nick Pisarsky, Note, *PoTAYto-PoTAHto-Let's Call the Whole Thing Off: Trademark Protection of Product Sounds*, 40 CONN. L. REV. 797, 805 (2008).

[45] Registration No. 2,712,396 (the mark consists of a unique sound comprising a fundamental sweeping tone that rises quickly).

[46] Registration No. 2,996,654 (the sound mark is comprised of a sequence of two tones in increasing pitch).

connect these sounds with the sources of the products that make them than other types of marks."[47] Pitbull's *grito* shares some similarities with this "sound product" category of trademarks, and fans certainly connect this sound to the recordings themselves and the source of the recordings.

VI
PITBULL'S *GRITO*, REGISTERED

Pitbull's *grito* presents an unusual situation because people are not just familiar with yelling, they are wired to respond to it. It is also not a traditional sound trademark "jingle": it does not function as an advertisement that is disconnected from the good or service. It shares some features of sound product marks, but it also goes beyond a sound to identify a product. In sound recordings, the use of Pitbull's sound trademark is actually a sound recording embedded in the very sound recordings that it identifies. Said another way, Pitbull's *grito* serves as a musical call sign within another musical work or performance that identifies him to audiences everywhere. That style of use, coupled with nearly 20 years of international use, has made his *grito* one of the most famous sound trademarks in the music industry. Listeners around the world hear Pitbull's *grito* and are instantly informed that the song originates from Pitbull himself.

Recognizing this, on October 8, 2019, the USPTO accepted Pitbull's evidence that his iconic *grito* had acquired distinctiveness and issued Pitbull two trademark registrations.[48] The newly issued registrations are U.S. Registration Nos. 5,877,076[49] and 5,877,077[50] for "entertainment services in the nature of live musical performances" and "musical sound recordings; musical video recordings," respectively.

The issuance of these trademark registrations provides a legal presumption of what his fans already knew: the *grito* "EEEEEEEYOOOOOO" means Pitbull has put his stamp on the recording or performance.

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[47] Daniel R. Bumpus, *Bing, Bang, Boom: An Analysis of In re Vertex Group LLC and the Struggle for Inherent Distinctiveness in Sound Marks Made During a Product's Normal Course of Operation*, 21 FED. CIR. B.J. 245, 278 (2011).

[48] The mark is a sound. The mark consists of a man yelling "EEEEEEEYOOOOOO" in falsetto with "E" drawn out followed by a "U" sound, Registration No. 5,877,076; The mark is a sound. The mark consists of a man yelling "EEEEEEEYOOOOOO" in falsetto with "E" drawn out followed by a "U" sound, Registration No. 5,877,077.

[49] Registration No. 5,877,076.

[50] Registration No. 5,877,077.

There is something else particularly noteworthy about this sound product mark. Based on our search of trademark records, we believe that Pitbull's registration of his *grito* for musical sound recordings is the first time a sound trademark within a song has been registered in the principal register for musical sound recordings.

After reading this essay, you might think that the idea of a sound functioning as a trademark within a larger musical sound recording is new, but that is not the case. Pop music offers no shortage of instances of recording artists employing a common sound bite or musical catchphrase across their respective catalogs as a branding technique for the artist. The unique melodic flourish of R&B artist Jason Derulo singing his name at the beginning of hits like "In My Head," "Whatcha Say," and "Don't Wanna Go Home" is one example.[51] Atlanta-based rapper DeAndre "Soulja Boy" Way opens many of his most popular recordings with the rhythmic phrase "Soul-ja-Boy-Tell-'Em."[52] These sounds are instantly identifiable to these artists' fans and efficiently inform listeners of who created the track in question.

We believe that there will likely be more of these important trademark registrations in the future. In terms of efficiency, there is no better way to stamp a sound recording than with a unique sound. Given the prevalence of these call signs throughout the music industry, it is only a matter of time before other music superstars embrace this valuable branding protection and seek to obtain registration for their unique sonic signatures, and they would be wise to do so. It stands to reason that an artist, in an effort to capitalize on another superstar's fame, could try to insert that superstar's musical catchphrase into their own tracks. Such an action would foster the sort of consumer confusion among music fans that the Lanham Act seeks to prevent.[53]

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[51] Jason Derulo, *Jason Derulo—In My Head (Video)*, YOUTUBE (Jan. 23, 2010), https://www.youtube.com/watch?v=UyG1FG3H6rY; Jason Derulo, *Jason Derulo—Whatcha Say (Video)*, YOUTUBE (Oct. 15, 2009), https://www.youtube.com/watch?v=pBI3lc18k8Q; Jason Derulo, *Jason Derulo—Don't Wanna Go Home (Official Video)*, YOUTUBE (May 25, 2011), https://www.youtube.com/watch?v=2CGF_Z3yZAo (0:38).

[52] *See, e.g.*, SOULJA BOY, CRANK THAT (Collipark Studio) (2007); SOULJA BOY, KISS ME THROUGH THE PHONE (Collipark Studio) (2008); SOULJA BOY, TURN MY SWAG ON (Collipark Studio) (2008).

[53] *See* Park 'N Fly, Inc. v. Dollar Park and Fly, Inc., 469 U.S. 189, 198 (1985) ("The Lanham Act provides national protection of trademarks in order to secure to the owner of the mark the goodwill of his business and to protect the ability of consumers to distinguish among competing producers.").

VII
CONFUSING *MI GENTE*

Returning back to "Mi Gente," it should not have come as a surprise that many listeners, upon hearing Pitbull's unmistakable *grito* in the song, would have thought that he contributed to Balvin and William's 2017 hit. In fact, the authors of this paper thought Pitbull collaborated on the track when we first heard the song.

The confusion results from a 2-3 second stretch of audio in "Mi Gente." First appearing at the 0:52 mark and repeated twice more on the track, "Mi Gente" features an excited yell that bears a near-identical similarity to Pitbull's *grito*. Some of Pitbull's fans, conditioned over dozens of the star's hits to associate that *grito* with the rapper's music, incorrectly thought that Pitbull was featured on "Mi Gente."[54]

Bill Teck again reflects: "The release of 'Mi Gente' by J Balvin and Willy William led to an interesting moment for me, in particular, when I heard the song for the first time. The track features a loud yell (towards the end of the first minute of the record) that sounds identical to Pitbull's distinctive *grito*. When I first heard the song, I texted Pitbull to congratulate him—only to find out later that he had nothing to do with the 2017 hit. Fans were confused. Many of them asked me, 'Is that Pitbull on there?"[55]

Pitbull's response to "Mi Gente" was a classic hip hop response. Within a few weeks, he released his own remix of the song dedicated to his fans, opening the track with his *grito*.[56] Then he registered the first call sign by a musical artist for sound recordings in the principal trademark register of the USPTO. And by doing so, Pitbull made trademark law a little bit louder.

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[54] Perez Interview, *supra* note 3; Teck Interview, *supra* note 3.

[55] Teck Interview, *supra* note 3.

[56] urkel 15, *J Balvin, Willy William, Pitbull "Mi Gente" (woldwild & urkel15 remix) extender version*, YOUTUBE (Aug. 30 2017), https://www.youtube.com/watch?v=tPvu12EUh0w (with a nod to those who could've sworn he was on the original track, Perez quips during the remix's intro: "Since everybody thought that I was on the record, I think it's only right that I jump on the remix.").

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ARTICLE

COPYRIGHT IN THE TEXTS OF THE LAW: HISTORICAL PERSPECTIVES

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Recently, state governments have begun to claim a copyright interest in their official published codes of law, in particular arguing that ancillary materials such as annotations to the statutory text are subject to state-held copyright protection because those materials are not binding commands that carry the force of law. Litigation over this issue and a vigorous policy debate are ongoing.

This article contributes a historical perspective to this ongoing debate over copyright in texts relating to the law. It reviews the history of government production and use of annotations, commentaries, legislative debates, and other related information relevant to the law but not pure statutory text, from Rome and China to England and America. These historical episodes reveal three lessons of relevance to the debate. First, there is consistent recognition that "the law" is not

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limited to binding statutory language. Second, exclusivity over nonbinding legal texts such as annotations, whether through copyright or other means, confers undue power on government and the legal profession over the public. Third, annotations and other nonbinding legal texts are historically distinguishable from case reports or private treatises, contrary to the arguments generally proffered by the copyright-claiming states. These lessons militate toward broad exclusion from copyright of state-authored informative legal texts, whether binding or not.

INTRODUCTION

The antecedents to copyright law are full of colorful historical episodes, but few outdo the time that the Mayor of London was thrown in jail.[1] In 1771, the British House of Commons initiated a campaign against several newspaper publishers, exercising an early copyright-like power to restrict publication of its speeches and debates.[2] Most of the publishers acquiesced in Commons' assertion of "parliamentary privilege," but one, John Miller of the *London Evening Post*, had a different idea.[3] Executing a plan hatched with London alderman John Wilkes, a renowned hero of freedom on both sides of the Atlantic, Miller lay in wait for Parliament's messenger to come arrest him.[4] When the messenger arrived, the Lord Mayor of London, Brass Crosby, asserted sole jurisdiction for arrests in his city and then charged the messenger with false imprisonment.[5] Enraged at this act of defiance, Commons summoned Crosby to answer for his actions.[6] Crosby was adjudged in breach of parliamentary privilege, and followed by a throng of Londoners cheering him on for his bravery, the Lord Mayor paraded himself into custody in the Tower of London.[7]

Thankfully, the Printers' Case of 1771 was a dying gasp of legislative restrictions on reporting debates—Congress has not imprisoned anyone recently[8]—but governments today appear no less keen on cutting off the flow of important legal texts they produce.[9] In *Code Revision Commission ex rel. General Assembly of Georgia v. Public.Resource.Org, Inc.*,[10] the State of Georgia asserts that it possesses

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[1] *See generally infra* text accompanying notes 123–127.

[2] *See* Peter D.G. Thomas, *The Beginning of Parliamentary Reporting in Newspaper*s, 1768–1774, 74 ENG. HIST. REV. 623, 628–30 (1959).

[3] *See* Horace Bleackley, Life of John Wilkes 261 (J. Lane 1917).

[4] See id.; The Annual Register, or a View of History, Politics, and Literature, for the Year 1771, 63–64 (6th ed., London, W. Otridge & Son 1803) [hereinafter The Annual Register].

[5] *See* 17 THE PARL. HIST. ENG., 96–97 (1813); THE ANNUAL REGISTER, *supra* note 4, at 64.

[6] *See* 17 THE PARL. HIST. ENG., *supra* note 5, at 102–04.

[7] *See id.* at 157–58; THE ANNUAL REGISTER, *supra* note 4, at 66–69; BLEACKLEY, *supra* note 3, at 262.

[8] *See* Amber Phillips, *How Would Congress Jail Trump Officials? History Says It's Not Easy*, WASH. POST (May 15, 2019, 1:08 PM), https://www.washingtonpost.com/politics/2019/05/15/how-would-congress-jail-trump-officials-history-says-its-not-easy/.

[9] *See, e.g.*, Brief for Arkansas et al. as Amici Curiae Supporting Petitioners at 3, Georgia v. Public.Resource.Org, Inc., 139 S. Ct. 2746 (2019) [hereinafter Brief for Arkansas et al.] (No. 18-1150) (arguing on behalf of 14 states that states require copyright protections in their official codes).

[10] Code Revision Comm'n ex rel. Gen. Assembly of Ga. v. Public.Resource.Org, Inc. (*Code Revision Comm'n II*), 906 F.3d 1229 (11th Cir. 2018), *cert. granted, Public.Resource.Org, Inc.*,

a copyright sufficient to prevent the copying or redistribution of the *Official Code of Georgia Annotated*, the sole official source of law in the state.[11] The state concedes that the statutory language itself is not subject to copyright protection by virtue of its being an edict of government.[12] Yet, it argues that ancillary matter in the official code, in particular the annotations containing citations to case law and legislative history, are not edicts of government for purposes of copyright law and thus are amenable to copyright protection sufficient to prevent copying of the official code *in toto*.[13]

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139 S. Ct. 2746 (2019). On April 27, 2020, just prior to this article's publication, the Supreme Court issued a decision in favor of Public.Resource.Org, Inc., holding that no copyright inheres in "non-binding, explanatory legal materials created by a legislative body vested with the authority to make law." Georgia v. Public.Resource.Org, Inc. (*Public.Resource.Org Opinion*), No. 18-1150, slip op. at 1–2 (U.S. Apr. 27, 2020) (emphasis omitted). The historical analysis in this article is not affected by the Court's decision, but a few notes are worthwhile. The majority opinion by Chief Justice Roberts appeals to the unfairness that could occur if copyright law enables the state to prepare an "economy-class version of the Georgia Code" and an annotated one for "first-class readers." *Id.* at 17. That analysis closely follows the discussion below, *infra* Section III.B, on how copyright in legal annotations can hand undue power to the state and members of the legal profession, who will tend to be those "first-class readers." Justices Thomas and Ginsburg, in separate dissents, premise their views in favor of copyrights in legal annotations on the notion that those annotations carry no legal force. *See Public.Resource.Org Opinion,* No. 18-1150, slip op. at 7 (Thomas, J., dissenting) ("[T]hese annotations do not even purport to embody the will of the people because they are not law."); *id.* at 3 (Ginsburg, J., dissenting) (arguing that annotations should be copyrightable because they "are descriptive rather than prescriptive"). Yet these dissenting views disregard the important political role that nonbinding pronouncements of government have played throughout history. *See infra* Section III.A. Finally, Justice Thomas attempts to distinguish judicial opinions from legislative work on the grounds that in 17th century England, judicial opinions were the property of the sovereign. *See Public.Resource.Org Opinion*, No. 18-1150, slip op. at 6 (Thomas, J., dissenting). That argument overlooks the fact that the works of Parliament in that historical period were also a matter of sovereign exclusivity under the royal prerogative. *See infra* text accompanying notes 90–93.

[11] *See* GA. CODE ANN. § 1-1-1; Brief for Petitioners at 20–21, *Public.Resource.Org, Inc*., 139 S. Ct. 2746 (2019) (No. 18-1150) [hereinafter Brief for Petitioners].

[12] See Brief for Petitioners, supra note 11, at 20; cf. State v. Harrison Co., 548 F. Supp. 110, 113–14 (N.D. Ga. 1982) (citing relevant case law).

[13] *See* Brief for Petitioners, *supra* note 11, at 20 ("Properly stated, the question here is whether the OCGA's *annotations*, which lack the force of law, are eligible for copyright protection.").

Much has been written on the merits of copyright in state legal texts such as annotated legal codes, from perspectives of copyright law,[14] constitutional rights,[15] economic incentives,[16] effects on key industries,[17] and public policy.[18] Yet scant attention has been paid to history.[19] This is unfortunate, because a review of the history of law and legal publication in fact reveals numerous useful precedents that inform the debate on copyright protection for texts of the law. History in particular can answer the question fundamental to the State of Georgia's contentions: whether there is in fact a clear distinction between binding statutes carrying the force of law, which are decidedly not copyrightable, and all other authorial products of government.

To fill this historical void in the record, this article surveys nonbinding pronouncements, particularly attached to statutes or codes of law, across time and around the world, from Rome and China to England and America. This historical

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[14] *See, e.g.*, Leslie A. Street & David R. Hansen, *Who Owns the Law? Why We Must Restore Public Ownership of Legal Publishing*, 26 J. INTELL. PROP. L. 205, 224–26 (2019); Brief for American Intellectual Property [Law] Association as Amicus Curiae Supporting Respondent, *Public.Resource.Org, Inc.*, 139 S. Ct. 2746 (2019) (No. 18-1150); Brief for The Copyright Alliance as Amicus Curiae Supporting Petitioners, *Public.Resource.Org, Inc.*, 139 S. Ct. 2746 (2019) (No. 18-1150).

[15] *See, e.g.*, Brief for American Civil Liberties Union et al. as Amici Curiae Supporting Respondent, *Public.Resource.Org, Inc.*, 139 S. Ct. 2746 (2019) (No. 18-1150); Brief for Center for Democracy and Technology and Cato Institute as Amici Curiae Supporting Respondent, at 4–13, *Public.Resource.Org, Inc.*, 139 S. Ct. 2746 (2019) (No. 18-1150).

[16] *See, e.g.*, Deborah Tussey, *Owning the Law: Intellectual Property Rights in Primary Law*, 9 Fordham Intell.Prop. Media & Ent. L.J. 173, 225–31 (1998).

[17] *See, e.g.*, Brief for American Library Association et al. as Amici Curiae Supporting Respondent, *Public.Resource.Org, Inc.*, 139 S. Ct. 2746 (2019) (No. 18-1150); Brief for Matthew Bender & Co., Inc. as Amicus Curiae Supporting Petitioners, *Public.Resource.Org, Inc.*, 139 S. Ct. 2746 (2019) (No. 18-1150); Brief for Internet Association as Amicus Curiae Supporting Respondent, *Public.Resource.Org, Inc.*, 139 S. Ct. 2746 (2019) (No. 18-1150).

[18] *See, e.g.*, Tussey, *supra* note 16, at 231–33 (considering constitutional objectives for copyright); Irina Y. Dmitrieva, *State Ownership of Copyrights in Primary Law Materials*, 23 HASTINGS COMM. & ENT. L.J. 81, 115 (2000) (arguing that "the state's ownership of copyright in primary law materials runs afoul of the fundamental public policy principle that citizens in a democratic society must have uninhibited access to the laws"). The author deeply regrets being unable to cite every excellent brief filed by his colleagues and others in this litigation.

[19] The scholar who comes closest to doing so is Professor Dingledy of William & Mary Law School, though his research focuses on historical access to the law generally, rather than the particular issue of nonbinding legal texts. *See* Frederick W. Dingledy, *From Stele to Silicon: Publication of Statutes, Public Access to the Law, and the Uniform Electronic Legal Material Act*, 111 L. LIBR. J. 165 (2019) [hereinafter Dingledy 2019]. The author extends special thanks to Professor Dingledy for a great deal of assistance with his research.

review—which traverses a Roman whistleblower, the Justinian Code, a dark side of Confucianism, English libertarianism, New York suppressing the press, and the Mayor of London being thrown in jail—reveals multiple important lessons that question the basis upon which Georgia's argument stands.

First, "the law," or that class of government edicts for which the interest of unrestricted citizen access is at its apex, is not limited to statutes of binding force. Law, and access thereto, serves many purposes: advising citizens on the state's normative views, crystallizing popular opinion on future policy, and delineating the relationship between citizen and state. Nonbinding pronouncements serve these purposes too, by demonstrating the logic, motivations, and reasoning of the sovereign, which is why governments have repeatedly treated nonbinding pronouncements as part and parcel of the law. A determinative distinction between binding law and other state-authored works has not existed for millennia.

Second, concealment of nonbinding legal pronouncements has long handed undue power to both the state and the legal bar. Where the reasons behind the law are not made available to the public, the sovereign enjoys outsized discretion over citizens. Furthermore, lawyers enjoy outsized power to shape the law toward their interests rather than the public's. These imbalances in power, both plainly anti-democratic and anti-libertarian in the broadest senses of those terms, demonstrate a danger in allowing states to have control over nonbinding state-authored works that often contain the reasons and logic of the sovereign and the law.

Third, states such as Georgia often support their claims for copyright by analogizing their annotations to privately authored case reports and legal treatises, both of which historically have been subject to copyright.[20] Yet, history shows that annotations to the law are unlike legal treatises and case reports. Historically, those private writings have been the domain of non-state-actor compilers;[21] as such, they are not traditional edicts of government. By contrast, codes of law—complete with annotations—have long been pronouncements of the sovereign's intentions.[22] To treat state-authored annotations like a private case report or treatise would thus be incongruous with history.

These lessons ultimately point in the same direction: exclusivity in state-authored legal texts, even those that do not carry direct legal force, can have and

[20] *See infra* note 180 and accompanying text.
[21] See *infra* notes 186–192 and accompanying text.
[22] *See infra* notes 181–185 and accompanying text.

have had grave legal consequences, and important public interests are served by ensuring that those works are broadly available to the public without restriction.

To be sure, little of this history speaks directly to the doctrines of copyright law. But the determinative principles for the relevant edicts-of-government doctrine under copyright law have always reached beyond the mere text of the statute. Those determinative principles are founded upon the relationship of a sovereign to its citizens, and what the state may withhold from them, regardless of the legal means. The relevant history is that of the law and how states have published or withheld it.

This article proceeds as follows. Section I gives a brief introduction to the practice of legal publication of annotated codes and the litigation that has given rise to the debate over copyright in legal texts.[23] Section II turns to historical episodes relating to annotations, commentaries, legislative histories, and other nonbinding but official texts of the law.[24] Section III synthesizes conclusions from these historical instances to draw lessons for the consequences of state-owned copyrights in those nonbinding but official texts.[25] The final section concludes.[26]

I
BACKGROUND

To set the stage for the historical discussion of state involvement with nonbinding but official legal texts, this section provides a brief background on the situation that has given rise to copyright litigation over annotations to official state legal codes.

A. State Publication of Annotated Codes

When legislatures enact laws, the record of those enactments is not automatically organized into topical volumes.[27] Statutes, or "session laws," have historically been organized serially in order of enactment.[28] Indeed, in early England, the statutes were literally sewn together in serial order to form rolls of attached parchment, which gives rise to the term "enrollment" of laws.[29]

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[23] *See infra* Section I.

[24] *See infra* Section II.

[25] *See infra* Section III.

[26] *See infra* Conclusion.

[27] *See, e.g.*, Erwin C. Surrency, *The Publication of Federal Laws: A Short History*, 79 L. LIBR. J. 469, 470–71 (1987) (describing early American practice of sending bills to newspapers for publication, under the Records Act of 1789).

[28] *See, e.g.*, 1 U.S.C. § 112 (2018); *id.* at 471–72.

[29] *See* G.R. Elton, *The Rolls of Parliament, 1449–1547*, 22 HIST. J. 1, 4 (1979).

Yet, multiple times throughout history, governments have recognized the value of preparing organized compilations or revisions of the extant statutes.[30] These are called "codes," after the most famous historical compilation, the Roman *Codex* of Justinian I.[31] Today, the *United States Code* is a familiar official code of law produced by the United States government,[32] and every state maintains a code or compilation of its laws as well.[33] Many of the states do not have in-house publishing resources, and so they outsource the printing and even preparation of their codes; increasingly as well, print versions are being dropped for online-only access to official legal codes.[34]

The public-private partnership for publication of state legal codes is largely responsible for provoking questions of copyright in those codes.[35] Because the private publishers seek to make profits from their partnerships with the states, they receive indirect value if copyright exclusivities inhere in the official codes that they prepare.[36] Unsurprisingly, those publishers impress upon the states that copyright protection in at least some aspect of their official legal codes is important to demand.[37]

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[30] See, e.g., Wienczyslaw J. Wagner, *Codification of Law in Europe and the Codification Movement in the Middle of the Nineteenth Century in the United States*, 2 ST. LOUIS U. L.J. 335, 340–55 (1953) (describing codification efforts in Europe and the United States).

[31] *See* CODEX JUSTIANIANUS (Paulus Krueger ed., Berlin, Weidmannsche Buchhandlung 1877) (c. A.D. 534). The literal word "codex" refers to nothing more than a bound book.

[32] *See* 1 U.S.C. § 204(a) (2018).

[33] *See* Street & Hansen, *supra* note 14, at 219 n.82, addendum (2019).

[34] *See id.*; Street & Hansen, *supra* note 14, at 220.

[35] The federal government is precluded from asserting copyright in this manner because by the terms of the Copyright Act, no copyright inheres in federal government works. *See* 17 U.S.C. § 105 (2018).

[36] *See* Street & Hansen, *supra* note 14, at 221 & n.92 (citing research); Brief for Matthew Bender & Co., Inc. as Amicus Curiae Supporting Petitioners at 9–13, Georgia v. Public.Resource.Org, Inc., 139 S. Ct. 2746 (2019) (No. 18-1150). The assumption throughout this article is that the state is the author and the original copyright recipient, so that benefits from any copyright inure to the publisher by virtue of contracts with the state. If the publisher or other third party is the original author of material in the codes, then different questions would arise. *See* Am. Soc'y for Testing & Materials v. Public.Resource.Org, Inc., 896 F.3d 437, 440 (D.C. Cir. 2018) (considering "whether private organizations whose standards have been incorporated by reference can invoke copyright and trademark law to prevent the unauthorized copying and distribution of their works").

[37] *See* Brief for Arkansas et al, *supra* note 9, at 20.

B. The Public.Resource.Org Litigation

On the other side of this debate over copyright in state legal materials is Carl Malamud, the self-described "rogue archivist" who operates the organization Public.Resource.Org ("Public Resource") that is dedicated to "making the laws easier to use and read" for the public.[38] In 2013, Public Resource scanned and uploaded to its website the entirety of the *Official Code of Georgia Annotated*, thereby triggering a series of cease-and-desist letters and ultimately a federal copyright lawsuit from the State of Georgia in 2015.[39]

Before the district court, Public Resource argued that its copying and distribution of the official Georgia code were permissible, either because the code as an edict of government was not amenable to copyright protection, or because Public Resource's copying and distribution constituted permissible fair use of a copyrighted work.[40] The district court rejected both arguments and found Public Resource's acts to be infringing.[41] Regarding copyrightability, the district court recognized that government edicts were not subject to copyright protection, but following guidance of the U.S. Copyright Office, the court held that annotations to an official code were distinguishable and thus copyrightable.[42] Turning to fair use, the court found that Public Resource, though a nonprofit organization, nevertheless "profits" from grants, donations, and public recognition;[43] in combination with the fact that the whole work was copied and the effect on Georgia's market for the work was substantial, the district court found no fair use.[44]

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[38] Michael Hiltzik, *Georgia Claims that Publishing its State Laws for Free Online is 'Terrorism'*, L.A. TIMES (July 27, 2015, 12:31 PM), https://www.latimes.com/business/hiltzik/la-fi-mh-state-of-georgia-copyright-wall-20150727-column.html; Adam Liptak, *Accused of 'Terrorism' for Putting Legal Materials Online*, N.Y. TIMES (May 13, 2019), https://www.nytimes.com/2019/05/13/us/politics/georgia-official-code-copyright.html.

[39] *See* Code Revision Comm'n *ex rel.* Gen. Assembly of Ga. v. Public.Resource.Org, Inc. (*Code Revision Comm'n II*), 906 F.3d 1229, 1235 (11th Cir. 2018).

[40] *See* Code Revision Comm'n v. Public.Resource.Org, Inc. (*Code Revision Comm'n I*), 244 F.Supp. 3d 1350, 1355 (N.D. Ga. 2017), *rev'd*, *Code Revision Comm'n II*, 906 F.3d 1229.

[41] *See id.* at 1361.

[42] *See id.* at 1356 (quoting U.S. COPYRIGHT OFFICE, COMPENDIUM OF U.S. COPYRIGHT OFFICE PRACTICES §§ 313.6(C)(2), 717.1 (3d ed. 2014)).

[43] *See id.* at 1359. Before the Eleventh Circuit, the author noted in an amicus brief that this argument of the district court was plainly inconsistent with the law. *See* Brief for Public Knowledge et al. as Amici Curiae Supporting Appellant at 16–23, *Code Revision Comm'n II*, 906 F.3d 1229 (11th Cir. 2018) (No. 17-11589).

[44] *See Code Revision Comm'n I*, 244 F. Supp. 3d at 1360–61.

On appeal, the Eleventh Circuit reversed the district court on the copyrightability issue and thereby did not address fair use.[45] Recognizing that the "question is a close one," the Court of Appeals recognized the need for a test for whether a state-authored work is subject to copyright and identified three relevant factors: "the identity of the public officials who created the work, the authoritativeness of the work, and the process by which the work was created."[46] Applying those factors, the court held that the official Georgia code was "sufficiently law-like so as to be properly regarded as a sovereign work," in total including the annotations.[47] As a result, the court concluded that "the People are the ultimate authors of the annotations," and so "the annotations are inherently public domain material and therefore uncopyrightable."[48]

The State of Georgia petitioned for certiorari in March 2019.[49] Unusually, Public Resource acquiesced in the petition, agreeing that the "Court's review is warranted" because the precedents and doctrine are "difficult to apply when a work does not fall neatly into a category, like statutes or judicial opinions, already held to be edicts."[50] The Supreme Court granted the petition for a writ of certiorari on June 24, 2019.[51]

II
OFFICIAL ANNOTATIONS HAVE LONG BEEN EDICTS OF GOVERNMENT AND INTEGRAL PARTS OF THE LAW

In assessing how history can inform the Public Resource litigation and the question of copyright in legal texts generally, the initial observation must be that state-authored but nonbinding legal materials, such as official statutory annotations, are far from unusual. History is replete with sovereigns propounding annotated codes, official commentaries, and other nonbinding pronouncements, and consideration of these historical examples is instructive not just on the disposition of the *Code Revision Commission* case, but also on basic theories of liberty and government.[52] This section endeavors to present several examples of these historical

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[45] See Code Revision Comm'n II, 906 F.3d at 1233.

[46] *Id.* at 1232–33.

[47] *Id.* at 1233.

[48] *Id.*

[49] *See* Petition for Writ of Certiorari for Plaintiffs-Appellees, Georgia v. Public.Resource.Org, Inc., 139 S. Ct. 2746 (2019) (No. 18-1150).

[50] Brief in Opposition of the Petition for Writ of Certiorari at 9, *Public.Resource.Org, Inc.*, 139 S. Ct. 2746 (2019) (No. 18-1150).

[51] *See Public.Resource.Org, Inc.*, 139 S. Ct. 2746 (2019) (No. 18-1150).

[52] See generally infra Section III.

legal texts and the motivations behind them, reactions to them, and consequences of them, to assist in answering the copyright question.[53]

A. Rome: Official Commentaries Were Jus Scripta from the Republic Through Justinian

The Roman Republic and Empire repeatedly treated official though nonbinding commentaries as a component of the law, and valued promulgation of both.[54] As early as 450 B.C., the Roman Republic publicized the famed Law of the Twelve Tables, inscribed in bronze and posted in the public square, thereby quelling a threatened class war arising from "the complaint on the part of the *plebs*, that the law was an affair of mystery."[55] In 304 B.C., a court clerk named Gnaeus Flavius became a local hero by leaking the Roman pontiffs' secret interpretations of the Twelve Tables, winning him high political offices.[56]

Emphasis on publicizing law developed into the Roman concept of *jus scripta*, written law that held a place higher than unwritten, customary law, *jus non scripta*.[57]

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[53] For an article on legal history, a few notes on conventions are in order. Spelling and capitalization have been modernized in quotations from historical sources, without notation, to simplify readability. Chinese transliterations have been canonicalized to *Pinyin*, and *j* is used rather than the consonantal *i* (e.g., *jus* rather than *ius*). No changes have been made to titles of works to facilitate locating them in catalogs, though historical abbreviations of personal names are expanded, and titles of Roman treatises are abbreviated according to Bluebook conventions. Page number citations to Roman law and histories follow the classical format [book].[section].[sentence] throughout. Because Locke's *Essay Concerning Human Understanding* is also organized into books and sections, the same format is followed for it. For each of these specially-paginated historical works, a specific translation or reprint is referenced; the volume and page numbers also given with the citations are indexed to that translation or reprint. Finally, to ensure maximum accessibility of the historical works in this Article, public domain editions have been cited wherever possible.

[54] For an overview of Roman publication of law, see generally Dingledy 2019, *supra* note 19, at 172–79.

[55] FREDERICK PARKER WALTON, HISTORICAL INTRODUCTION TO THE ROMAN LAW, at 82–89 (Edinburgh W. Green & Sons, 1903); *see* 2 LIVY WITH AN ENGLISH TRANSLATION IN FOURTEEN VOLUMES, 3.33–.34, 3.57.10, at 109–13, 195 (B.O. Foster trans., Harvard Univ. Press 1922) (c. 27 B.C.).

[56] *See* 4 LIVY WITH AN ENGLISH TRANSLATION IN FOURTEEN VOLUMES, 9.46.5, at 351 (B.O. Foster trans., Harvard Univ. Press 1926) (c. 27 B.C.); THE DIGEST OF JUSTINIAN 1.2.2.7, at 8 (Charles Henry Monro trans., 1904) (c. A.D. 533).

[57] *See* THE INSTITUTES OF JUSTINIAN 1.2.10, at 6 (J.B. Moyle trans., 5th ed., Clarendon Press 1913) (c. A.D. 533) (comparing this division to Athenian and Lacedaemonian practice that "observed only what they had made permanent in written statutes").

Jus scripta was not limited only to statutes, though.[58] Among other things, it encompassed the Senate's opinions, *senatus consulta*, which at least during the Republic were treated as nonbinding commentary on statutes: "It could not annul a *lex*. . . . It could, however, interpret enactments of the popular assembly."[59] Nevertheless, *senatus consulta* weighed heavily on judges, and magistrates ignored them at their peril.[60]

Roman written law also incorporated private legal scholars' opinions, in the form of responses to questions of law called *responsa prudentium*.[61] Even here the imperial imprimatur was important. Roman scholars were free to opine on cases to judges, but starting with Augustus, the emperors conferred *jus respondendi* upon select scholars, such that their answers were "in pursuance of an authorization" and thus effectively binding precedent.[62] Multiplication of unofficial commentaries prompted Valentinian III in A.D. 426 to issue the Law of Citations, designating several prominent jurists as official—but not binding, for when the jurists "were all ranged on one side and an imperial rescript was on the other, the latter would prevail."[63]

The apex of symbiosis between private commentary and imperial power was Justinian I's law of A.D. 529–534, modernly called the *Corpus Juris Civilis*.[64] Though often called a "code," the *Corpus* was more than just the *Codex*. Concerned

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[58] *See* GAIUS, INSTITUTES OF ROMAN LAW 1.2, at 1 (Edward Poste trans., 4th ed., Clarendon Press 1904) (c. A.D. 161).

[59] FRAN FROST ABBOTT, A HISTORY AND DESCRIPTION OF ROMAN POLITICAL INSTITUTIONS 233 (3d ed., Harvard Univ. Press 1911); *see id.* 1.4, at 2; 3 POLYBIUS, THE HISTORIES 6.16.2, at 305–07 (W.R. Paton trans., Harvard Univ. Press 1972) (c. A.D. 150). By the time of the Empire, *senatus consulta* were considered statutes, owing to the decline of the *comitia* representing the people. *See id.* 1.4, at 2; THE INSTITUTES OF JUSTINIAN, *supra* note 57, 1.2.5, at 5.

[60] *See* ROBERT C. BYRD, THE SENATE OF THE ROMAN REPUBLIC: ADDRESSES ON THE HISTORY OF ROMAN CONSTITUTIONALISM 44 (1995); A. Arthur Schiller, *Senatus Consulta in the Principate*, 33 Tul. L. Rev. 491, 492 (1959).

[61] *See* GAIUS, INSTITUTES OF ROMAN LAW, *supra* note 58, 1.7, at 2.

[62] THE DIGEST OF JUSTINIAN, *supra* note 56, 1.2.2.49, at 18; *see* JOHN CHIPMAN GRAY, THE NATURE AND SOURCES OF THE LAW sec. 426, at 190 (Columbia Univ. Press 1909); Kaius Tuori, *The Ius Respondendi and the Freedom of Roman Jurisprudence*, 51 REVUE INTERNATIONALE DES DROITS L'ANTIQUITE (3E SERIE) 295, 297 (2004). There appears to be some debate as to the reliability of evidence for the *jus respondendi* and its effect. Some scholars treat it as a license to opine on law, such that others may not issue *responsa* at all; the latter view appears fairly weak.

[63] ALAN WATSON, SOURCES OF LAW, LEGAL CHANGE, AND AMBIGUITY 8–9 (Univ. of Pa. 1984); CODEX THEODOSIANUS 1.4, at 19–20 (Paulus Krueger ed., Weidmannsche Buchhandlung 1923) (c. A.D. 426).

[64] Frederick W. Dingledy, *The Corpus Juris Civilis: A Guide to Its History and Use*, 35 LEGAL REFERENCE SERVICES Q. 231 (2016).

as Valentinian was with the proliferation of private commentaries, Justinian formed a Law Commission (not unlike Georgia's Code Revision Commission that prepared its official code[65]) to abridge the commentaries.[66] The resulting *Digest* was, in effect, an official annotation to the *Codex*, and yet the *Digest* received no lesser treatment as a component of Justinian's law.[67]

The *senatus consulta*, *jus respondendi*, and *Digest* reflect a consistent inclusion of nonbinding annotations and commentaries as a critical part of the complete body of law in Rome. Any distinction between statutes and annotations is difficult to reconcile with this important precedent to American government.

B. Dynastic China: Official Annotations Literally Intertwined with Statutory Law

Like Rome, historical China treated official annotations as integral components of the law, meriting promulgation to the same extent as statutes.[68]

China has favored promulgation of law since at least the Legalist-Confucian debate spanning the late Spring and Autumn Period, 591–453 B.C.[69] The Legalist (*fajia*) school preferred efficient, predictable government under published laws.[70] By contrast, the Confucians eschewed written law in favor of *li*, or virtue, theorizing that written laws would encourage mere compliance rather than moral perfection, and preferring the discretion over punishment that *li* offered rulers.[71]

The Legalists prevailed as early as 536 B.C., when the kingdom of Zheng publicly displayed its penal text (*xing shu*), cast onto three-legged vessels.[72] A neighboring leader criticized this publication, saying, "When the people know what

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[65] *See* Code Revision Comm'n *ex rel.* Gen. Assembly of Ga. v. Public.Resource.Org, Inc., 906 F.3d 1229, 1234 (11th Cir. 2018).

[66] *See* Dingledy, *supra* note 64, at 234–36.

[67] *See On the Confirmation of the Digest (Constitutio Tanta)*, *in* 1 THE DIGEST OF JUSTINIAN, *supra* note 56, at xxv, §§ 19, 21, at xxxiv (prohibiting use or creation of other commentaries, other than translations to Greek or "paratitla"); Giuseppe Falcone, *The Prohibition of Commentaries to the Digest and the Antecessorial Literature*, *in* 9 SUBSECIVA GRONINGANA 1, 5–6 (2014).

[68] For an overview of the history of Chinese legal codes, see generally John W. Head & Yanping Wang, Law Codes in Dynastic China: A Synopsis of Chinese History in the Thirty Centuries from Zhou to Qing (Carolina Academic Press 2005).

[69] *See id.* at 48–57.

[70] See Liang Zhiping, Explicating "Law": A Comparative Perspective of Chinese and Western Legal Culture, 3 J. CHINESE L. 55, 80–84 (1989).

[71] *See* HEAD & WANG, *supra* note 68, at 49 (2005).

[72] See Ernest Caldwell, Social Change and Written Law in Early Chinese Legal Thought, 32 L. & HIST. REV. 1, 14–15 (2014).

the exact laws are, they do not stand in awe of their superiors."[73] Indeed, Confucius himself is apocryphally said to have lamented, "People will study the tripods, and not care to know their men of rank."[74]

Nevertheless, the Chinese would publish legal codes for millennia, complete with official but nonbinding commentary.[75] The Han dynasty code of about 200 B.C. supposedly included decisions from prior dynasties (*ko*) and "comparisons" (*bi*) to be used as precedent; these had less binding power than the statutes but nevertheless were included in the code.[76] The Tang code of A.D. 653 also included extensive commentaries; indeed its original title was "The Code and the Subcommentary."[77] It is "probable that the commentary was an integral part" of the code, omission of which "would have deprived the unsuspecting reader of a great deal of necessary information, as well as of explanations without which the meaning and intent of the articles [i.e., statutes] could not properly be understood."[78]

Nonbinding annotations to the law were especially prominent in the Ming dynasty code of 1585, which would evolve into the Qing dynasty code of 1740.[79] In addition to the statutes (*lü*), the codes contained "sub-statutes" (*li*), which literally translates to "principle, pattern, norm, or example," and which contained descriptions of precedents often arising out of imperial edicts explaining *lü*.[80] The sub-statutes were widely recognized not to be statutes, but nevertheless carried such interpretive force that they might effectively nullify the original intent of the statute.[81] The Qing code also included commentaries on the statutes (but not the sub-statutes), some official and some private; the official commentaries were considered

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[73] *The Ch'un Ts'ew [Chunqiu]; with the Tso Chuen [Zuozhuan]*, *in* 5 JAMES LEGGE, THE CHINESE CLASSICS 609 (London, Trübner & Co. 1872).

[74] HEAD & WANG, *supra* note 68, at 53. Commentators have questioned the reliability of these Confucian claims. *See* Herrlee Glessner Creel, *Legal Institutions and Procedures During the Chou Dynasty*, *in* ESSAYS ON CHINA'S LEGAL TRADITION 26, 37–40 (Jerome Alan Cohen et al. eds., 1980), *quoted with approval in* HEAD & WANG, *supra* note 68, at 55–56.

[75] *See* HEAD & WANG, *supra* note 68, at 93-96, 125, 210.

[76] *See id.* at 93–96; Xin Ren, Tradition of the Law and Law of the Tradition: Law, State, and Social Control in China 23 (Univ. of Pa. 1997).

[77] Wallace Johnson, *Introduction* to THE T'ANG CODE 3, 39, 43 (Wallace Johnson trans., Princeton Univ. Press 1979) (c. A.D. 653).

[78] *Id.* at 43; HEAD & WANG, *supra* note 68, at 125.

[79] *See* DERK BODDE & CLARENCE MORRIS, LAW IN IMPERIAL CHINA EXEMPLIFIED BY 190 CH'ING DYNASTY CASES 57, 65–66 (Harvard Univ. Press 1967).

[80] *See id.* at 64–65.

[81] *See id.* at 67.

so integral to the statutes that they were often written in small print literally in between the lines of the statutory text.[82]

Three millennia of Chinese history reveal a commitment to government promulgation of the law, both statutes and official annotations. The Han through Qing codes are thus strong markers of the close ties between official annotations and law.

C. England, 1485–1490: Nonbinding "Englished" Law Secures the Crown's Authority

Throughout the history of England, official but nonbinding pronouncements have been a critical component of the law, even from the first days of printed matter.

While there is much to be gleaned from the formative years of the parliamentary statute in medieval English times,[83] this article begins with the critical moment of the introduction of printing to England at the end of the 15th century. The evidence from this time demonstrates that nonbinding legal texts were an integral part of the law worthy of public promulgation no less than statutes.

At the onset of printing in the late 15th century, the official language of English law was not English. Statutes were titled in Latin and officially written in so-called "law French," as exemplified by William de Machlinia's 1484 printing of Richard III's statutes.[84] When Henry VII took the throne in 1485, Parliament also

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[82] *See id.* at 69; HEAD & WANG, *supra* note 68, at 210 box VI-3.

[83] It was during this time that the concept of statutory legislation, and indeed the word "statute" itself, came into being. *See* H.G. Richardson & George Sayles, *The Early Statutes, Part I*, 50 L.Q. REV. 201, 202–03 (1934). One primary lesson from medieval English law is that the law is not the same as enacted statutes: an unenacted royal writ directed to a specific person could come to be a statute of general applicability by popular acclaim, for example. *See* David K. Millon, *Circumspecte Agatis Revisited*, 2 L. & HIST. REV. 105, 107–08 & n.7 (1984). Conversely, statutes enacted by Parliament were seen as "affirmances of the ancient law"—essentially commentaries on the common law—resulting in the courts occasionally disregarding statutes that they found to be in conflict with the common law. *See* Thomas Bonham v. Coll. of Physicians (Dr. Bonham's Case), 77 Eng. Rep. 638 (C.P. 1610) (Coke, C.J.) (describing medieval cases rejecting statutes in this manner).

[84] *See Introduction* to THE STATUTES OF THE REALM, at xxi, xl (London, Dawsons 1810), [hereinafter Introduction]; Katharine F. Pantzer, *Printing the English Statutes, 1484–1640: Some Historical Implications*, *in* BOOKS AND SOCIETY IN HISTORY 69, 71–73 (Kenneth E. Carpenter ed., 1983).

produced statutes, again officially in law French.[85] Yet when around 1490 the Crown commissioned William Caxton to print the statutes, Caxton did so in English.[86]

No doubt the lawyers of the time would have understood Caxton's translations, although as emanations of the king, not as law. The prevailing view was that law could be "express[ed] more aptly in French than in English" owing to the many technical terms of law French.[87] An English translation would have been considered not merely unofficial but indeed ambiguous.

Yet England made and promulgated these nonbinding explanations of the law—at no cost to English subjects—because doing so served important purposes. By informing the public on the law, the Crown hoped to instill virtue in its subjects—and, selfishly, to propagandize its own majesty and justness.[88] That required the law to be not just public, but understandable to the average English subject. Not long after Caxton's publication, lawyer and printer John Rastell would deem Henry VII "worthy to be called the second Solomon" by virtue of having the statutes "written in the vulgar English tongue and to be published, declared, and imprinted so that then universally the people of the realm might soon have the knowledge of the said statutes."[89]

Perhaps a state legal code is not so arcane as law French, but the terseness of statutes can make them opaque absent interpretive aids. Official annotations offer a window into the legislator's reasoning just as "Englishing" of statutes did in the 15th century. Neither can be disregarded as part of the law.

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[85] *See Introduction*, *supra* note 84, at xli; Pantzer, *supra* note 84, at 74.

[86] *See Introduction*, *supra* note 84, at xli; Pantzer, *supra* note 84, at 74–75; THE STATUTES OF HENRY VII (John Rae ed., London, John Camden Hotten 1869) (c. 1489). Pantzer puts the date of Caxton's publication at 1490, but the facsimile copy dates it to 1489.

[87] JOHN FORTESCUE, DE LAUDIBUS LEGUM ANGLIÆ, *translated in* COMMENDATION OF THE LAWS OF ENGLAND 80 (Francis Grigor trans., Sweet & Maxwell 1917) (c. 1468–1471); *see* 2 W.S. HOLDSWORTH, A HISTORY OF ENGLISH LAW, at 481 (3d ed. 1923) ("French continued to be the language of the law because the technical terms were nearly all French.").

[88] *See* Pantzer, *supra* note 84, at 73–75; David J. Harvey, THE LAW EMPRYNTED AND ENGLYSSHED: THE PRINTING PRESS AS AN AGENT OF CHANGE IN LAW AND LEGAL CULTURE 1475–1642, at 24 (Hart Publ'g 2015).

[89] John Rastell, *Prohemium* to THE ABBREVIATION OF THE STATUTES (1519), *reprinted in* 1 TYPOGRAPHICAL ANTIQUITIES 327, 328–29 (Joseph Ames & William Herbert eds., London, Soc'y of Antiquaries 1785) (spelling modernized, *see supra* note 53). The various editions of *Typographical Antiquities* give different titles and dates for Rastell's work; the original appears to be lost.

To be sure, England did not allow for unrestricted access to the law.[90] Authority to print the statutes and other official documents was (and technically still is) closely held by royal prerogative and monopolized by the King's or Queen's Printer;[91] the printing of case reports and other common law texts was also monopolized under a patent for printing the common law.[92] But these elements of what today is called "Crown copyright" should provide little solace to states who assert the monopoly of copyright in their legal texts: along with the general printing monopoly of the Stationers' Guild and the Star Chamber decrees of 1586 and 1637, the prerogative and patent were elements of the English government's comprehensive scheme to censor information and dominate the press out of fear of inciting in England the religious unrest of the Protestant Reformation.[93] American states presumably do not justify their copyright claims upon religious censorship.

D. England, 1520–1640: Promulgated Explanations of Law Counteract Absolutist Monarchy

The printing press sparked a debate over the propriety of printing the law, a debate that reveals grave risks in restricting access to official but nonbinding edicts of government.[94]

The "publicists" supported printing the law of England, particularly in English, to improve social morals.[95] Lawyer-printer John Rastell, in praising the English translation of Henry VII's statutes (and in printing his own translation of older statutes into that "vulgar tongue"), explained in 1519 that "knowledge of the

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[90] *See* JOSEPH CHITTY, JR., A TREATISE ON THE LAW OF THE PREROGATIVES OF THE CROWN; AND THE RELATIVE DUTIES AND RIGHTS OF THE SUBJECT 238–41 (London, Joseph Butterworth & Son 1820) (describing "prerogative copyright" of the Crown).

[91] *See* MINISTRY OF JUSTICE, REVIEW OF THE EXECUTIVE ROYAL PREROGATIVE POWERS: FINAL REPORT 32 (2009).

[92] *See* H.J. Byrom, *Richard Tottell—His Life and Work*, 8 LIBR. 4TH 199, 223–25 (1927) (describing a dispute over whether abridgments of statutes fell under the jurisdiction of the Queen's Printer or under the common law printing patent).

[93] *See* Richard J. Ross, *The Commoning of the Common Law: The Renaissance Debate over Printing English Law, 1520–1640*, 146 U. PA. L. REV. 323, 338–39, 417 n.269 (1998); *see also* An Act for Abolishing of Diversity of Opinions in Certain Articles Concerning Christian Religion 1539, 31 Hen. 8 c. 14.

[94] *See* Ross, *supra* note 93, at 326–27.

[95] *See id*. at 329–42; Howard Jay Graham, *"Our Tong Maternall Maruellously Amendyd and Augmentyd": The First Englishing and Printing of the Medieval Statutes at Large*, 1530–1533, 13 UCLA L. REV. 58, 70–72 (1965).

said statutes" would allow people "better to live in tranquility and peace."[96] Politician-turned-poet Lord Brooke, after alluding to Gnaeus Flavius,[97] wrote:

> Again, laws ordered must be, and set down
> So clearly as each man may understand,
> Wherein for him, and wherein for the crown,
> Their rigor or equality doth stand. . . .[98]

Opponents of the publicists were primarily lawyers who stood to lose their monopoly over knowledge of the law.[99] The arguments of these "anti-publicists" illuminate why access to the law ought to encompass official annotations.

The anti-publicists generally did not oppose publishing binding law, protesting instead publication of the reasoning behind the law.[100] It is "assuredly no matter of necessity to publish the reasons of the judgment of the law, or *apices* [fine points] or *fictiones juris* to the multitude," wrote one lawyer.[101] Like the Confucians, the anti-publicists feared that "the unlearned by bare reading" of the law without the training of the Inns of Court "might suck out errors" and thus "endamage themselves."[102] Worse yet, miscreants could use knowledge of law as "shifts to cloak their wickedness, rather than to gain understanding."[103] More selfishly, the anti-publicists feared that publicizing the law would deny the bar the ability to characterize and evolve the law through in-guild decisions and manuscript-exchange norms that controlled the development of precedents.[104]

But the most important—and insidious—objection to law printing was one "married uneasily" to a larger debate over absolutist monarchy.[105] Presaging

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[96] Rastell, *supra* note 89, at 329 (spelling modernized).

[97] *See supra* note 56 and accompanying text.

[98] 1 FULKE GREVILLE, *Poems of Monarchy*, *in* THE WORKS IN VERSE AND PROSE COMPLETE 5, 101 (New York, AMS Press 1966) (1870) (spelling modernized).

[99] *See* Ross, *supra* note 93, at 390.

[100] *See id.* at 354–55.

[101] William Hudson, *A Treatise on the Court of Star-Chamber*, *in* 2 COLLECTANEA JURIDICA, CONSISTING OF TRACTS RELATIVE TO THE LAW AND CONSTITUTION OF ENGLAND 1, 1–2 (Francis Hargrave ed., London, W. Clarke & Sons 1792) (spelling modernized); *see* Ross, *supra* note 93, at 358.

[102] 2 EDWARD COKE, *To the Reader*, *in* THE REPORTS OF SIR EDWARD COKE iii, xxxix–xl (London, J. Butterworth & Son 1826) (c. 1600); *see* Ross, *supra* note 93, at 374–75.

[103] Hudson, *supra* note 101, at 2; Ross, *supra* note 93, at 376.

[104] *See* Ross, *supra* note 93, at 432–38 (reviewing the bar's use of manuscript copying policies and marginal notes, which "inculcated conventions of reading . . . that guided the amendment of texts").

[105] *Id.* at 452.

Georgia's view of its official code as the state's intellectual property, many anti-publicists supposed that because the Crown was the sole fount of power, the law was its "property"; as such there was no more need for the monarch to explain a law than for a parent to explain punishing a child.[106]

Few would accept absolutism today; the contrary view that law binds the sovereign is foundational to American government. And insofar as absolutism is rejected, one ought also to reject the anti-publicists'—and Georgia's—corollary view that sovereign explanations of the law do not implicate access concerns.

E. England, 1640–1642: Printing of Parliamentary Debates Plants Seeds of Democracy

The publishing of English parliamentary debates in the mid-1600s demonstrates how access to nonbinding but official materials, in this case legislative history, fosters popular sovereignty and public representation.

Parliament, even today, nominally holds the power to render its debates secret and to punish those who publish its proceedings.[107] The parliamentary privilege of "freedom of speech" provides that "Debates or Proceedings in Parlyament [sic] ought not to be impeached or questioned in any Court or Place out of Parlyament [sic]."[108] The Houses of Parliament interpreted this liberty to entail a copyright-like power to prohibit anyone—even their own members—from publishing debates.[109]

Certainly, privilege was enforceable only by contempt, as the common law courts refused to apply and indeed disparaged the secrecy privilege.[110] But contempt

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[106] *Id.* at 455; *see* 11 JAMES USSHER, *The Power Communicated by God to the Prince*, *in* THE WHOLE WORKS OF THE MOST REV. JAMES USSHER, D.D. 223, 349 (Charles Richard Elrington ed., Dublin, Hodges, Smith, & Co. 1864) ("And who seeth not what confusion would be brought, as well into a family as a state, if a son or a servant, or a subject might have liberty to stand upon terms and chop logic with his father master, or prince, and refuse to yield obedience to their commands, until he should see some reason for it?").

[107] *See* Clive Parry, *Legislatures and Secrecy*, 67 HARV. L. REV. 737, 741–43 (1954). Parliamentary privilege differs from Crown copyright discussed above.

[108] Bill of Rights, 1 W. & M. sess. 2, c. 2 (1689), 6 THE STATUTES OF THE REALM 143 (Eng.) (London, Dawsons 1819).

[109] *See* Wason v. Walter, [1868] 38 Eng. Rep. 34, 45 (QB); Carl Wittke, *The History of English Parliamentary Privilege*, 26 OHIO ST. U. BULL. 2, 50–51 (1921); H. Tomás Gómez-Arostegui, *The Untold Story of the First Copyright Suit Under the Statute of Anne in 1710*, 25 BERKELEY TECH. L.J. 1247, 1252–53 (2010).

[110] *See, e.g.*, *Wason*, 38 Eng. Rep. at 45; The King v. Wright, [1799] 101 Eng. Rep. 1396, 1399 (KB) ("it is of advantage to the public, and even to the legislative bodies, that true accounts of their proceedings should be generally circulated").

punishments could be severe.[111] In 1581, the House of Commons charged its member Arthur Hall with "publishing the conferences of this House abroad in print," and sentenced him with expulsion, a fine of 500 marks (about $130,000 today), and six months' imprisonment in the Tower.[112]

Nevertheless, a healthy industry of printing parliamentary debates began during the Long Parliament of 1640.[113] Disregard of the privilege was flagrant: Members not only published their speeches but occasionally registered them with the Company of Stationers.[114] Apart from sanctions against Sir Edward Dering for publishing not just speeches but also private conversations of Parliament, parliamentary privilege was essentially unenforced during this period.[115]

It was a good thing, too, that printing of debates flourished through the Long Parliament, because promulgation of those debates arguably catalyzed modern participatory democracy. Prior to 1640, the average English subject petitioned Parliament not for public policy change but with private grievances.[116] With the publication of parliamentary debates, an informed public could understand and thus engage in the political process: "[p]olitical discourse in printed texts encouraged readers to interpret conflict between King and Parliament, and subsequently among parliamentary factions, as an ongoing debate."[117] In particular, printed political debates allowed for a new form of petitioning Parliament, in which proponents of change could stir up support by presenting and critiquing the speeches of members.[118]

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[111] *See* THOMAS ERSKINE MAY, A TREATISE ON THE LAW, PRIVILEGES, PROCEEDINGS AND USAGE OF PARLIAMENT 88–92 (10th ed., London, William Clowes & Sons, Ltd. 1893) (noting unlimited fines and imprisonment as possible punishments).

[112] 1 H.C. JOUR. 125, 127 (1802) (Eng.) (resolution and order of Feb. 14, 1581). To be sure, this was not Commons' only charge against Hall, and Hall's publication was apparently particularly salacious. On the present-value computation, see Eric W. Nye, *A Method for Determining Historical Monetary Values*, https://www.uwyo.edu/numimage/currency conversion.htm (last visited Mar. 27, 2020).

[113] *E.g.*, SPEECHES AND PASSAGES OF THIS GREAT AND HAPPY PARLIAMENT: FROM THE THIRD OF NOVEMBER, 1640, TO THIS INSTANT JUNE, 1641 (London, William Cooke 1641); A.D.T. Cromartie, *The Printing of Parliamentary Speeches November 1640–July 1642*, 33 HIST. J. 23, 23 (1990).

[114] *See* Cromartie, *supra* note 113, at 35.

[115] *See id.* at 37.

[116] *See* David Zaret, *Petitions and the "Invention" of Public Opinion in the English Revolution*, 101 AM. J. SOC. 1497, 1509–10 (1996).

[117] *Id.* at 1530.

[118] *See id.* at 1532.

Printing parliamentary debates thus gave rise to "public opinion" as a political force. Public opinion, in turn, gave way to notions of popular sovereignty, including Locke's "law of opinion"[119] and Madison's "all governments rest on opinion."[120] Publication of nonbinding, official pronouncements of the legislature thus engendered this fundamental principle of American government.

F. Great Britain and New York, 1762–1796: Suppression of Debate Printing Sparks Demand for Freedom of Speech

Debate printing in the next century had a starker impact on America: it instigated freedom of the press.

When English newspapers began printing parliamentary debates in the mid-1700s, the House of Commons remarkably did exercise its parliamentary privilege.[121] In January 1762, Commons imprisoned the printer of the *London Chronicle* for printing a speech of the Speaker, deterring further printing of debates for several years.[122]

The 1768 Middlesex election affair reinvigorated debate reporting, and Parliament again tried to block it.[123] In what came to be called the Printers' Case of 1771, the House of Commons, led by its member Colonel George Oslow, summoned eight newspaper printers for contempt of privilege by printing debates.[124] Most confessed and made contrition on their knees, but John Miller, publisher of the *London Evening Post*, refused to appear.[125] Commons sent for Miller's arrest but was thwarted by Brass Crosby, Lord Mayor of London, who asserted sole jurisdiction for arrests in his city.[126] In an infamous move that triggered days of protests, the

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[119] 1 JOHN LOCKE, AN ESSAY CONCERNING HUMAN UNDERSTANDING 2.28.10–.12, at 476–77 (Alexander Campbell Fraser ed., Oxford, Clarendon Press 1894) (c. 1689).

[120] THE FEDERALIST NO. 49 (James Madison); *see* Zaret, *supra* note 116, at 1540; Elisabeth Noelle-Neumann, *Public Opinion and the Classical Tradition: A Re-Evaluation*, 43 PUB. OPINION Q. 143, 144–46 (1979).

[121] *See* Thomas, *supra* note 2, at 623.

[122] *See id.* at 624.

[123] *See id.*

[124] *See* 17 PARL. HIST. ENG., *supra* note 5, at 59–62. That treatise was originally titled *Cobbett's Parliamentary History* after its proprietor William Cobbett, but in 1810 Cobbett was imprisoned for criticizing the government's military discipline. *See* J.C. TREWIN & E.M. KING, PRINTER TO THE HOUSE: THE STORY OF *HANSARD* 94–101 (Methuen 1952).

[125] *See* 17 PARL. HIST. ENG., *supra* note 5, at 85–90.

[126] *See id.* at 98, 101.

House of Commons, frustrated with Crosby for protecting Miller, threw the Lord Mayor into the Tower instead.[127]

It is easy to imagine how parliamentary censorship in 1771 might have influenced Revolution-era American thinking on liberty and speech. There is considerable evidence that it did.[128] The *Virginia Gazette* predicted that "the present dispute about the liberty of the press will, in all probability, give a mortal wound to arbitrary power";[129] a week later it ran an open letter of the pseudonymous English polemicist Junius, excoriating Parliament's actions.[130] Benjamin Franklin knew of the incident,[131] as did Samuel Adams, who called the affair "a stretch of arbitrary power."[132] Americans celebrated John Wilkes, the London alderman who helped orchestrate the showdown between Parliament and the printers,[133] for championing freedom of the press.[134]

Americans continued to find parliamentary privilege antithetical to their principles.[135] One member of Congress declared that congressional debates were "offered to the public view, and held up to the inspection of the world."[136] And when in 1796, the New York Assembly jailed newspaper writer William Keteltas for "a

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[127] *See id.* at 157–58, 186–90; *Brass Crosby's Case*, [1771] 95 Eng. Rep. 1005 (K.B.) 1005–07.

[128] For another historian connecting the Printers' Case to the development of American freedom of the press, see JEFFERY A. SMITH, PRINTERS AND PRESS FREEDOM: THE IDEOLOGY OF EARLY AMERICAN JOURNALISM 23 (Oxford Univ. Press 1988).

[129] *See* Alex Purdie & John Dixon, *London, April 2*, VA. GAZETTE, June 13, 1771, at 1, 2.

[130] *See* William Rind, *Letter of Junius, from the Public Advertiser*, April 22, VA. GAZETTE, June 20, 1771, at 1.

[131] *See* Letter from Benjamin Franklin to Joseph Galloway, *in* 18 THE PAPERS OF BENJAMIN FRANKLIN 77 (Ellen R. Cohn et al. eds., Yale Univ. Press 1974).

[132] *See* Letter from Samuel Adams to Arthur Lee, *in* 2 RICHARD HENRY LEE, LIFE OF ARTHUR LEE, LL. D. 173, 174 (Boston, Wells & Lilly 1829).

[133] *See* Peter D.G. Thomas, *John Wilkes and the Freedom of the Press (1771)*, 33 BULL. INST. HIST. RES. 86, 88–91 (1960).

[134] *See* Roger P. Mellen, *John Wilkes and the Constitutional Right to a Free Press in the United States*, 41 JOURNALISM HIST. 2, 8 (2015). Mellen misattributes several colonial newspaper reports to Wilkes's earlier printing disputes; in fact those papers were referring to the Printers' Case.

[135] *See* David S. Bogen, *The Origins of Freedom of Speech and Press*, 42 MD. L. REV. 429, 434–35 (1983). *Compare* David A. Anderson, *The Origins of the Press Clause*, 30 UCLA L. REV. 455, 511–12 (1983), *with* Leonard W. Levy, *On the Origins of the Free Press Clause*, 32 UCLA L. REV. 177, 192–94 (1984). Anderson and Levy appear to agree that public opinion about parliamentary privilege played into views on sedition laws and thus the free speech clause; they disagree as to the degree to which legislatures themselves asserted the privilege.

[136] 1 ANNALS OF CONG. 443 (Joseph Gales ed., 1834) (statement of Rep. Jackson on June 8, 1789).

breach of the privileges" by reporting a debate, among his supporters was "Camillus Junius," a pseudonym that surely recalls the 1771 English episode.[137]

There is little daylight between parliamentary privilege and copyright when it comes to a legislature suppressing publication of nonbinding yet official pronouncements. In both cases the state levies powerful, even criminal[138] remedies against its citizens for publicizing information crucial for public dialogue. History has denounced state-asserted privilege as contrary to freedoms of speech and press;[139] state-asserted copyright ought to fare no better.

G. Virginia, 1846–1887: The Commonwealth Annotates Official Codes Despite Flagrant Copying

Although the states of America have been making legal codes since before they were states,[140] interest in codification accelerated in the mid-1800s as a result of successes of the Napoleonic *Code Civil* and lobbying by Jeremy Bentham.[141] Some of the resulting codes were annotated, such as Alabama's 1852 code, for which the General Assembly directed "a suitable person to make head notes to the titles, chapters, and articles."[142] Virginia was one of the first to enact a civil code during this period,[143] and its experience particularly reflects both recognition of the public value of official annotations and a lack of concern for copyright exclusivity.

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[137] *See* ALFRED F. YOUNG, THE DEMOCRATIC REPUBLICANS OF NEW YORK: THE ORIGINS 1763–1797, at 482–87 (Univ. of N.C. Press 1967).

[138] *See* 17 U.S.C. § 506(a) (2018).

[139] *See supra* notes 121–137 and accompanying text.

[140] *See, e.g.*, THE LAWS AND LIBERTIES OF MASSACHUSETTS (Max Farrand ed., Harvard Univ. Press 1929) (1648).

[141] *See* CHARLES WARREN, A HISTORY OF THE AMERICAN BAR 512–13 (Little, Brown, and Co. 1911). Other commentators correctly observe that there was not necessarily a "codification movement" insofar as most of the codification efforts failed, but nevertheless there was a wave of interest in and debate on the topic of codification. *See* Robert W. Gordon, *Book Review*, 36 VAND. L. REV. 431, 434 (1983) (reviewing CHARLES M. COOK, THE AMERICAN CODIFICATION MOVEMENT, A STUDY OF ANTEBELLUM LEGAL REFORM (1981)) (inferring that Cook shows "that a codification movement never really existed").

[142] Act to Provide for the Adoption, Printing and Distribution of the Code of Alabama, ch. 9, § 1, 1851 ALA. ACTS 22 (Feb. 5, 1852); ALA. CODE 797 (John J. Ormond et al. eds., Montgomery, Brittan and De Wolf 1852) (noting appointment of Henry C. Semple to this position).

[143] *See* Kent C. Olson, *State Codes*, *in* VIRGINIA LAW BOOKS: ESSAYS AND BIBLIOGRAPHIES 1, 5–6 (W. Hamilton Bryson ed., Am. Philosophical Soc'y 2000). Virginia already had a long tradition of compilations and revisions of its laws. *See generally* Dingledy 2019, *supra* note 19, ¶¶ 47–59, at 183–88.

In 1846, the General Assembly of Virginia appointed a commission "to revise and digest the civil code of this commonwealth," and in so doing to include "such notes and explanations as they shall deem essential to a clear understanding of the same."[144] The revisors, John M. Patton and Conway Robinson, produced five reports over the next few years in response.[145]

The revisors' reports are notable because they contain not just a code of law but also extensive annotations summarizing and analyzing case law. To head off criticisms that their revisions would undermine existing case law, Patton and Robinson presented their proposed code "accompanied by notes referring to decisions, and giving such explanations as we deemed essential to a clear understanding of our views."[146] In the section on amending pleadings at trial, for example, the report contains an extensive annotation laying out the cases and concluding that the judicial decisions "go to show the propriety of that statute; we approve the mode in which, under it, justice was administered."[147] The revisors' reports are thus much like a state annotated code, containing both statutes that were ultimately enacted into law and nonbinding explanatory annotations.[148]

Nevertheless, the revisors' annotations were openly copied.[149] In 1856, attorney James M. Matthews published his *Digest of the Laws of Virginia*, which not only copied the text of the statutes but also explicitly reproduced "the very valuable notes of the Revisors of the Code, contained in their Reports to the Legislature."[150] Among other things, the digest reproduces wholesale the annotation on pleading amendments.[151]

In its amicus brief in the *Georgia v. Public.Resource.Org, Inc.* case, Virginia contends that without copyright protection, it might "cease production of an official

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[144] Act to Provide for the Revisal of the Civil Code of This Commonwealth, ch. 34, § 1, 1845 VA. ACTS 26 (Feb. 20, 1846).

[145] JOHN M. PATTON & CONWAY ROBINSON, REPORT OF THE REVISORS OF THE CODE OF VIRGINIA (Richmond, Samuel Shepherd 1847–1849). The reports are unnumbered and bound inconsistently, so volume numbers are used to identify each of the five reports.

[146] 1 *id.* at ix.

[147] 4 *id.* ch. 177, § 7, at 873–74 n.*.

[148] The enacted code did not contain the explanatory annotations, so they could not be binding law. *See, e.g.*, VA. CODE ch. 177, § 7, at 672 (1849) (lacking annotation from the revisors' report noted above). Curiously, other annotations were added to the enacted and published code; their provenance is unclear. *See, e.g.*, ch. 177, § 4 note, at 671.

[149] *See* 1 JAMES M. MATTHEWS, DIGEST OF THE LAWS OF VIRGINIA OF A CIVIL NATURE iv (Richmond, J.W. Randolph 1856).

[150] *Id.*

[151] 1 *id.* ch. 19, § 7, n.5, at 235–36.

annotated code."[152] Yet the Commonwealth's actions belie its claim. No copyright suit against Matthews or his publisher appears to exist, despite the legislature's knowledge of its copyright registration and of the value of its work.[153] Indeed, the Secretary of the Commonwealth, Colonel George W. Munford, appeared to approve of Matthews's digest in the preface to Virginia's 1860 code.[154]

To be sure, the lack of litigation may reflect the more limited nature of copyright law at the time,[155] but the important point is that the copyright incentive was unnecessary. Even without it, Virginia continued undeterred to publish not only official codes but also annotations. The act authorizing publication of the 1860 code directed the secretary to include "such notes in each case of repeal, alteration, or amendment."[156] Munford did so extensively, providing both well-researched citations to case law and analysis of legislative history, for example opining on the supersessional effect of Virginia's 1847 telegraph statutes.[157] Virginia's 1887 code also contained notes and references to cases, for example, on protecting householders from certain debt collections.[158] In their preface to the 1887 code, the revisors note it was "much desired" to have fuller references within the code; tellingly, the obstacle to their doing so was not a lack of copyright or compensation, but excess page length.[159]

That Virginia produced annotated official codes for decades despite knowing its annotations were being copied shows that copyright was not a necessary incentive for state production of annotated codes. The revisors and preparers of those annotations would no doubt agree. In the prefaces to the 1849, 1860, and 1887 Virginia codes, they all acknowledge "a deep sense of [the] importance" of the legislature's charge not merely to compile the laws but to provide a "clear understanding of the same."[160] They understood that the task of the state explaining

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[152] Brief for Arkansas et al., *supra* note 9, at 2.

[153] *See* Act to Provide for the Publication of the Code of Virginia, ch. 2, §§ 3, 7, 1849 VA. ACTS 255 (Aug. 16, 1849).

[154] George W. Munford, *Preface* to VA. CODE iii, iii (2d ed., Richmond, Ritchie, Dunnavant & Co. 1860).

[155] The published revisors' reports appear to lack formalities. Furthermore, there was "painful uncertainty" on whether abridgments, such as Matthews' digest, were infringing. Story's Ex'rs v. Holcombe, 23 Fed. Cas. 171, 172 (C.C.D. Ohio 1847).

[156] Munford, *supra* note 154, at iii, v.

[157] *See* VA. CODE ch. 65, §30 at 337.

[158] VA. CODE ch. 178, §20 at 674 (1887).

[159] *See* E.C. Burks et al., *Preface* to VA. CODE iii, v (1887).

[160] 4 PATTON & ROBINSON, *supra* note 145, at iii–iv; *see also* Munford, *supra* note 154, at iv (compiler acknowledging that "he has felt the responsibility deeply, and no thought or labor has

the law devolves not from private pecuniary interests but from basic duties of a sovereign to its citizens.

III
HISTORY COUNSELS A CONSERVATIVE APPROACH TO STATE ASSERTION OF COPYRIGHT IN LEGAL MATERIALS

History carries multiple insights relevant to disposition of the question of copyright in state legal texts, namely whether copyright law allows a government to muzzle access to official state-authored materials, such as annotations to a legal code. Three such conclusions are discussed below.

A. Edicts of Government, and Law Generally, Are Not Limited to Acts of Binding Legal Force

First, the law consists not merely of sovereign acts carrying binding force. Pronouncements of government instead fall on a spectrum of binding power. Georgia's repeated insistence that edicts of government for this case are limited to those that "establish any enforceable rights or obligations,"[161] then, is inconsistent with millennia of history.

From the beginning, nonbinding commentaries and annotations have carried legal weight.[162] The Romans respected the nonbinding advice of the Senate and gave special weight to commentators having the imprimatur of *jus respondendi*.[163] The Qing dynasty code visually distinguished official and private commentaries, literally interweaving the former with the statutory text.[164] Furthermore, the 16th-century anti-publicists who acquiesced in printing statutes but feared giving the uneducated masses the "*apices* or *fictiones juris*"—points and fictions of legal reasoning that explained the rules—illustrate the potency of those nonbinding sources of law.[165]

The consistent blurring of what constitutes the law is unsurprising, because the purpose of promulgated law is broader than merely putting citizens on notice of punishable acts. As the Chinese legalists[166] and English publicists[167] understood, law

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been spared in the earnest endeavor to accomplish the task"); Burks et al., *supra* note 159, at v ("[O]ur utmost endeavor has been to discharge our whole duty faithfully and conscientiously.").

[161] Brief for Petitioners, *supra* note 11, at 3.

[162] *See* discussion *supra* notes 54–60 and accompanying text.

[163] *See* discussion *supra* notes 62–67 and accompanying text.

[164] *See* discussion *supra* notes 68–82 and accompanying text.

[165] *See* discussion *supra* notes 100–106 and accompanying text.

[166] *See* discussion *supra* notes 69–74 and accompanying text.

[167] *See* discussion *supra* notes 95–98 and accompanying text.

promotes civic virtue and informs people of the will of the sovereign. Promulgated law enables citizens, apprised of the sovereign's reasoning, to participate in government and to sway that reasoning based on public opinion, as Parliament learned from publishing its debates.[168] Promulgated law checks arbitrary government power, much to the chagrin of the Confucians[169] and Colonel Oslow.[170] Moreover, promulgated law sets a historical marker of a society's culture, without which a study such as the present article could not exist.

Nonbinding but official pronouncements of government at issue in this case serve these purposes equally, if not *a fortiori*. It was announcement of English law not in its binding law-French form but in the unofficial vulgar tongue that enhanced the Crown's reputation and advised the people on how to live in "tranquility and peace."[171] It was the printing of parliamentary debates that spurred public participation in the legislative process.[172]

In particular, nonbinding pronouncements uniquely serve an essential function of law: statutory interpretation and construction. Both China and Rome recognized that the statutes alone could not clearly expound the law, so their official commentaries contained "a great deal of necessary information" for understanding statutes.[173] And official explanations of law are, in Justice Scalia's words, "ordinarily *the* most persuasive" extrinsic information for judicial construction, a theory put into practice by the Georgia courts that have repeatedly relied on the state's official annotations.[174]

That the full body of law encompasses both binding and nonbinding texts counsels against discarding any of them from rights of public access in view of copyright or other laws. History and contemporary practices show that a nonbinding official pronouncement can play an important role in delineating the rights of citizens, making it no less a part of "the law," and no less an edict of government, than a statute.

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[168] *See* discussion *supra* notes 107–118 and accompanying text.
[169] *See* discussion *supra* notes 71–74 and accompanying text.
[170] *See* discussion *supra* notes 123–127 and accompanying text.
[171] *See* discussion *supra* notes 83–89 and accompanying text.
[172] *See* discussion *supra* notes 116–120 and accompanying text.
[173] 1 Johnson, *supra* note 77, at 43; *see* Dingledy, *supra* note 64, at 235.
[174] Tome v. United States, 513 U.S. 150, 167 (1995) (Scalia, J., concurring); *see* Code Revision Comm'n ex rel. Gen. Assembly of Ga. v. Public.Resource.Org, Inc., 906 F.3d 1229, 1250-51 (11th Cir. 2018).

B. Control over the Reasons and Explanations of Law Confers Undue Power on Government and the Legal Profession

History also reveals the danger of allowing states the power to restrain access to nonbinding legal pronouncements, whether under copyright law or otherwise. That power can exacerbate both government centralization and undue influence of the bar.

The arguments of states wishing to wield copyright against their citizens find uneasy company with the ancient Confucians[175] and the English anti-publicists,[176] who preferred the absolutist sovereign meting out law and punishment while leaving those without means blind to the reasons. No doubt this regime promotes obedience, but to contemporary ears it smacks of autocracy. Similarly, should a state such as Georgia exercise its copyright privilege to deny access to reasoning contained in official annotations, the state would potentially wield undue power. It could, for example, selectively conceal its views on whether a statute should be construed narrowly or broadly, perhaps leading risk-averse citizens to forgo rights or liberties they otherwise would enjoy.[177]

Control over official annotations to law also hands improvident power to the bar. The anti-publicist English lawyers knew that legal printing stood to cost them their monopoly over the written reasoning of the law and thus their political power to shape the direction of legal reform.[178] New York lawyer James Coolidge Carter similarly led opposition to state codification efforts in the 1850s, again to maintain the bar's control over evolving the law.[179] State assertion of copyright also places the official annotations largely in the hands of well-funded lawyers, raising the same concern that those with the most access to the official, promulgated commentary—and thus the ability to shape it—are a professional class uncharacteristic of the general public.

C. Unlike Case Reports or Treatises, Annotated Official Codes Are a Traditional State Dictum

Attempting to avert the strangeness of a state wielding copyright against citizens, states such as Georgia and their supporters repeatedly analogize to private

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[175] *See* discussion *supra* notes 71–74 and accompanying text.

[176] *See* discussion *supra* notes 100–106 and accompanying text.

[177] *Cf.* Yates v. United States, 135 S. Ct. 1074, 1090 (2015) (Alito, J., concurring) (relying in part on a statute's nonbinding title to narrow construction).

[178] *See* discussion *supra* note 104 and accompanying text.

[179] *See* Mathias Reimann, *The Historical School against Codification: Savigny, Carter, and the Defeat of the New York Civil Code*, 37 AM. J. COMP. L. 95, 110–13 (1989).

legal treatises and headnotes to cases, supposing that the state, as annotator of the official code, is acting less like a government and more like a private scholar.[180] History again disputes this claim, because unlike treatises and case reports, official annotated codes of law have long been the province of sovereigns.

State-published annotations are a tradition going back centuries.[181] Justinian declared two commentaries, the *Digest* and *Institutes*, official components of the *Corpus Juris Civilis* alongside the statutes.[182] Annotations have been part of the Chinese legal tradition since at least the 200 B.C. Han dynasty code.[183] England did not develop a tradition of publishing official commentaries on laws until about the 20th century,[184] but annotated codes were frequent in Virginia and other states.[185]

By contrast, neither case reports nor private treatises have traditionally been promulgations of the state.[186] Private treatises on law abounded in Rome, but the emperors distinguished the unofficial from the official through proclamations and *jus respondendi*.[187] English case reports were also understood to be private works: the medieval Year Books were unofficial and generally attributed to lawyers or law students,[188] and the nominate reports that followed identified the names of private

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[180] In particular, they rely on *Callaghan v. Myers*, 128 U.S. 617 (1888), which held copyrightable a private court reporter's headnotes and syllabi, and *Howell v. Miller*, 91 F. 129 (6th Cir. 1898), which dealt with a privately prepared statutory code. *See* Brief for Petitioners, *supra* note 11, at 37, 41–42.

[181] *See supra* Section II.A–.B.

[182] *See* discussion *supra* notes 64–67 and accompanying text.

[183] *See* discussion *supra* notes 75–82 and accompanying text.

[184] Starting in 1882, the Public Bill Office prepared summaries of bills introduced in Parliament. *See* MAY, *supra* note 111, at 442; 260 PARL. DEB., H.C. (3d ser.) (1881) 423–24 (Eng.). These summaries are now published and called "explanatory notes." *See* CABINET OFFICE, GUIDE TO MAKING LEGISLATION para. 11.9, at 78 (July 2017). "Briefs" attached to bills in Parliament date back to at least the 17th century, but it is likely that the briefs were never made public. *See* MAY, *supra* note 111, at 441; 6 H.C. JOUR. 570 (1651) (resolving that "Mr. Speaker ought not to open any Bill, nor to command the same to be read, unless a Brief thereof be first delivered unto him").

[185] *See* discussion *supra* notes 140–160 and accompanying text.

[186] *Cf.* Tussey, *supra* note 16, at 174 n.1 (1998) (distinguishing "primary law," the "direct products of judicial, legislative, and executive action," from "[s]econdary law" made up of "treatises, casebooks, encyclopedias, and practice guides"). Unsurprisingly, contemporary commentators classify case reports as state-promulgated works because, today, they frequently are. *See, e.g.*, 28 U.S.C. § 411(a) (2018) (providing for printing of the *United States Reports*).

[187] *See* discussion *supra* notes 61–67 and accompanying text.

[188] *See* 2 HOLDSWORTH, *supra* note 87, at 532–36; Michael Bryan, *Early English Law Reporting*, 4 U. MELB. COLLECTIONS 45, 46 (2009).

compilers—Plowden, Dyer, Coke.[189] When Lord Coke opined in *Dr. Bonham's Case*[190] that the king's statutes were not above the law (an early exercise of judicial review), James I kicked him off the court and then in 1616 ordered Coke to "correct his *Reports*" of the case.[191] Coke refused, and because the reports were his own and not the Crown's, he could.[192]

To be sure, the common law printing patent encompassed treatises in addition to Year Books, perhaps implying that England placed private treatises on the same level as case law.[193] But insofar as the Crown at that time had a "custom of granting privileges for the printing of whole classes of books" besides legal texts,[194] the fact that Littleton's treatise on land tenures was one such monopoly is not indicative of much.

When states such as Georgia deem their official annotated codes akin to treatises and case reports, it grates against history that has long treated official codes as mouthpieces of the state. That a private firm under state commission often holds the pen in preparing these codes is of little consequence: the Justinian *Digest*[195] and Virginia codes[196] were also privately authored under commission and subsequently ratified. Nor is there much weight to the states' supposedly benign motive of using copyright to subsidize production of annotations[197]—the state was free to subsidize a private treatise under a private publisher's own name; that would make for a different case but also for a far less valuable treatise owing to the absence of "Official" on the cover.

The inescapable conclusion is that by designating an annotated code as *official*, a state is not an ordinary market participant. It instead taps into a long arc of history of sovereigns propounding their will through pronouncements, binding or not, upon their citizens. Those pronouncements are part and parcel of the law, and they are edicts of government to which citizens are entitled access.

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[189] *See* W.S. HOLDSWORTH, SOURCES AND LITERATURE OF ENGLISH LAW 89–90 (1925).

[190] Thomas Bonham v. Coll. of Physicians (Dr. Bonham's Case), [1610] 77 Eng. Rep. 638 (C.P.).

[191] Theodore F.T. Plucknett, *Bonham's Case and Judicial Review*, 40 HARV. L. REV. 30, 50 (1926).

[192] *See id.* at 49–50.

[193] *See* Byrom, *supra* note 92, at 223–24.

[194] *See id.* at 229.

[195] *See* Dingledy, *supra* note 64, at 235.

[196] *See* discussion *supra* notes 143–160 and accompanying text.

[197] *See* Brief for Arkansas et al., *supra* note 9, at 20–23.

CONCLUSION

The English jurist Sir Frederick Pollock posited that "the greater have been a lawyer's opportunities of knowledge, and the more time he has given to the study of legal principles, the greater will be his hesitation in the face of the apparently simple question, What is Law?"[198] The State of Georgia and others (and Pollock, for that matter) suppose a simple answer: the law is statutes, and nothing more. Yet history stretching as far back as ancient Rome and China refutes that simple equation. The law is and long has been an amalgam of texts of varying levels of compulsion, including commentary, dicta, preambles, and indeed annotations.

The history reviewed in this article demonstrates governments sometimes aggressively promoting publication and enjoying the benefits of doing so, and sometimes vigorously opposing publication in ways that reveal substantial harms to society. That history, in the end, demonstrates that the value of access to the law, with which copyright can interfere, spans beyond binding statutory texts; foundational principles of limited government, popular sovereignty, and basic liberty depend on access to the law in whole.

[198] FREDERICK POLLOCK, FIRST BOOK OF JURISPRUDENCE FOR STUDENTS OF THE COMMON LAW 4 (London, Macmillan & Co. 1896).

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NOTE

TOWARDS A TRADEMARK RULE OF REASON

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* J.D. Candidate, New York University School of Law, 2020. This Note is dedicated to my fiancée for her infinite support and encouragement. I am grateful to Professors Christopher J. Sprigman and Barton Beebe for inspiring my interest in trademark law.

INTRODUCTION

Some perceive trademark protection as a reward for a mark owner's labor in cultivating his business goodwill.[1] However, among legal scholars and academics, the prevailing theoretical explanation for trademark protection is utilitarian, focusing on increasing consumer welfare.[2] Based on the "search costs" theory of trademark law, legal protection is justifiable because trademarks produce two welfare-increasing effects.[3] First, trademarks reduce consumer search costs.[4] Second, trademarks incentivize producers to invest in product quality and consistency.[5]

Importantly, not all means of reducing search costs maximize consumer welfare. For example, consumer search costs would be reduced if competition was eliminated and products were offered by single providers. But nobody supports the monopolization of markets as a desirable method of reducing search costs. It is generally believed that consumers are better served by competition, even though competitive markets require more searching than do markets with single providers.[6] This conflict suggests that trademark law must strive to achieve the goal of reducing consumer search costs only insofar as doing so facilitates the functioning of a competitive market.[7]

It follows that enforcement of trademark rights rests on the assumption that mark owners, acting as quasi-economic regulators, will prevail when their infringement claim runs parallel to the consumer welfare goal of promoting effective competition. All other conduct should be left unregulated. Trademark law

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[1] *See* Mark P. McKenna, *The Normative Foundations of Trademark Law*, 82 NOTRE DAME L. REV. 1839, 1873–93 (2007) (setting out the Lockean account of trademark law).

[2] *See* William M. Landes & Richard A. Posner, *Trademark Law: An Economic Perspective*, 30 J.L. & ECON. 265 (1987) (setting out the economic account of trademark law).

[3] *See* Mark P. McKenna, *A Consumer Decision-Making Theory of Trademark Law*, 98 VA. L. REV. 67, 73–74 (2012) (explaining the "search costs" theory of trademark law).

[4] *See infra* notes 19–20 and accompanying text.

[5] *See infra* note 21 and accompanying text.

[6] *See* McKenna, *supra* note 3, at 87 n.45 ("Indeed, the Supreme Court has rejected the argument that horizontal agreements to eliminate credit sales can be justified under the antitrust laws on the ground that an industry-wide agreement reduces the cost of learning price and credit terms.").

[7] Stacey L. Dogan & Mark A. Lemley, *A Search-Costs Theory of Limiting Doctrines in Trademark Law*, 97 TRADEMARK REP. 1223, 1227 (2007) [hereinafter Dogan & Lemley, *Search-Costs*]; *see also* Stacey L. Dogan & Mark A. Lemley, *The Merchandising Right: Fragile Theory or Fait Accompli?*, 54 EMORY L.J. 461, 467 (2005) [hereinafter Dogan & Lemley, *Merchandising Right*].

built on enhancing competition should limit liability to conduct that has a net effect of harming competition and should avoid liability for conduct that has a net effect of benefiting competition.

Unfortunately, in the name of reducing search costs, courts have lost sight of trademark law's underlying competition policy.[8] Rather than develop a system in which consumer confusion is actionable only insofar as it relates to the competitive goals of trademark law, over time courts have created one in which consumer confusion is the harm itself. Because of this confusion-centric analysis, trademark liability has expanded over the past half-century to encompass many different forms of confusion, such as initial-interest confusion and post-sale confusion.[9] Trademark's expansion of actionable confusion, coupled with its distribution of proof burdens, has contributed to its departure from its goal of promoting competitive markets.

In this Note, I argue that the unitary per se rule is ill-suited for assessing the vast amount of confusion that trademark law now governs. Trademark liability should, instead, reflect the model set out in the field of antitrust, a body of law similarly tasked with condemning conduct that distorts the competitive markets. Antitrust teaches that liability should oscillate between rules and standards and that, in designing a binary liability scheme, a preference for reducing false positives is most appropriate. As applied to trademark law, infringement liability would reflect a similar binary regime.

This Article proceeds as follows. Part I provides an overview of the competition policy justification that grounds trademark law. Part II will discuss trademark infringement liability and the various confusion-based liability doctrines. Part III will describe the weaknesses of trademark law's current liability scheme. Drawing inspiration from antitrust law in Part IV, I will argue for a reformation in trademark liability that reflects antitrust by featuring rules and standards and reducing false positives.

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[8] *See* McKenna, *supra* note 3, at 71 ("Anything that can be characterized in confusion-based terms seems to raise search costs, and if search costs are the harm to be avoided, then anything that causes confusion ought to be at least prima facie actionable.").

[9] *See infra* Part II.B.

I.
AN OVERVIEW OF TRADEMARK LAW AS A SPECIES OF COMPETITION POLICY

While it is well recognized that trademark law aims to promote competition,[10] most accounts of trademark law begin with the two economic functions that trademarks serve.[11] A trademark is a word, symbol, or other signifier used to distinguish a good or service produced by one firm from the goods or services of the other.[12] The range of what constitutes a trademark is broad; it includes words,[13] colors,[14] building shapes,[15] and even scents.[16] However, regardless of what form they take, at their most basic level, trademarks

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[10] *See* Barton Beebe & C. Scott Hemphill, *The Scope of Strong Marks: Should Trademark Law Protect the Strong More Than the Weak?*, 92 N.Y.U. L. REV. 1339, 1387–89 (detailing the ways in which several elements of trademark doctrine attempt to achieve this goal); John F. Coverdale, Comment, *Trademarks and Generic Words: An Effect-on-Competition Test*, 51 U. CHI. L. REV. 868, 869 ("The law regulating trade and commerce frequently seeks to promote competition as a means of allocating resources efficiently and insuring reasonable prices.").

[11] These economic functions have dominated both judicial and scholarly accounts. *See* Qualitex Co. v. Jacobsen Prods. Co., 514 U.S. 159, 163–64 (1995) (stating that trademark law "reduce[s] the customer's costs of shopping and making purchasing decisions [and] . . . helps assure a producer that it (and not an imitating competitor) will reap the financial, reputation-related rewards associated with a desirable product") (internal citations omitted); Union Nat'l Bank of Tex., Laredo, Tex. v. Union Nat'l Bank of Tex., Austin, Tex., 909 F.2d 839, 844 (5th Cir. 1990) ("The idea is that trademarks are 'distinguishing' features which lower consumer search costs and encourage higher quality production by discouraging free-riders."); 1 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 2:3 (5th ed.) (quoting William N. Landes & Richard A. Posner, *The Economics of Trademark Law*, 78 TRADEMARK REP. 267, 267 (1988), for the proposition that trademark law is best understood as "trying to promote economic efficiency"); Barton Beebe, *The Semiotic Analysis of Trademark Law*, 51 UCLA L. REV. 621, 623–24 (2004) ("The Chicago School of law and economics has long offered a totalizing and, for many, quite definitive theory of American trademark law. . . . The influence of this analysis is now nearly total. . . . No alternative account of trademark doctrine currently exists.").

[12] 15 U.S.C. § 1127 (1994).

[13] *See, e.g.*, U.S. Reg. No. 1,078,312, Nov. 29, 1977 (APPLE for computers).

[14] *See, e.g.*, *Qualitex*, 514 U.S. at 159.

[15] *See, e.g.*, Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763 (1992).

[16] *See* U.S. Reg. No. 5,467,089, May 15, 2018 (for toy modeling compounds, where "[t]he mark is a scent of a sweet, slightly musky, vanilla fragrance, with slight overtones of cherry, combined with the smell of a salted, wheat-based dough").

communicate information to consumers about the source and quality of the products on which they are displayed.[17]

Trademarks serve two critical functions in the marketplace.[18] First, trademarks reduce consumer search costs. Consumers can rely on trademarks as a method of obtaining accurate information about a product, such as its source and quality, and of ensuring, based on that information, that the item has the desired characteristics.[19] By providing the means for consumers to obtain purchase-relevant information without having to expend endless time and effort in search, trademarks reduce transaction costs and thereby enhance competition.[20] The ability of consumers to rely on trademarks in order to distinguish between producers gives rise to the second function of trademarks in the marketplace. Specifically, trademarks allow producers to profit from the goodwill they cultivate among consumers. By restricting the ability of other producers to use identical or confusingly similar marks on their competing products, trademark law ensures that producers themselves, and not their competitors, reap the benefit of their investments in quality and consistency. This profit-motive incentivizes producers to continue to make such investments, which in turn enhances competition.[21]

Again, while the reduction of consumer search costs and the encouragement of goodwill investment represent critical *intermediate* objectives of the trademark system, it is important not to lose sight of the fact that neither of these goals is an end in itself. The ultimate policy goal of trademark law is to facilitate the functioning of a competitive marketplace.[22] Informed consumers make well-

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[17] Although trademarks originally indicated source explicitly, consumers today rely on these marks principally for information about product features and quality, which—in turn—depend upon consistency of source. *See* Nicholas S. Economides, *The Economics of Trademarks*, 78 TRADEMARK REP. 523, 527 (1988) ("Presently the trademark typically identifies the product (the full combination of features that constitute the product), and its role of identifying the source is secondary in the minds of consumers.").

[18] *See* Landes & Posner, *supra* note 2 (providing the definitive statement of the economic model of trademark law).

[19] *See* Robert G. Bone, *Enforcement Costs and Trademark Puzzles*, 90 VA. L. REV. 2099, 2105 (2004).

[20] *See* Stacey Dogan, *Bounded Rationality, Paternalism, and Trademark Law*, 56 HOUS. L. REV. 269, 275 (2018); McKenna, *supra* note 3, at 73–74 (describing the "search costs" theory of trademark law).

[21] *See* Economides, *supra* note 17, at 525–27 (suggesting that trademarks primarily exist to enhance consumer decisions and create incentives for firms to produce desirable products).

[22] This ultimate goal is illustrated in several areas of trademark law. For example, the non-protectability of generic and functional marks, and the defense of nominative fair use. *See* Beebe

informed purchase decisions, which increases their overall utility and spurs producers to offer higher quality products.[23] Thus, the underlying aim of this body of law is to encourage more competitive markets by improving the quality of information in those markets.[24] Conceptualized this way, trademark law is a species of competition law.[25]

The goal of promoting competition justifies not only the affirmative rights trademark law confers on markholders, but also the limitations that the law should place on those rights. A trademark law that is built on enhancing competition should limit liability to information-distorting conduct that has a net effect of harming competition and should avoid imposing liability for conduct that has a net effect of benefiting competition. As will be discussed in Part III, the current trademark liability regime offends these basic principles.

II.
TRADEMARK INFRINGEMENT LIABILITY

In the name of reducing search costs, courts focus on the narrow issue of consumer confusion when determining liability for trademark infringement.

A. The Likelihood of Confusion Test

The bedrock of a trademark infringement action is the likelihood of confusion test.[26] The "likelihood of confusion" is the probability that an alleged

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& Hemphill, *supra* note 10, at 1387 ("Limitations on the scope of a mark reduce consumer search costs, freeing up rivals to use similar marks and thereby increasing industry supply and consumer welfare.").

[23] *See* Maureen A. O'Rourke, *Shaping Competition on the Internet: Who Owns Product and Pricing Information?* 53 VAND. L. REV. 1965, 1968 (2000) (describing conditions for perfectly competitive market).

[24] *See* Dogan & Lemley, *Merchandising Right*, *supra* note 7, at 467; *see also* Dogan & Lemley, *Search-Costs*, *supra* note 7, at 1224 ("The evolution of trademark law reflects a continual balancing act that seeks to maximize the informational value of marks while avoiding their use to suppress competitive information.").

[25] *See* Landscape Forms, Inc. v. Columbia Cascade Co., 113 F.3d 373, 379 (2d Cir. 1997) ("[T]he Lanham Act must be construed in light of a strong federal policy in favor of vigorously competitive markets, which is exemplified by the Sherman Act and other antitrust laws."); Coverdale, *supra* note 10, at 870 ("Because the policy of the trademark law is to promote competition, a trademark, unlike a patent or copyright, affords no monopoly over the product to which it is affixed . . . indeed, the Supreme Court has noted that there is a strong federal policy that goods unprotected by patents or copyrights should be copyable by anyone.").

[26] *See* Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 769 (1992) ("It is, of course, also undisputed that liability under § 43(a) requires proof of the likelihood of confusion.");

infringer's mark is the cause in fact of confusion in the minds of potential consumers. Liability depends on whether the defendant's use of a mark is likely to cause consumers to be confused or deceived as to the source or nature of the defendant's product or service.[27] Courts use a multi-factor test to determine whether such a likelihood is present.[28] Although the factors differ among the circuit courts,[29] the traditional set of factors developed by the Second Circuit in *Polaroid Corp. v. Polarad Electronics Corp.*[30] is illustrative of the typical factors considered. These factors include: (1) the strength of the plaintiff's mark; (2) the degree of similarity between plaintiff's and defendant's marks; (3) the proximity of the products or services; (4) the likelihood that plaintiff will bridge the gap; (5) evidence of actual confusion; (6) defendant's good faith in adopting the mark; (7) the quality of defendant's product or service; and (8) the sophistication of the buyers.[31]

Importantly, the plaintiff's prima facie case starts and ends with a confusion analysis. If the plaintiff succeeds in establishing a likelihood of confusion, the court will hold the defendant liable for infringement, implicitly presuming that the confusion causes harm to the consumer, the mark owner, and the market.

RESTATEMENT THIRD, UNFAIR COMPETITION § 20, comment d (1995) ("The term 'likelihood of confusion' has long been used to describe the standard of liability for trademark infringement in actions at common law and under federal and state trademark and unfair competition statutes.").

[27] Lanham Act § 32, 15 U.S.C.A. § 1114(1) (2018).

[28] *See* 4 MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 24:28 (5th ed.) [hereinafter McCarthy] ("Through decades of case law precedent and the influence of the Restatement, the federal courts have developed a multi-factor test to assist in the difficult determination of whether there is or is not a likelihood (probability) of confusion.").

[29] The following cases set forth the factors considered by the Circuits: First Circuit, *see* Keds Corp. v. Renee Int'l Trading Corp., 888 F.2d 215, 222 (1st Cir. 1989); Third Circuit, *see* Merchant & Evans, Inc. v. Roosevelt Bldg. Prods. Co., 963 F.2d 628, 637 (3d Cir. 1992); Fourth Circuit, *see* Anheuser-Busch, Inc. v. L & L Wings, Inc., 962 F.2d 316, 320 (4th Cir. 1992); Fifth Circuit, *see* Sno-Wizard Mfg., Inc. v. Eisemann Prods. Co., 791 F.2d 423, 428 (5th Cir. 1986); Sixth Circuit, *see* Homeowners Group, Inc. v. Home Mktg. Specialists, Inc., 931 F.2d 1100, 1106 (6th Cir. 1991); Seventh Circuit, *see* Smith Fiberglass Prods., Inc. v. Ameron, Inc., 7 F.3d 1327, 1329 (7th Cir. 1993); Eighth Circuit, *see* Squirtco v. Seven-Up Co., 628 F.2d 1086, 1091 (8th Cir. 1980); Ninth Circuit, *see* E. & J. Gallo Winery v. Gallo Cattle Co., 967 F.2d 1280, 1290 (9th Cir. 1992); Tenth Circuit, *see* Coherent, Inc. v. Coherent Techs., Inc., 935 F.2d 1122, 1125 (10th Cir. 1991); Eleventh Circuit, *see* Dieter v. B&H Indus. of Sw. Fla., Inc., 880 F.2d 322, 326 (11th Cir. 1989); Federal Circuit, *see In re* E.I. DuPont DeNemours & Co., 476 F.2d 1357, 1361 (C.C.P.A. 1973).

[30] 287 F.2d 492 (2d Cir. 1961).

[31] *See id*. at 495.

B. Expansion of Trademark Liability Over Time[32]

Traditionally, the scope of consumer confusion targeted by trademark law was limited to purchaser confusion as to the source of goods or services at the time of sale.[33] This is known as point-of-sale confusion. However, over the last fifty years the number of forms of actionable confusion has expanded dramatically. For example, the point of purchase is no longer the only relevant period in which to assess confusion. Under the modern initial-interest confusion[34] and post-sale confusion[35] theories of liability, actionable confusion now extends to the periods *before* and *after* the transaction has taken place.

Additionally, the population of confused persons is no longer limited to purchasers or likely purchasers. In a claim of post-sale confusion, the confusion does not arise among the class of purchasing consumers; rather, actionable confusion arises among third-party observers who view the product on the street and mistake the source of that product.[36] For example, Levi Strauss launched a post-sale confusion theory to enjoin Lois Sportswear from selling designer denim

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[32] It is important to note that modern trademark doctrine has expanded beyond its traditional core in many ways. Trademark law now recognizes more types of symbols as protectible than ever before and extends protection beyond the trademark owner's primary market. However, while these issues are important and require further discussion, they lie outside the scope of my analysis. In this article, I focus on the doctrinal expansion of the circumstances that create a basis for liability and specifically on the expansion of actionable confusion to now include confusion at every stage of the transaction.

[33] Under the Lanham Act of 1946, to establish trademark infringement, the plaintiff had to prove that the infringing mark was "likely to cause confusion or mistake or to deceive purchasers as to the source of origin of such goods." Lanham Act, Pub. L. No. 79-489, § 32(1), 60 Stat. 427, 437 (1946) (codified as amended at 15 U.S.C. § 1114(1) (1994)). Because of the express reference to purchasers, courts accordingly focused their likelihood of confusion examination on whether actual purchasers were likely to buy a product bearing an infringing mark while mistakenly believing it to be the plaintiff's product.

[34] *See* Jennifer E. Rothman, *Initial Interest Confusion: Standing at the Crossroads of Trademark Law*, 27 CARDOZO L. REV. 105, 160–61 (2005) (describing the history of initial-interest confusion).

[35] *See* Jeremy N. Sheff, *Veblen Brands*, 96 MINN. L. REV. 769, 776–77 (2012) (explaining how the idea of point-of-sale confusion has dramatically expanded with the creation of doctrines like post-sale confusion); Lois Sportswear, U.S.A., Inc. v. Levi Strauss & Co., 799 F.2d 867 (2d Cir. 1986); Bone, *supra* note 19, at 609–10 (discussing the Lois Sportswear case).

[36] Ferrari S.P.A. v. Roberts, 944 F.2d 1235, 1245 (6th Cir. 1991) (where the plaintiff's proposition was that "members of the public, but not necessarily purchasers, were actually confused by the similarity of the products").

jeans with stitching that resembled Levi's trademarked stitching pattern.[37] Even though the packaging and labeling of Lois's jeans eliminated any possibility of consumer confusion at the time of purchase, Levi claimed that third parties who view the jeans when worn in public would mistakenly infer from the stitching pattern that Lois's jeans were Levi's jeans.[38]

Under a theory of initial-interest confusion, the plaintiff claims that consumers are attracted to the defendant's product due to the resemblance between the defendant's mark and that of the plaintiff, but then realizes the true source of the goods before the sale is consummated.[39] The doctrine originated from the prohibition of bait-and-switch advertising, where the concern was that consumers, once drawn into the decision-making process, may not back out even upon discovering that the offered product or service is not what they expected.

In recent years, however, courts have gone well beyond this traditional instance of initial-interest confusion. Some have found liability even when there is no confusion beyond a moment of uncertainty; others have gone even further, holding defendants liable for using another's mark merely to gain attention and hence not to confuse.[40] For example, courts have used an initial-interest confusion theory to enjoin the use of a competitor's mark to attract customers to websites. In *Brookfield Communications v. West Coast Entertainment*,[41] the plaintiff, which sold software that allowed customers to look up movie information, was able to prevent the defendant, an internet video rental and movie information supplier,

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[37] *Lois Sportswear*, 799 F.2d at 867.

[38] The alleged harm to the trademark owner is not that the third-party observers will go on to wrongly buy the defendant's product—that would be point-of-sale confusion. Rather, the harm is that the third-party observers will *not* buy the plaintiff's product due to the misinformation they received upon viewing the defendant's product, such as the notion that the real item is low quality. *See* Sheff, *supra* note 35, at 802.

[39] *See* Promatek Indus., Ltd. v. Equitrac Corp., 300 F.3d 808, 812 (7th Cir. 2002), as amended (Oct. 18, 2002) ("Initial interest confusion, which is actionable under the Lanham Act, occurs when a customer is lured to a product by the similarity of the mark, even if the customer realizes the true source of the goods before the sale is consummated."); *see also* Grotrian, Helfferich, Schulz, Th. Steinweg Nachf. v. Steinway & Sons, 523 F.2d 1331, 1342 (2d Cir. 1975) (finding "initial confusion" when the declaratory plaintiff used the mark GROTRIAN-STEINWEG for pianos even though no consumers ultimately purchased the plaintiff's pianos believing them to be STEINWAY pianos).

[40] *See, e.g.*, Brookfield Commc'ns, Inc. v. W. Coast Entm't Corp., 174 F.3d 1036, 1062–63 (9th Cir. 1999) (finding trademark liability, even though consumer confusion was not likely, because consumers might be diverted to defendant's website).

[41] 174 F.3d 1036 (9th Cir. 1999).

from using the plaintiff's mark, MOVIEBUFF, as part of a website metatag. Use of the plaintiff's mark in a metatag means that an internet user who enters the term "MOVIEBUFF" into a search engine would pull up a list of websites that includes both the plaintiff's and the defendant's domain names. Although the court acknowledged that the user was not likely to be confused about any connection with the plaintiff after visiting the defendant's site, it was enough for the court that she might click on the defendant's site believing it to be related to the plaintiff, simply because it appeared in the same search results.[42]

Despite the expansion of actionable confusion across both the temporal axis—to include confusion occurring before and after purchase, as well as at the time of purchase—and the consumer population axis—to include non-purchasers, as well as purchasers—liability for all three types of actionable confusion is governed by the same likelihood of confusion test outlined above.[43] Trademark doctrine has expanded to impose liability for new types of confusion, but no mechanism has developed to distinguish between confusion that always or almost always results in trademark-related harms from confusion that is less likely to produce those harms. Upon demonstrating that the defendant's conduct is likely to create confusion pre, post or at the point of sale, such conduct is deemed illegal per se. No further inquiry is made into whether that particular form of confusion is likely to harm or benefit consumers, producers, or competition at large. In this way, the confusion analysis operates as a per se rule.

III.
PROBLEMS POSED BY TRADEMARK'S UNITARY LIABILITY REGIME

By implementing the same likelihood of confusion test as a threshold for liability under all three theories, courts implicitly make two key assumptions: (1) that each type of confusion is equally likely to result in trademark-related harm, and (2) that the defendant's proscribed conduct provides insignificant, if any, procompetitive benefits. However, these assumptions are unsupported in cases of initial-interest and post-sale confusion cases, which have lower likelihoods of competitive harm and may, in fact, increase competition.

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[42] *Id*. at 1062–63 (holding the defendant liable for creating "initial interest confusion" by using the plaintiff's website in its metatag terms and by diverting people to its website through confusion about the domain name). *But see* Network Automation, Inc. v. Advanced Sys. Concepts, Inc., 638 F.3d 1137, 1148–49 (9th Cir. 2011) (limiting *Brookfield* to domain name disputes).

[43] *See* discussion *supra* Part II.A.

A. Presumes Harm for All Forms of Confusion

As stated above, upon finding a likelihood of confusion, courts simply presume harm to the plaintiff and rule in her favor.[44] This presumption is justified when the confusion arises at the point of sale. According to the current doctrinal reasoning, causing confusion at the point of sale undermines both the intermediate goals of trademark law, namely reducing search costs and incentivizing producer investments in product quality, and trademark law's ultimate goal of promoting competitive markets. Consumers who are confused as to the source or nature of a good at the time of purchase are harmed in two ways—first, they end up with unwanted or misidentified products, and second, they can no longer rely on the trademark in the future to relay accurate information, thereby increasing their search costs.[45] Similarly, producers are harmed twofold: first, they will suffer lost sales, and second, they may suffer injury to their reputations when consumers mistakenly identify them as the source of shoddy products.[46] Therefore, when consumers are confused about source at the point-of-sale, the defendant's conduct is harmful to competition generally. Because confusion at the point-of-sale results in the archetypal harms that trademark law seeks to avoid, presuming harm from a showing of a likelihood of such confusion is justified and consistent with overarching trademark principles.

The relationship between consumer confusion and harm to both consumers and producers is far more attenuated in the context of initial-interest and post-sale confusion. In the context of initial-interest confusion, consumer confusion, though ultimately dispelled, may increase search costs. This harm can be better understood by way of a helpful analogy. A job-seeker embellishes his skills and background on his resume, is invited for an interview by an interested employer and then, at the interview, admits to the employer that his inflated resume is not completely

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[44] *See* Qualitex Co. v. Jacobsen Prods. Co., 514 U.S. 159, 160–66 (1995); *see also* RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 2 cmt. a (1995) ("As confidence in the truth of advertising diminishes, prospective purchasers may be forced to expend additional resources.").

[45] *See* Smith v. Chanel, Inc., 402 F.2d 562, 566 (9th Cir. 1968) ("Preservation of the trademark as a means of identifying the trademark owner's products . . . makes effective competition possible in a complex, impersonal marketplace by providing a means through which the consumer can identify products which please him and reward the producer with continued patronage. Without some such method of product identification, informed consumer choice, and hence meaningful competition in quality, could not exist.").

[46] *See* Bone, *supra* note 19, at 2108 ("[I]f consumers lacked the ability to distinguish one brand from another, firms would have no reason to create brands with more costly but higher quality characteristics.").

accurate.[47] In this scenario, the misrepresentation enables the job-seeker to obtain a coveted interview, giving him a clear advantage over other interested parties with the same skill set and background who honestly stated their achievements on their resumes. Similarly, a producer who misrepresents the source of its products or services by likening itself to another desirable producer may put others at a competitive disadvantage even though consumers are not confused at the time of purchase.[48]

However, this potential harm may not always be realized. The scenario described above is one in which the misrepresentation effectively supplants a competitor from being considered, impairing their ability to compete effectively in the market.[49] However, if the misrepresentation merely offers consumers an alternative, without preventing the competitor's products from being considered at all, no market harm will manifest. In other words, if the employer in the previous example offered an infinite number of interview slots and bore no opportunity costs in conducting them, no competitive injury would result from the job-seeker's misrepresentations.

Importantly, whether or not the producer is able to effectively compete depends on the costs of the search and the ease with which the purchaser's confusion is dispelled.[50] For example, a consumer in search of a pain reliever may initially be looking for the Advil brand. While searching through the shelves, she comes across a pain reliever with packaging resembling that of Advil, but upon closer examination realizes that it is produced by a generic brand and offered at a cheaper price. The generic contains ibuprofen—the active ingredient of Advil—making it chemically identical to Advil. If the consumer sincerely favors Advil, possibly out of concerns for quality assurance,[51] her search costs of finding it have not been raised in any meaningful respect—she puts the generic down, sees the Advil on the same shelf, and moves on. Because the effect on search costs is

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[47] *See* McCarthy, *supra* note 28, § 23:6 (using this resume hypothetical to illustrate the harms of initial-interest confusion).

[48] *See id*. ("In such a situation, it is not possible to say that the misrepresentation caused no competitive damage.").

[49] *See id*.; Michael Grynberg, The Road Not Taken: Initial Interest Confusion, Consumer Search Costs, and the Challenge of the Internet, 28 SEATTLE U. L. REV. 97, 112 (2004).

[50] *See* Grynberg, *supra* note 49, at 110.

[51] *See* Landes & Posner, *supra* note 2, at 275 ("The fact that two goods have the same chemical formula does not make them of equal quality to even the most coolly rational consumer. That consumer will be interested not in the formula but in the manufactured product and may therefore be willing to pay a premium for greater assurance that the good will actually be manufactured to the specifications of the formula.").

trivial, the mark owner does not lose the capacity to compete on the basis of price, quality, or reputation. This inference is supported by the fact that the confusion did not displace the competing product, rather the purchaser considered the products of both producers and made an informed, unconfused decision.

Furthermore, unlike in the point-of-sale context, where consumer confusion is directly related to the purchasing decision and is therefore the proximate cause of the producer's harm, in the post-sale context, there is no indication that confused parties are likely to be potential consumers of the plaintiff's product. In fact, there is no indication that the observations made by those who are confused are likely to be material to a purchasing decision. Therefore, the link between the confusion caused and harm felt by producers is severely weakened; the latter cannot be presumed from the former.

Trademark-relevant harm arises post-sale only when a third-party observes a product bearing the defendant's allegedly confusing mark, inaccurately identifies its source as the plaintiff, makes an adverse judgment as to the quality of the product, attributes that judgment to the plaintiff, and subsequently refrains from purchasing products correctly attributed to the plaintiff based on that prior false association.[52] This is a tenuous chain of events. Only in these narrow circumstances, where the confusion of a bystander is linked to a negative purchasing decision, would a plaintiff alleging post-sale confusion suffer harm that undermines the goals of trademark law. Because harm to the producer, in the form of lost sales or harm to reputation for quality, is significantly less likely to result from confusion in this context, such harm cannot and should not be presumed from mere confusion.

A review of judicial decisions reveals that in post-sale confusion cases, courts have credited theories of harm that lie outside the confines of trademark interests. This is particularly apparent in cases brought by luxury brands seeking to enjoin the production of knock-off, or look-alike, goods—the same class of cases in which post-sale confusion was originally invoked.[53] In *Hermès International v.*

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[52] *See generally* Kal Raustiala & Christopher Sprigman, *Rethinking Post-Sale Confusion*, 108 TRADEMARK REP. 881, 881–891 (2018) (identifying the chain of events needed to create post-sale observer confusion).

[53] *See* Mastercrafters Clock and Radio Co. v. Vacherin-Constantin Le Coultre Watches, Inc., 221 F.2d 464 (2d Cir. 1955).

Lederer de Paris Fifth Avenue, Inc.,[54] the Second Circuit identified the harms flowing from post-sale confusion as the following:

> [T]he purchaser of an original is harmed by the widespread existence of knockoffs because the high value of originals, which derives in part from their scarcity, is lessened. . . . A loss [to the public] occurs when a sophisticated buyer purchases a knockoff and passes it off to the public as the genuine article, thereby confusing the viewing public and achieving the status of owning the genuine article at a knockoff price.[55]

The first harm affects the purchasers of the original, authentic luxury goods in that the dilution of the market with similar goods diminishes the exclusivity of the original. The second harm affects the general public who will be less able to attribute the "appropriate" status to other members who use products bearing luxury marks. These harms laid out by the Second Circuit and many other courts[56] are not the product of anticompetitive conduct—rather, they are simply the result of competition over something that has consumptive value, in this case the mark itself.[57] Because trademark is a species of competition law, protecting against these harms is not only unfounded, but is counterproductive to the trademark cause in that it undermines the overarching goal of promoting competition.

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[54] 219 F.3d 104 (2d Cir. 2000).

[55] *Id*. at 108–109.

[56] *See, e.g.*, Rolex Watch U.S.A., Inc. v. Canner, 645 F. Supp. 484, 495 (S.D. Fla. 1986) ("Others who see the watches bearing the Rolex trademarks on so many wrists might find themselves discouraged from acquiring a genuine because the items have become too common place and no longer possess the prestige once associated with them."); Ferrari S.P.A. v. Roberts, 944 F.2d 1235, 1244 (6th Cir. 1991); I.P. Lund Trading ApS v. Kohler Co., 163 F.3d 27, 44 (1st Cir. 1998); Gucci Am., Inc. v. Dart, Inc., 715 F. Supp. 566, 567 (S.D.N.Y. 1989) ("Others will be discouraged from acquiring a genuine Gucci because the items have become too commonplace and no longer possess the prestige and status associated with them."); Coach, Inc. v. Treasure Box, Inc., 2013 WL 2402922, at *8 (N.D. Ind. May 31, 2013).

[57] *See e.g.*, Glynn S. Lunney, *Trademark Monopolies*, 48 EMORY L.J. 367, 408 (claiming that the rationale for trademark protection against knockoffs, "while it may couch itself in terms of confusion and reputation, seems to rest on the sense that the ordinary rule of competition should not apply to prestige goods. . . . Thus, where competition resulting in lower priced goods is generally thought desirable, courts often complain about the lower prices that imitations of prestige goods generate.").

B. Does Not Consider Procompetitive Benefits

In addition to the faulty presumption of harm across the varying liability theories, another shortcoming of the current trademark liability regime is its failure to consider the potential procompetitive benefits of the defendant's conduct. Focusing on the narrow question of whether the defendant's conduct is likely to confuse consumers, without assessing the possible procompetitive effects of that conduct, may be appropriate in the context of point-of-sale confusion because the potential anticompetitive effects are so substantial. On balance, the likelihood that the conduct is actually a net benefit to competition is extremely low.[58]

In contrast, confusion that arises prior to the sale is more likely to result in procompetitive benefits. In the Advil example described above, if the purchaser is satisfied that the generic pain reliever is an adequate substitute for Advil, it follows that her "initial confusion" is what enabled her to identify that substitute and thus to cut costs. Because she was not previously familiar with the alternative option, the temporary, pre-sale confusion she experienced worked to her benefit by broadening her awareness of Advil's cheaper competitors. This consumer's preference was not for Advil, but rather for the most economical ibuprofen product she could find. By resembling Advil, the trade dress of the generic company signals to purchasers that it is in the same product category.[59] In this scenario, a trademark plaintiff may complain that the conduct injures it personally, due to the lost sale, even though the conduct actually benefits competition overall. Some

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[58] There are, of course, cases that do produce procompetitive benefits. Take, for example, a twist on the classic case of point-of-sale confusion. A plaintiff sells a simple product, such as bars of soap, and the defendant sells the identical product under the same mark at a lower price. Here, one could argue that only the plaintiff suffers harm in the form of lost sales, but that consumers, despite being confused as to the source of the soap, actually benefit from the ability to buy the same product at a cheaper price. However, such cases are outweighed by the great social costs of false negatives. *See infra* Part IV.B.

[59] As the district court explained in *Am. Home Prods. Corp. v. Barr Labs., Inc.*, 656 F. Supp. 1058, 1068 (D.N.J. 1987), *aff'd*, 834 F.2d 368 (3d Cir. 1987):

> The resemblance between two products can alert consumers to the functional or utilitarian equivalence between them, to the fact that one product may be substituted for the other in the ultimate uses for which the products are intended. The free flow of information regarding the substitutability of products is valuable to individual consumers and to society collectively, and by providing it a supplier engages in fair competition based on those aspects—for example, price—in which the products differ.

courts recognize this benefit in trade dress cases,[60] and the same dynamic is likely to be at play in initial-interest confusion cases involving other types of marks.

These potential benefits also extend to the Internet. In the online context, for instance, the use of metatags in search engines can give rise to a claim of initial-interest confusion.[61] However, this same conduct can reduce consumer search costs and provide easy access to comparative quality and price information, thereby enhancing competition.[62] Competition on the merits improves consumer welfare by providing consumers with competing goods.[63] As long as any confusion is dispelled by the time consumers buy goods or services, which a theory of initial-interest confusion assumes, consumers may have actually found alternative goods at least as desirable as the mark owners' goods.

Similarly, in the context of post-sale confusion, the defendant's conduct does in fact have potential procompetitive effects. The factual presumption in a claim of post-sale confusion is that the actual purchasers of the product bearing the defendant's confusing mark are fully aware of its source at the time of purchase.[64] These consumers entered into the transaction with the full and accurate knowledge that, although the sneakers resembled those of the plaintiff, they were in fact made

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[60] *See, e.g.*, Gibson Guitar Corp. v. Paul Reed Smith Guitars, LP, 423 F.3d 539 (6th Cir. 2005) (rejecting the plaintiff's claim that the defendant's guitar impermissibly created initial-interest confusion, explaining that "many *legitimately competing* product shapes are likely to create some initial interest in the competing product due to the competing product's resemblance to the better-known product when viewed from afar") (emphasis added).

[61] *See, e.g.*, Horphag Research, Ltd. v. Pelligrini, 337 F.3d 1036, 1039–42 (9th Cir. 2003) (holding that the metatags used by the defendant were infringing because they caused initial-interest confusion).

[62] *See* Rothman, *supra* note 34, at 132.

[63] The potential procompetitive benefits associated with a competitor advertising its products and services extend further. In recent years, plaintiffs have successfully utilized the doctrine in "knock-off cases." For example, the district court in *Cartier, Inc. v. Four Star Jewelry Creations, Inc.*, No. 01 Civ. 11295, 2003 WL 21056809, at *1 (S.D.N.Y. May 8, 2003), held that watches designed to look similar to Cartier watches could be found to infringe Cartier's trade dress if consumers were initially "attracted" to the watches, even if consumers knew that the knock-offs were not Cartier watches at the time of purchase.

[64] *See*, *e.g.*, Karl Storz Endoscopy-Am., Inc. v. Surgical Techs., Inc., 285 F.3d 848, 854 (9th Cir. 2002) ("The law in the Ninth Circuit is clear that 'post-purchase confusion,' i.e., confusion on the part of someone other than the purchaser who, for example, simply sees the item after it has been purchased can establish the required likelihood of confusion under the Lanham Act."); *see also* Adidas Am., Inc. v. Payless Shoesource, Inc., 546 F. Supp. 2d 1029, 1058 (D. Or. 2008) (finding that the plaintiff's failure to allege point-of-sale confusion "is of no consequence" to the viability of its initial-interest and post-sale claims).

by the defendant. This is important because the purchasers in a post-sale confusion world benefit from a competitive market for the merchandised goods and therefore benefit from the defendant's conduct.[65]

The heated and long-fought battle between luxury and knockoff brands is demonstrative of this point. Luxury brands are often highly litigious and aggressive in their efforts to protect one of the most important aspects of their businesses, namely their trademarks. However, the countervailing consumer interest is the availability of products with similar aesthetic appearance to prestige goods but at cheaper prices. The recent rise in companies producing knockoff goods, such as H&M, Forever21, and Zara, provide further evidence of the high consumer demand for cheaper alternatives to designer goods. The availability of designer look-alikes can be characterized as a procompetitive benefit of the allegedly infringing conduct at issue in post-sale confusion cases, and it is this benefit that is lost when producers are enjoined from producing similar goods.

Resolving post-sale confusion claims without consideration for the benefited consumers effectively subordinates their interests to the interests of producers who seek to protect the prestige and exclusivity associated with their luxury goods and of consumers of luxury goods who wish to project their prestige to society.[66] Whether or not it is economically or morally desirable to provide legal protection for prestige and exclusivity is a discussion for another day. However, it is plain that such interests are outside the scope of interests that trademark law is designed to protect.[67] As such, claims of post-sale confusion that result in enjoining defendant's conduct risk stifling competition and innovation.

VI.
RECONSTRUCTING TRADEMARK LIABILITY: TOWARDS A TRADEMARK RULE OF REASON

Trademark's unitary liability regime fails to take into account the different market effects, both harmful and beneficial, produced by the various forms of confusion. This failure likely gives rise to an influx of "false positives," that is, cases that wrongly find violations where no trademark-related harm exists. These

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[65] Michael Grynberg, *Trademark Litigation as Consumer Conflict*, 83 N.Y.U. L. REV. 60, 102 (2008) (criticizing post-sale confusion for "subordinat[ing] the interests of these consumers to those wishing to cultivate the status that comes with the purchase of artificially scarce goods").

[66] *See id.* at 107.

[67] *See* discussion *supra* Part I.

false positives produce associated social costs by preventing or chilling procompetitive conduct. Other areas of competition policy, such as antitrust, deal with similar risks of error by applying a combination of rules and standards that attempt to minimize the total cost of false positives.[68] This approach would be appropriate in the world of trademark.

A. Lessons from Antitrust

It is only natural to look to antitrust and its terms for inspiration in redesigning trademark liability because, like trademark law, antitrust is designed to ensure that the competitive market functions well. In this sense, both bodies of law are species of competition policy. Trademark law achieves this goal by ensuring that consumers can rely on signs and symbols in order to glean information and ultimately make informed purchasing decisions.[69] Antitrust law accomplishes this goal by deterring collusive and monopolistic conduct that impairs valuable competition.[70] Additionally, both trademark law and antitrust law represent affirmations of, rather than departures from, the competitive model that drives the U.S. economy.[71] Therefore, inherent in both legal doctrines is the default assumption that under ordinary circumstances, competitive markets will ensure

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[68] *See* Thomas F. Cotter, *The Procompetitive Interest in Intellectual Property Law*, 48 WM. & MARY L. REV. 483, 490–91 & n.17 (2006) (discussing the use of error-costs analysis in antitrust and intellectual property law).

[69] *See* discussion *supra* notes 22–25 and accompanying text.

[70] *See* Steven C. Salop, *Exclusionary Conduct, Effect on Consumers, and the Flawed Profit-Sacrifice Test*, 73 ANTITRUST L. J. 311, 311–12 (2006); Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 488 (1977); (stating that "the antitrust laws . . . were enacted for 'the protection of competition not competitors'") (*quoting* Brown Shoe Co. v. United States, 370 U.S. 294, 320 (1962)); 15 U.S.C. § 14 (1914) (stating that practices are unlawful when they "may . . . substantially lessen competition or tend to create a monopoly. . . .").

[71] *See* Dogan & Lemley, *Search-Costs*, *supra* note 7, at 1224–27. The primacy of competition makes trademark law distinct from the rest of intellectual property law, which protects authors and inventors from competition in order to incentivize investments in invention and creation. *See* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989 (1997); Dogan & Lemley, *Merchandising Right*, *supra* note 7, at 467–68; 17 U.S.C. § 106 (2000) (enumerating the exclusive rights of copyright holders); 35 U.S.C. § 271 (2000) (setting forth the exclusive rights of patent holders). Copyright and patent law grant authors and inventors exclusive economic rights to remedy the perceived market failure that would arise if copiers were able to replicate expressive works and inventions without incurring the costs of creating them. Coverdale, *supra* note 10, at 869 ("Unlike the patent and copyright laws, however, trademark protection is intended to promote, not hinder, competition."); *see generally* Wendy J. Gordon, *Asymmetric Market Failure and Prisoner's Dilemma in Intellectual Property*, 17 U. DAYTON L. REV. 853 (1992).

efficient resource allocation and bring consumers the highest quality products at the lowest prices.[72] As we will see in the following section, this default assumption plays an important role in the way liability rules are structured in competition law.[73] Of course, the goal of protecting competition is much more explicit in the field of antitrust and as a result, its legal rules are tailored to achieve that goal.[74] Trademark law, on the other hand, has had a more checkered history,[75] resulting in liability rules that are disconnected from competition policy.[76]

For these reasons, antitrust should serve as guidance in the process of realigning trademark liability with its original underlying purpose of promoting competition.

1. Binary Liability Structure: Rules and Standards

Unlike trademark law, antitrust law operates under a binary liability structure. This two-tiered liability scheme divides conduct into two general categories: per se violations and rule of reason violations.[77] The per se category is effectively a rule, making the treatment of the conduct quite simple. If a plaintiff shows that the defendant deliberately engaged in such conduct, courts will hold the defendant liable for engaging in anticompetitive behavior in violation of the Sherman Act.[78] Importantly, a plaintiff need not provide economic evidence of

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[72] *See generally* Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031 (2005).

[73] *See* discussion *infra* Part IV.B.

[74] *See Brown Shoe*, 370 U.S. at 320 (stating that the antitrust laws were enacted for "the protection of competition, not competitors").

[75] Robert G. Bone, *Taking the Confusion Out of "Likelihood of Confusion": Toward a More Sensible Approach to Trademark Infringement*, 106 NW. U. L. REV. 1307, 1316–20 (2012).

[76] *See* discussion *supra* Part III.

[77] *See* Thomas A. Piraino, Jr., *Reconciling the Per Se and Rule of Reason Approaches to Antitrust Analysis,* 64 S. CAL. L. REV. 685, 685–93 (1991); Richard M. Steuer, *Indiana Federation of Dentists: The Per Se-Rule of Reason Continuum (and a Comment on State Action)*, 8 CARDOZO L. REV. 1101, 1120 (1987) ("[T]he Supreme Court labored at defining two categories of antitrust offenses—those that were illegal per se and those that violated the 'rule of reason.'").

[78] *See* Thomas Krattenmaker, *Per Se Violations in Antitrust Law: Confusing Offenses with Defenses*, 77 GEO. L.J. ("[T]he configuration of 'per se violation' seems to mean . . . that once certain conduct by a defendant is proved—e.g., horizontal price fixing, a group boycott, a tie-in sale—the plaintiff has established without doubt a violation of the antitrust laws. Nothing remains to be said, or can be said, by either side on the question of whether the defendant violated the antitrust laws.").

actual harm to competition; instead, harm to competition is presumed, and the defendant is held liable per se.[79]

The second liability category involves a standard, confusingly referred to as the rule of reason standard.[80] In rule of reason cases, courts require a well-developed investigation into the competitive effects of the defendant's behavior. In other words, plaintiffs must conduct a more searching investigation into the harms and benefits produced by the defendant's allegedly anticompetitive conduct.[81] In order to establish a prima facie case, plaintiffs must demonstrate that the conduct in question has harmed or will harm competition.[82] If successful,[83] the burden shifts to defendants to offer plausible economic theories that justify their conduct as procompetitive.[84] If the defendant does present evidence of a procompetitive justification, the plaintiff will have an opportunity to prove that the same

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[79] *See, e.g.*, Newman v. Universal Pictures, 813 F.2d 1519, 1522–23 (9th Cir. 1987) (explaining that the per se rule "relieves plaintiff of the burden of demonstrating an anticompetitive effect, which is assumed"); *see also* United States v. Topco Assocs., Inc., 405 U.S. 596, 607 (1972) ("[T]here are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are *conclusively presumed to be unreasonable and therefore illegal* without elaborate inquiry as to the precise harm they have caused or the business excuse for their use.") (*quoting* N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958)).

[80] The rule of reason is not a rule at all; rather, it is a standard. Generally speaking, standards set forth a general decree, leaving interpretation for later adjudication. By contrast, rules specify ex-ante which types of conduct are forbidden, leaving only factual determinations remaining ex-post. For instance, when confronting the issue of speeding, a legislature could impose a rule making it illegal to drive above "fifty-five miles per hour," or alternatively could set a standard making it illegal to drive at "unreasonable speeds." The debate about which regime is better is a topic that has been heavily theorized before, both in the realm of intellectual property and elsewhere. *See* Matthew D. Adler & Eric A. Posner, *Rethinking Cost-Benefit Analysis*, 109 YALE L.J. 165 (1999).

[81] *See* Cont'l Television v. GTE Sylvania, 433 U.S. 36, 49 (1977) (noting that in rule of reason cases "the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition"). Generally, harm to competition is demonstrated using economic models and data.

[82] *See, e.g.*, Mark A. Lemley & Christopher R. Leslie, *Categorical Analysis in Antitrust Jurisprudence*, 93 IOWA L. REV. 1207, 1214–15 (2008).

[83] In *California Dental*, for example, because the majority concluded that the FTC failed to make out a prima facie case, the burden never shifted. *See* Cal. Dental Ass'n v. FTC, 526 U.S. 756, 775 n.12 (1999). The dissenters in that case disagreed with this conclusion. *Id*. at 783.

[84] *See* Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Okla., 468 U.S. 85, 113 (1984); *California Dental*, 526 U.S. at 788 (Breyer, J., concurring in part and dissenting in part) ("In the usual Sherman Act § 1 case, the defendant bears the burden of establishing a procompetitive justification.").

procompetitive effects could have been achieved by a less restrictive alternative.[85] If no less restrictive alternative is available, the court will attempt to calculate the net effect of the defendant's conduct, by balancing the procompetitive justification of the conduct against its potential for anticompetitive harm.[86]

The scope of each of the two categories of liability differs quite drastically. The per se category is narrow in scope—it only includes conduct that courts have previously identified as harmful to competition and that, as a whole, have no redeeming procompetitive justifications.[87] Some examples include horizontal price fixing,[88] bid rigging, and dividing markets. These classes of conduct are archetypally harmful to competition and are therefore deemed to be per se anticompetitive, with no opportunity to put forth redeeming justifications.[89] In comparison, the rule of reason category is much wider in scope.[90] It includes conduct that has ambiguous effects on competition, and which therefore requires a

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[85] *See, e.g.*, Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc., 996 F.2d 537, 543 (2d Cir. 1993) ("Assuming [the] defendant comes forward with such proof, the burden shifts back to [the] plaintiff . . . to demonstrate that any legitimate collaborative objectives proffered by [the] defendant could have been achieved by less restrictive alternatives, that is, those that would be less prejudicial to competition as a whole."); *see also* C. Scott Hemphill, *Less Restrictive Alternatives in Antitrust Law*, 116 COLUM. L. REV. 927, 941 (2016). Of course, if the defendant is unable to offer a procompetitive justification, then the plaintiff should prevail.

[86] *See* United States v. Microsoft Corp., 253 F.3d 34, 59 (D.C. Cir. 2001) ("[C]ourts routinely apply a . . . balancing approach" requiring plaintiff to "demonstrate that the anticompetitive harm . . . outweighs the procompetitive benefit."); Am. Ad Mgmt., Inc. v. GTE Corp., 92 F.3d 781, 789 (9th Cir. 1996) (suggesting that the rule of reason requires a showing that "the restraint is unreasonable as determined by balancing the restraint and any justifications or pro-competitive effects of the restraint").

[87] *See* Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 127 S. Ct. 2705, 2713 (2007) ("To justify a per se prohibition a restraint must have 'manifestly anticompetitive' effects and 'lack . . . any redeeming virtue.'") (citations omitted); Herbert J. Hovenkamp, *The Rule of Reason*, 70 FLA. L. REV. 81, 96 (2018) ("Per se illegality is appropriate if judicial experience indicates that a particular class of restraints rarely has any effect but to reduce output and increase price.").

[88] *See* Robert H. Bork, *The Rule of Reason and the Per Se Concept: Price Fixing and Market Division*, 75 YALE L.J. 373, 391 (1966) (stating that "all horizontal price-fixing and market division is illegal per se"); Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, L.L.P., 540 U.S. 398, 408 (2004) (identifying collusion for purposes such as price fixing as the "supreme evil of antitrust").

[89] N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958) (identifying price fixing, division of markets, group boycotts, and tying arrangements as unlawful activities "in and of themselves").

[90] Notably, most conduct analyzed as antitrust violations are considered under a rule of reason standard rather than a per se rule. *See* Cont'l T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49 (1977) (noting that the rule of reason is "applied for the majority of anticompetitive practices challenged under § 1 of the Act"); *see also* State Oil Co. v. Khan, 522 U.S. 3, 10 (1997).

more searching investigation into the harms and benefits produced by the conduct.[91]

The makeup of these two categories is not random, but rather is driven by the courts' avoidance of certain undesirable outcomes, known as false positives.

2. A Preference for Reducing False Positives

Although the social costs of erroneous outcomes play a role in the development of all legal regimes, they are particularly important for laws that police marketplace behavior, like antitrust and trademark.[92] Due to the limitations of current economic empirical analysis, legal decisions regarding the marketplace are necessarily made under uncertainty. The chronic degree of uncertainty throughout competition law makes mistaken conclusions inevitable to some degree—but it does not render them any less costly. Therefore, competition laws display a unique fixation with error costs.[93]

Errors come in two forms—false positives and false negatives. A false positive occurs when a result is reached that should not have been reached. By contrast, a false negative occurs when a result is not reached but should have been. The social costs of these errors are the product of two factors: (1) the probability that the error will occur, and (2) the magnitude of the social cost when it does occur.[94] It is important to distinguish between the two types of errors because they may produce different social costs. Many laws reduce the frequency of one type of error only to increase the frequency of the other, and thus, all legal regimes must determine which of the two types of errors is most crucial to avoid. For example,

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[91] *Sylvania*, 433 U.S. at 49 (noting that in rule of reason cases "the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition").

[92] *See* John M. Newman, *Procompetitive Justifications in Antitrust Law*, 94 IND. L.J. 501, 530(2019) ("The modern antitrust enterprise is concerned with the social costs of erroneous decisions.").

[93] *See* Andrew I. Gavil, *Antitrust Bookends: The 2006 Supreme Court Term in Historical Context, 22 ANTITRUST 21, 21 (2007); C. Scott Hemphill, An Aggregate Approach to Antitrust: Using New Data and Rulemaking To Preserve Drug Competition*, 109 COLUM. L. REV. 629, 669 (2009).

[94] *See* Richard A. Posner, *An Economic Approach to Legal Procedure and Judicial Administration*, 2 J. LEGAL STUD. 399 (1973); RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 16–17 (5th ed. 1998). The expected value of each error cost can be illustrated as a mathematical formula, $E.V. = P(x)*n$. Here, $P(x)$ is the probability of the event (either a false positive or false negative); n is the social cost produced by that type of error; by multiplying the $P(x)$ with n, we get $E.V.$ or the expected value of the type of error.

the rule imposing a beyond-a-reasonable-doubt burden of persuasion in criminal cases reduces the frequency of erroneous convictions but increases the frequency of erroneous acquittals. The rule can be justified on the grounds that, in terms of lost liberty, the social cost of an erroneous conviction is much higher than the social cost of an erroneous acquittal.[95]

Like criminal law, antitrust rules and burdens of proof reflect a preference for reducing false positives, while tolerating a somewhat increased possibility of false negatives.[96] Though not applied as an explicit rule, this preference has significantly influenced what types of conduct fall into each of the two categories of antitrust liability. Indeed, minimizing false positives and mitigating their chilling effects on procompetitive conduct are often cited as justifications for abandoning some of the per se rules that were applied prior to the late 1970s, especially with regard to vertical agreements.[97]

This is most clearly illustrated in *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, where the Supreme Court addressed the question of whether resale-price maintenance ("RPMs") should be analyzed under a per se rule.[98] The Court found that RPMs have ambiguous welfare effects on the market. In other words, they could have procompetitive or anticompetitive effects, depending upon the circumstances in which the resale agreements are formed.[99] The Court acknowledged the risk of false positives under a per se rule and the associated costs of "prohibiting procompetitive conduct the antitrust laws should encourage" and thus, notwithstanding the risk of allowing unlawful conduct to go unpunished, it decided to abandon the per se rule in favor of the rule of reason standard.[100] As

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[95] *See* Scott E. Sundby, *The Reasonable Doubt Rule and the Meaning of Innocence*, 40 HASTINGS L.J. 457, 460 (1989).

[96] *See* Alan Devlin & Michael Jacobs, *Antitrust Error*, 52 WM. & MARY L. REV. 75, 83–84 (2010) (comparing standards used in antitrust to criminal law). In the antitrust context, the condemnation of procompetitive behavior is deemed a "false positive," while allowing anticompetitive behavior is called a "false negative."

[97] *See, e.g.*, Richard A. Posner, *Antitrust Policy and the Supreme Court: An Analysis of the Restricted Distribution, Horizontal Merger and Potential Competition Decisions*, 75 COLUM. L. REV. 282, 283–99 (1975) (discussion of restricted-distribution cases); Howard A. Shelanski, *The Case for Rebalancing Antitrust and Regulation*, 109 MICH. L. REV. 683, 712 (2011) ("[A]ntitrust jurisprudence has evolved to reduce significantly the likelihood of false positives.").

[98] *See* Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 127 S. Ct. 2705 (2007).

[99] *Id*. at 2718.

[100] *Id*.; *see also* Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 414 (2004) ("Mistaken inferences and the resulting false condemnations 'are especially

applied to RPMs, the Court explained that the per se rule proscribes a significant amount of procompetitive conduct, making RPMs ill-suited for per se condemnation.[101]

By adopting the rule of reason standard for conduct that produces ambiguous welfare effects, courts have not only expressed a preference for reducing false positives, but also an acceptance of increased false negatives.[102] This preference finds its roots in a principle of competition policy that was famously espoused by Judge Frank Easterbrook: Preventing procompetitive behavior is more harmful than allowing anticompetitive behavior.[103] The assumption is that the social costs of false positives far exceed the social costs of false negatives.[104] Additionally, the correction costs of false positives are much higher than those of false negatives because court decisions have lasting impact on behavior in the market.[105] By contrast, false negatives would largely be dissipated by the self-correcting tendencies of markets.[106] As a species of competition policy, these same principles apply with equal force to trademark law.

B. Details of Implementation

Trademark law's current unitary liability scheme should be restructured to resemble something approximating the binary structure applied in antitrust law.[107] Under this new, but not novel, liability regime, some forms of confusion would fall

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costly, because they chill the very conduct the antitrust laws are designed to protect.'") (*quoting* Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 594 (1986)).

[101] *See Leegin*, 127 S. Ct. at 2718.

[102] *See* Fred S. McChesney, *Talking 'Bout My Antitrust Generation: Competition for and in the Field of Competition Law*, 52 EMORY L.J. 1401, 1413 (2003).

[103] *See* Frank H. Easterbrook, *The Limits of Antitrust*, 63 TEX. L. REV. 1, 2–3 (1984).

[104] *See* Joshua D. Wright, *Abandoning Antitrust's Chicago Obsession: The Case for Evidence-Based Antitrust*, 78 ANTITRUST L.J. 241, 248 ("[T]he costs of false convictions in the antitrust context are likely to be significantly larger than the costs of false acquittals.").

[105] For example, the Supreme Court's decision in *Dr. Miles Med. Co. v. John D. Park & Sons Co.*, 220 U.S. 373 (1911), holding that a RPM is illegal per se, took nearly a century to be overturned by the Court in *Leegin*. The durability of erroneous judicial precedent was a principle concern for Judge Easterbrook. *See* Easterbrook, *supra* note 103, at 2. ("If the court errs by condemning a beneficial practice, the benefits may be lost for good. Any other firm that uses the condemned practice faces sanctions in the name of stare decisis, no matter the benefits."); *id*. at 15 ("There is no automatic way to expunge mistaken decisions of the Supreme Court."); *Wright*, *supra* note 104, at 248 ("[J]udicial errors that wrongly excuse an anticompetitive practice may eventually be undone by competitive forces attracted by the presence of monopoly rents.").

[106] *See* Easterbrook, *supra* note 103, at 2–3 (1984).

[107] *See* discussion *supra* Section IV.A.1.

in the per se category, while others would fall within a rule of reason category. The per se form of liability would serve as a rule—once a likelihood of confusion is shown, trademark harm is presumed and the defendant is held liable. Under the rule of reason category, a plaintiff would face a two-pronged burden. First, she must establish a likelihood of confusion under the current multifactor likelihood of confusion test. Second, she would be required to show that the confusion is likely to produce a trademark-related harm. If the plaintiff successfully satisfies her burden, the burden would shift to the defendant to put forth procompetitive justifications for her conduct. Finally, if the defense succeeds, the court would balance the harms against the procompetitive justifications before reaching its decision.

The question remains, what is the guiding principle by which the types of confusion should be delegated to the rule category or the standard category? By treating consumer confusion as a proxy for harm for all claims of infringement,[108] trademark liability in its current form guards most vigorously against the wrong type of error, false negatives, and as a result does more harm to competition than good.[109] For the reasons discussed above in the context of antitrust law, it is now clear that a reformed trademark liability structure should be designed to reduce false positives and to tolerate a somewhat increased possibility of false negatives. Where the chance of a harmful false negative is remote, trademark liability should lean toward protecting potentially procompetitive behavior. Trademark law must incorporate this priority when determining the relevant liability rule for different claims of confusion.

According to this guiding principle, conduct with ambiguous effects on the market would be held under a rule of reason standard. The expansive forms of confusion-based liability, namely initial-interest and post-sale confusion, would be analyzed within this rule of reason framework. Conduct that gives rise to these forms of confusion produces ambiguous welfare effects on the market—it could have procompetitive or anticompetitive effects, depending upon the circumstances.[110] A rule that presumes harm from these types of confusion results

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[108] *See* discussion *supra* Part II.A.

[109] William McGeveran & Mark P. McKenna, *Confusion Isn't Everything*, 89 NOTRE DAME L. REV. 253, 304 (2013) ("Instead of protecting legitimate competition interests notwithstanding the accompanying risk of some consumer confusion, courts strive to prevent confusion even if doing so harms competition.").

[110] *See supra* Part III.B (detailing how conduct found liable under initial-interest confusion can produce procompetitive effects by reducing consumer search costs and providing easy access to comparative quality and price information); *id*. (detailing how, in a post-sale confusion world,

in an increased number of false positives and, in turn, such errors chill procompetitive conduct. Bearing in mind the aforementioned preference for reducing false positives, a rule of reason standard is the more appropriate treatment for these types of claims, as it will ensure that liability is imposed only when the underlying conduct produces greater market harms than benefits.[111] Furthermore, for the reasons described above, the likelihood of harmful false negatives is much lower in the context of these types of confusion.[112]

Mirroring antitrust, the per se category of trademark liability would consist of conduct that in most cases results in a net-negative effect on the market.[113] This class of conduct would include confusion as to source or quality at the point-of-sale. Because confusion at the point of sale is harmful to both consumers and producers in most instances in which it arises, it merits a more stringent per se rule that treats confusion as a proxy for harm. It follows that a per se rule conclusively presuming harm from confusion at the point of sale will eliminate erroneous acquittals and their associated costs. To be sure, the rule also increases erroneous liability findings, but given the fact that there is likely no benefit that the underlying conduct produces, the increase would be slight and the social costs not terribly high. Applying a standard, rather than a rule, would result in a large increase in seriously harmful false negatives.[114] Those errors are much more likely to produce anticompetitive effects and thus relatively high social costs and a decrease in overall welfare.

CONCLUSION

Trademark law should be seen, first and foremost, as a law aimed at promoting competition. With this framework in mind, the doctrine should be reformed to differentiate between confusion likely to have a net harm to

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the actual purchasers of the defendant's product benefit from a competitive market for the merchandised goods and therefore benefit from the defendant's conduct).

[111] *See* Grynberg, *supra* note 49, at 99 ("[P]ermitting initial interest confusion may also harm consumers. The class of initially confused consumers includes those who are specifically seeking a particular brand to the *exclusion* of others. They must expend extra effort to determine which product is which, and to find their preferred choice. For these consumers, initial interest confusion impedes the trademark's function of reducing consumer search costs. This perspective suggests that a balancing is possible: Courts should police initial interest confusion only when it produces greater harms than benefits." (emphasis in original)).

[112] *See supra* Part III.A.

[113] *See supra* notes 78–79 and accompanying text (discussing antitrust's per se category of liability).

[114] *See supra* Part III.A.

competition and confusion likely to have a net benefit. To do so, trademark liability should take its cue from the world of antitrust, a doctrine similarly grounded in the protection of competition. Antitrust law teaches that liability should oscillate between rules and standards and that a preference for reducing false positives, even at the expense of causing a slight increase in false negatives, should be adopted. Accordingly, conduct with ambiguous effects on the market should be reviewed under a rule of reason standard. As such, the expanded forms of confusion-based liability, namely initial-interest and post-sale confusion, should be analyzed within a rule of reason framework.

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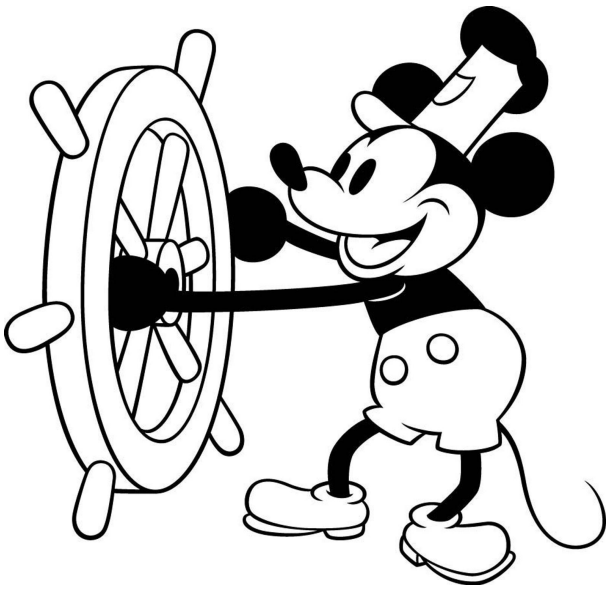
NOTE

OF MOUSE AND MEN: WILL MICKEY MOUSE LIVE FOREVER?

SARAH SUE LANDAU*



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INTRODUCTION

Mickey Mouse, the iconic mascot of the Walt Disney Company, is one of the most recognizable and beloved characters in the world.[1] Ever since his first appearance in 1928 in the cartoon *Steamboat Willie*,[2] Mickey Mouse has made his mark on popular culture appearing in cartoons,[3] movies,[4] video games, [5] "in person" at Disney theme parks,[6] and on almost every type of merchandise imaginable.[7] In fact, just recently, Mickey Mouse celebrated his 90th birthday in an extravagant

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[1] *Mickey Mouse: From Walt to the World*, WALT DISNEY: THE WALT DISNEY FAMILY MUSEUM, https://www.waltdisney.org/exhibitions/mickey-mouse-walt-world (last visited Jan. 23, 2020).

[2] *Steamboat Willie*, IMDB, https://www.imdb.com/title/tt0019422/ (last visited Jan. 23, 2020).

[3] *Mickey Cartoons*, DISNEY MICKEY MOUSE, https://mickey.disney.com/mickey-cartoons (last visited Jan. 23, 2020).

[4] *Movie Series*, DISNEY MICKEY MOUSE, https://mickey.disney.com/movies-series (last visited Jan. 23, 2020).

[5] *Mickey Mouse in Videogames*, FANDOM, https://disney.fandom.com/wiki/Mickey_Mouse_in_video_games (last visited Jan. 23, 2020).

[6] Heather Thomas, *Where to Meet Mickey Mouse at Disney World (no more Talking Mickey)*, WDW PREP SCH. (Sep. 26, 2016), https://wdwprepschool.com/where-to-meet-mickey-mouse-at-disney-world/.

[7] *Mickey Mouse*, SHOP DISNEY, https://www.shopdisney.com/characters/mickey-mouse (last visited Jan. 23, 2020).

televised prime time special.[8] However, from a copyright law standpoint, Mickey Mouse's venerated old age has not been a cause of celebration for the Walt Disney Company. For years, intellectual property lawyers at Disney have approached the subject of Mickey Mouse's aging with trepidation because the older Mickey Mouse gets, the closer the date gets to December 31, 2023—the date on which the copyright on *Steamboat Willie* expires. After that point, starting on January 1, 2024, Disney will begin to lose its exclusive right to Mickey Mouse as the *Steamboat Willie* version of Mickey Mouse will have fallen into the public domain.[9]

Some have suggested that the loss of this copyright would not make much of a practical difference because Mickey Mouse is also protected by trademark.[10] Unlike copyright, trademark protection does not expire and can continue indefinitely as long as a mark maintains its association with a source. Today, Mickey Mouse is undeniably associated with the Disney brand, and there is no indication that this will change any time in the future. As such, it would seem that the Mickey Mouse mark would maintain its trademark protection indefinitely.

However, a statement from a 2003 United States Supreme Court case, *Dastar Corp. v. Twentieth Century Fox Film Corp.,* suggests that using trademarks as a workaround for protecting expired copyrights is prohibited.[11] Specifically, the opinion reasoned that the Lanham Act was not meant to be used to extend expired copyrights since doing so *"*would create a species of *mutant copyright law*" that limits the public's right to use expired copyrighted materials that have entered the public domain (emphasis added).[12]

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[8] Brooks Barnes, *Disney Turns 90, and the Disney Marketing Machine Celebrates*, N.Y. TIMES (Nov. 2, 2018), https://www.nytimes.com/2018/11/02/business/media/mickey-mouse-anniversary-90th.html.

[9] *See* Joseph P. Liu, *The New Public Domain*, 2013 U. ILL. L. REV. 1395, 1440-41 (2013) (explaining that January 1, 2024 marks the loss of protection of the version of Mickey Mouse presented in *Steamboat Willie*. Future iterations of Mickey Mouse created since *Steamboat Willie*, for example, those featuring Mickey Mouse wearing white gloves or Mickey Mouse in color, are considered derivative works and are granted their own copyrights. These future iterations are protected until their copyrights expire.).

[10] Cory Doctorow, *We'll Probably Never Free Mickey, But That's Beside the Point*, ELEC. FRONTIER FOUND. (Jan. 19, 2016), https://www.eff.org/deeplinks/2016/01/well-probably-never-free-mickey-thats-beside-point.

[11] Dastar Corp. v. Twentieth Century Fox Film Corp., 539 U.S. 23 (2003).

[12] *Id.* at 34 ("[A]llowing a cause of action under § 43(a) for that representation would create a species of mutant copyright law that limits the public's federal right to copy and to use, expired copyrights." (internal quotations omitted)).

Yet, while the *Dastar* court cautioned against the use of "mutant copyright[s]," it did not provide any practical guidance regarding how to address issues of overlapping copyright and trademark protection.[13] As such, lower courts have had little direction on how to implement *Dastar* when these issues arise. The Supreme Court has yet to clarify its decision, and Congress has not amended the Copyright Act to address the matter. Therefore, between now and 2024, the fate of Mickey Mouse remains uncertain.

This paper will analyze this Mickey Mouse dilemma in more depth. In particular, Part 1 of this paper will provide a brief overview of copyright protection in the U.S. and will explain the significance of new works entering the public domain in the modern era. Part 2 will provide an overview of trademark protection. Part 3 will touch upon the problem of overlapping protection as illustrated through the example of Mickey Mouse. Finally, Part 4 will propose and examine possible solutions.

I
THE HISTORY OF COPYRIGHT AND "THE COPYRIGHT BARGAIN"

Moments before midnight on December 31, 2018, over a million people stood shivering in the cold in Times Square as they counted down the seconds until the ball dropped, thus officially ringing in the New Year.[14] As in years past, the emergence of a New Year elicited excitement, fireworks, displays of affection, and New Year's resolutions. However, 2019 would be different. The arrival of January 1, 2019 was of particular significance to American copyright law because, on that historic day, all copyrighted works from the year 1923 officially entered the public domain—a phenomenon, the likes of which had not occurred in 20 years.[15] To understand the significance and implications of this occasion, it is necessary to review the history of and rationales behind U.S. copyright law.

The traditional rationale given for U.S. copyright law is utilitarian[16] and is reflected in the U.S. Constitution, which grants Congress the power "to promote the

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[13] See Viva R. Moffat, *Mutant Copyrights and Backdoor Patents: The Problem of Overlapping Intellectual Property Protection*, 19 BERKELEY TECH. L.J. 1474, 1476 (2004).

[14] Dianne Pham, *New Year's Eve in Numbers: Fun Facts About the Times Square Ball Drop*, 6SQFT (Dec. 27, 2018), https://www.6sqft.com/new-years-eve-in-numbers-fun-facts-about-the-times-square-ball-drop/.

[15] *See generally* Timothy B. Lee, *Sorry Disney —Mickey Mouse Will Be Public Domain Soon—Here's What That Means*, ARS TECHNICA (Jan. 1, 2019, 12:10 PM), https://arstechnica.com/tech-policy/2019/01/a-whole-years-worth-of-works-just-fell-into-the-public-domain/.

[16] Moffat, *supra* note 13, at 1478-82.

progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[17] Congress's power to administer copyrights can be thought of as a "copyright bargain" since it enables Congress to simultaneously incentivize innovation while avoiding the granting of unlimited monopolies.[18] Additionally, the copyright system provides a mechanism for weighing the interests of rewarding artists for their work while also providing society at large with raw materials for future creative works.[19] Congress uses copyright law to protect authors (artists, producers, etc.) for a limited time period from having others copy or use their work without permission.[20] Once that designated period has passed, the works enter the public domain where they may be used, copied, changed, or adapted by anyone for free without any compensation to the original author or copyright holder.

Over time, the subject matter of what can be protected by copyright has expanded.[21] While the original Copyright Act of 1790 only applied to maps, charts, and books,[22] the current copyright statute applies broadly to "original works of authorship fixed in any tangible medium of expression," including literary works; musical works; dramatic works; pantomimes and choreographic works; pictorial, graphic and sculptural works; motion pictures and other audiovisual works; sound recordings; and architectural works.[23] Case law that interpreted these listed categories expanded upon them. For example, some courts have concluded that some

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[17] U.S. CONST. art. I, § 8, cl 8.

[18] Moffat, *supra* note 13, at 1478-88.

[19] Leslie A. Kurtz, *The Methuselah Factor: When Characters Outlive Their Copyrights*, 11 U. MIAMI ENT. & SPORTS L. REV. 437, 439-40 (1994) ("Copyright strikes a balance between providing incentives to create and protecting the public domain from being stripped of the raw materials needed for new creations.").

[20] *See id.*

[21] Moffat, *supra* note 13, at 1491.

[22] Act of May 31, 1790 ch. 15, 1 Stat. 124 (Copyright Act of 1790, current version at 17 U.S.C. § 102 (2018)).

[23] 17 U.S.C. § 102 (2018).

cartoon characters[24] and corporate logos[25] may be copyrightable as "pictorial, graphic and sculptural works."

Under the 1976 Copyright Act, protection begins as soon as the artist "fixes" an "original work," rather than at the time of publication.[26] Registration is not required,[27] and protection lasts 70 years after the author's death. However, this was not always the case.[28]

The initial 1790 Copyright Act protection lasted 14 years from publication and was renewable for another 14 years, for a maximum of 28 years.[29] Congress increased the length of copyright protection with each subsequent iteration of the Copyright Act in 1831, 1870, and 1909.[30] The 1976 Copyright Act greatly extended it to the length of the life of the author plus an additional 50 years or a total of 75 years for corporate authorship.[31] In the 1998 Sonny Bono Copyright Term Extension Act (CTEA), Congress gave into the pressure of lobbyists (primarily Disney

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[24] *See* Kurtz, *supra* note 19, at 438-39 (explaining that in determining whether a character merits protection, courts look to whether the character is sufficiently distinctive or well-developed); s*ee also* DC Comics v. Towle*,* 802 F.3d 1012, 1021 (9th Cir. 2015) (setting forth a "three-part test for determining whether a character in a comic book, television program, or motion picture is entitled to copyright protection. First, the character must generally have 'physical as well as conceptual qualities.' . . . Second, the character must be 'sufficiently delineated' to be recognizable as the same character whenever it appears. . . . Third, the character must be 'especially distinctive' and 'contain some unique elements of expression.' . . . It cannot be a stock character."). *But see* Kurtz, *supra* note 19, at 438-39 ("Courts have found less difficulty in protecting characters with a visual component, such as cartoons, than in protecting literary characters, which exist as more abstract mental images."). *See generally* Warner Bros. Pictures v. Columbia Broad. Sys., 216 F.2d 945, 950 (9th Cir. 1954) *cert. denied*, 348 U.S. 971 (1955) (finding that a character is protected if it "constitutes the story being told").

[25] See Moffat, *supra* note 13, at 1491.

[26] 17 U.S.C. § 102 (2018).

[27] Moffat, *supra* note 13, at 1491; *see* 17 U.S.C. § 302 (2018). *But see* 17 U.S.C. §§ 410-12 (2018) (explaining that while registration is not required, there are some benefits to registration such as: creating a presumption of ownership, allowing the copyright holder to file an infringement lawsuit and enabling the copyright holder to be eligible for certain damages and remedies in a copyright lawsuit).

[28] 17 U.S.C. § 302 (2018) (in the case of a work made for hire, including many corporate creative works, protection lasts "95 years from the year of its first publication, or a term of 120 years from the year of its creation, whichever expires first").

[29] Act of May 31, 1790, ch. 15, 1 Stat. 124 (Copyright Act of 1790, current version at 17 U.S.C. § 102 (2018)).

[30] 17 U.S.C. § 24 (1909) (current version at 17 U.S.C. § 302 (2018)) (setting the term of protection at 28 years, renewable for another 28 years, resulting in a maximum of 56 years).

[31] 17 U.S.C. § 302 (2018).

lobbyists who were hoping to extend the protection of Mickey Mouse)[32] and once again extended this term an additional 20 years, totaling the life of the author plus 70 years (or for a work made for hire—120 years after creation or 95 years after publication, whichever is earlier).[33] As a result of the CTEA, works that were set to go into the public domain in 1999 were "frozen" for another 20 years. No works entered the public domain between 1999 and 2018. While there was speculation that lobbyists might try to further delay and convince Congress to pass an additional Extension Act, this did not occur.[34] Therefore, as of January 1, 2019, works of famous authors, filmmakers, and musicians from the year 1923, such as Cecil B. DeMille's *The Ten Commandments*,[35] Charlie Chaplin's *The Pilgrim*,[36] and Edgar Rice Burroughs' *Tarzan and the Golden Lion*,[37] finally entered the public domain just as creative works used to do every year prior to 1998.[38] Barring a change in the laws, works will continue to enter the public domain in each successive year.[39] Therefore, in under four years from now, on January 1, 2024, Mickey Mouse, too, will enter the public domain.[40] It will be followed in subsequent years by many of

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[32] *See generally* Lawrence Lessig, *Copyright's First Amendment*, 48 UCLA L. REV. 1057, 1065 (2001) (referring to the CTEA as the Mickey Mouse Protection Act).

[33] 17 U.S.C. § 302 (2018); s*ee also* Eldred v. Ashcroft, 537 U.S. 186 (2003) (upholding the constitutionality of the CTEA).

[34] *See* Timothy B. Lee, *Free Mickey—Why Mickey Mouse's 1998 Copyright Extension Probably Won't Happen Again*, ARS TECHNICA (Jan. 1, 2018, 8:00 AM), https://arstechnica.com/tech-policy/2018/01/hollywood-says-its-not-planning-another-copyright-extension-push/ (discussing some of the changes in politics, lobbying efforts, and the rise of internet companies which oppose strong copyright over the past 20 years).

[35] THE TEN COMMANDMENTS (Paramount Pictures 1923).

[36] THE PILGRIM (Associated First National Pictures 1923).

[37] EDGAR RICE BURROUGHS, TARZAN AND THE GOLDEN LION (A. C. McClurg, 1923).

[38] *See January 1, 2019 Is (Finally) Public Domain Day: Works From 1923 Are Open To All!*, DUKE L. SCH. CTR. FOR THE STUDY OF THE PUB. DOMAIN, https://law.duke.edu/cspd/publicdomainday/2019/ (last visited Jan. 23, 2020) (featuring a list of works entering the public domain in 2019 and a comparison of works that would have entered the public domain in 2019 if not for the CTEA).

[39] *See* Lee, *supra* note 15 (discussing other works that will fall into the public domain in the next few years, including George Gershwin's *Rhapsody in Blue*, F. Scott Fitzgerald's *The Great Gatsby,* and Ernest Hemingway's *The Sun Also Rises*. Additionally, the copyrights to Superman, Batman, Disney's *Snow White*, and early Looney Tunes characters will all fall into the public domain between 2031 and 2035.).

[40] *Steamboat Willie* was published in 1928 and granted a 28-year term copyright under the 1909 Copyright Act (renewable for an additional 28 years). Disney renewed, and therefore the copyright would have expired in 1984 (1928+28+28). However, when the Copyright Act of 1976 was passed, it tacked on 19 additional years of protection for works published before 1978, to

Disney's other classic films including *Snow White and the Seven Dwarves*[41] (in 2027), *Pinocchio*[42] (in 2030), *Fantasia*[43] (in 2030), *Dumbo*[44] (in 2031), *Bambi*[45] (in 2032), and *Cinderella*[46] (in 2040).[47]

In his article *The New Public Domain*, Professor Joseph Liu, argues that things might not proceed so simply.[48] He contends that the "new public domain," works that will enter the public domain after 2019, is different from the simplicity of the public domain of the past, which contained works that entered the public domain prior to 1998, and is therefore likely to be treated differently by copyright holders. This is because the *types* of works entering the public domain today are different.[49] Because of the CTEA, the works entering the public domain in 2019 were created in 1923 and thus largely consisted of literature, music (in the form of public performance or sheet music), and early black and white silent films.[50] However, shortly after 1923, creative works began to take on new and more sophisticated forms, due to technological developments in the music and film industries that were made possible by the invention of radio and introduction of colored full-length movies with sounds.[51]

Additionally, since 1998, technologies of dissemination have greatly improved.[52] With the rise of the Internet, the availability of streaming services, and the ability to instantly download almost anything digital, a work entering the public domain today means something very different than it did in 1998. Today, as soon as

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bring duration for pre-1976 Act works into line with those under the 1976 Act. 17 U.S.C. § 304 (2012). Then, under the CTEA, an additional 20 years were added, bringing *Steamboat Willie* Mickey Mouse's expiration date to December 31, 2023 (1984+19+20). Thus, Mickey Mouse will enter the public domain on January 1, 2024. *But see* Douglas A. Hedenkamp, *Free Mickey Mouse: Copyright Notice, Derivative Works and the Copyright Act of 1909*, 2 VA. SPORTS & ENT. L.J. 254, 255 (2003) (arguing that, technically, Mickey Mouse should already be in the public domain because Disney did not follow the proper formalities in registering Mickey Mouse under the 1909 Copyright Act).

[41] SNOW WHITE AND THE SEVEN DWARVES (Walt Disney Animation Studios 1937).
[42] PINOCCHIO (Walt Disney Animation Studios 1940).
[43] FANTASIA (Walt Disney Animation Studios 1940).
[44] DUMBO (Walt Disney Animation Studios 1941).
[45] BAMBI (Walt Disney Animation Studios 1942).
[46] CINDERELLA (Walt Disney Animation Studios 1950).
[47] Doctorow, *supra* note 10.
[48] Liu, *supra* note 9, at 1397.
[49] *Id.*
[50] *Id*. at 1397-98.
[51] *Id.*
[52] *Id.*

a work is made public, it can immediately be uploaded to the Internet and added to any website, including Google books, Amazon, Facebook, YouTube, Hulu, Netflix, etc. and be instantly accessible to the public at little to no cost. Moreover, if one wanted a physical printed copy of a literary work, there are many online publishing services and an abundance of copy shops that one has easier access to than one might have had in 1998.

Furthermore, the average person in 2020 has more technical prowess than one probably thought possible in 1998. Most people today have smart phones and/or personal computers. Through user-friendly applications, such as Photoshop,[53] Garageband,[54] Final Cut Pro,[55] and even Instagram filters, every-day individuals, rather than only experts, are easily able to use raw public domain materials to manipulate and create new works.

Liu argues that these observations lead to the conclusion that the public domain will become increasingly important in upcoming years and will likely shift the balance of the copyright bargain towards the public and away from the copyright holders.[56] While this shift might be exciting for the public and lead to more creativity overall, Liu argues that it may cause concern for copyright holders, likely leading them to turn to other overlapping intellectual property areas—such as trademarks—for protection instead.[57]

II
TRADEMARK PROTECTION

Unlike copyright protection, which expires after a limited period of time, trademark protection can be indefinite. As such, it would seem to be a reasonable strategy for copyright holders to try to claim trademark protection for their works as well. However, while there is certainly overlap, trademark is a separate area of law from copyright, with different objectives and requirements. This discussion will focus on statutory trademark protection, although state common law trademark protection is also available in some circumstances.[58]

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[53] A photo editing program.
[54] A music editing program.
[55] A movie editing program.
[56] Liu, *supra* note 9, at 1398.
[57] *Id.*
[58] *See generally*, Rebecca Tushnet, *Registering Disagreement: Registration in Modern America Trademark Law*, 130 HARV. L. REV. 867 (2017) (discussing the importance of Federal

For instance, although it may inadvertently do so, trademark law, unlike patent and copyright law, is *not* meant to foster innovation. As usually described, the goal of trademark protection is to constrain unfair competition[59] and to limit search costs for consumers seeking to identify products with their sources.[60] By marking a product in a uniquely identifiable way (in a "distinctive" way), it signals to consumers that the product was made by a specific brand and therefore embodies certain qualities or will deliver a certain experience associated with that brand. For instance, when a consumer purchases a laptop with the Apple logo on it, the logo serves as an indicator that the laptop will be of the quality and functionality associated with other Apple devices. If the laptop were to have a Windows logo on it instead, a different set of assumptions would be warranted. Being able to make these assumptions allows consumers to make quicker and more efficient purchasing decisions.

Based on this rationale, there is no reason to limit the duration of trademark protection since marks serve this "minimizing search costs" function as long as they are being used. Thus, trademark protection under the Lanham Act can be indefinite so long as a mark holder can continue to show that his or her marks meet the requirements of a trademark—that the mark has acquired or inherent distinctiveness,[61] is non-functional,[62] and continues to be used in commerce.[63]

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registration in the trademark system and its status in the context of the common law protection of trademarks at both the Federal and state levels).

[59] *See* BARTON BEEBE, TRADEMARK LAW AN OPEN SOURCE CASEBOOK 13 (2018) (ebook).

[60] *Id.* at 23.

[61] *See* 15 U.S.C. §§ 1052(e)(1), 1052(f) (2018).

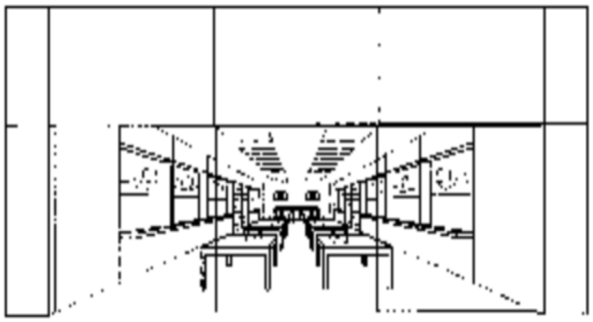
[62] *See* 15 U.S.C. § 1052(e)(5) (2018).

[63] 15 U.S.C. § 1127 (2018); *see also* BEEBE, *supra* note 59, at 30.

However, exactly what is considered a trademark under the law is quite broad and continues to expand as courts interpret the Lanham Act. The most common types of trademarks are logos and brand names, but U.S. trademark protection also covers colors, smells, sounds, product design, and product configuration.[64] For example, some trademarks include the name Apple for computers,[65] the color red for the bottom of Christian Louboutin shoes,[66] the smell of Play-Doh,[67] the sound of

Trademark Registration No. 3,361,597 for red soles of Christian Louboutin shoes.

Trademark Registration No. 4,242,307 for the shape of the Coca-Cola bottle.



Trademark Registration No. 4,277,914 for the Interior of the Apple Store.

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[64] *See* BEEBE, *supra* note 59, at 30-33.

[65] APPLE, Registration No. 1,078,312; BEEBE, *supra* note 59, at 30.

[66] The color(s) red is/are claimed as a feature of the mark. The mark consists of a red lacquered outsole on footwear that contrasts with the color of the adjoining ("upper") portion of the shoe. The dotted lines are not part of the mark but are intended only to show placement of the mark, Registration No. 3,361,597; *see also* Christian Louboutin S.A. v. Yves Saint Laurent Am. Holding, Inc., 696 F.3d 206, 225 (2d Cir. 2012).

[67] The mark is a scent of a sweet, slightly musky, vanilla fragrance, with slight overtones of cherry, combined with the smell of a salted, wheat-based dough, Registration No. 5,467,089; see also BEEBE, *supra* note 59, at 31.

Tarzan's yell,[68] the interior of the Apple store,[69] and even the shape of the Coca-Cola bottle.[70]

Under American trademark law, the *use* of a mark in commerce entitles a mark holder to protection. Therefore, as with copyright law, registration of a trademark is not required to gain protection. Despite this, many choose to register anyway because registration provides additional benefits, such as nationwide priority even if the mark has not yet been used throughout the nation,[71] a prima facie presumption of validity,[72] and the possibility of reaching incontestable status after five years of continuous use.[73] Additionally, one has the option of registering a trademark on an "intent to use" basis[74] so one can benefit from registration prior to actual use.

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[68] The mark consists of the sound of the famous Tarzan yell. The mark is a yell consisting of a series of approximately ten sounds, alternating between the chest and falsetto registers of the voice, as follow—1) a semi-long sound in the chest register, 2) a short sound up an interval of one octave plus a fifth from the preceding sound, 3) a short sound down a Major 3rd from the preceding sound, 4) a short sound up a Major 3rd from the preceding sound, 5) a long sound down one octave plus a Major 3rd from the preceding sound, 6) a short sound up one octave from the preceding sound, 7) a short sound up a Major 3rd from the preceding sound, 8) a short sound down a Major 3rd from the preceding sound, 9) a short sound up a Major 3rd from the preceding sound, 10) a long sound down an octave plus a fifth from the preceding sound, Registration No. 2,210,506; *see also* BEEBE, *supra* note 59, at 31.

[69] The mark consists of the design and layout of a retail store. The store features a clear glass storefront surrounded by a paneled facade consisting of large, rectangular horizontal panels over the top of the glass front, and two narrower panels stacked on either side of the storefront. Within the store, rectangular recessed lighting units traverse the length of the store's ceiling. There are cantilevered shelves below recessed display spaces along the side walls, and rectangular tables arranged in a line in the middle of the store parallel to the walls and extending from the storefront to the back of the store. There is multi-tiered shelving along the side walls, and a [sic] oblong table with stools located at the back of the store, set below video screens flush mounted on the back wall. The walls, floors, lighting, and other fixtures appear in dotted lines and are not claimed as individual features of the mark; however, the placement of the various items are considered to be part of the overall mark. Registration No. 4,277,914; *see also* BEEBE, *supra* note 59, at 32-33.

[70] The mark consists of a three dimensional configuration of a version of the Coca Cola Contour Bottle, rendered as a two-liter bottle, having a distinctive curved shape with an inward curve or pinch in the bottom portion of the bottle and vertical flutes above and below a central flat panel portion. The matter shown in the mark with dotted lines is not a part of the mark and serves only to show the position or placement of the mark, Registration No. 4,242,307; *see also* BEEBE, *supra* note 59, at 33.

[71] *See* 15 U.S.C. § 1057(c) (2018).

[72] *Id.*

[73] *See* 15 U.S.C. §§ 1065, 1115 (2018).

[74] *See* 15 U.S.C. § 1051(b) (2018).

Because the goal of trademark law is to reduce consumer search costs and make it easy for consumers to associate products with their sources, the Lanham Act does not prohibit infringers who copy or make unauthorized uses of a mark simply because it is the property of someone else. Instead, the Lanham Act protects against infringing marks that cause confusion with or dilution of the mark holder's mark and in doing so reduce the ease with which consumers can make the proper product-source association. The mark holder of a registered *or* unregistered mark can bring a claim under the Lanham Act if he or she can prove that an infringing mark will cause a likelihood of consumer confusion or dilution.[75]

Each circuit has its own slightly different test, but generally speaking, to prove that an infringing mark will cause a likelihood of confusion, the plaintiff may try to prove the following factors: 1) that the mark is strong; 2) that there is a high degree of similarity between the two marks; 3) that the two products being compared are proximate and that the plaintiff might try to bridge the gap; 4) actual confusion by consumers; 5) that the defendant acted in bad faith; and 6) that the defendant's product is of differing quality and that the buyers are unsophisticated.[76] These factors are non-exhaustive, and courts may take other variables into account as well.[77]

To make a claim for dilution, that is, to show that the infringing mark causes "damage to the positive associations or connotations of [the mark holder's] trademark,"[78] a plaintiff must show, "1) that the plaintiff owns a famous mark that is distinctive; 2) that the defendant has commenced using a mark in commerce that allegedly is diluting the famous mark; 3) that a similarity between the defendant's mark and the famous mark gives rise to an association between the marks; and 4) that the association is likely to impair the distinctiveness of the famous mark or likely to harm the reputation of the famous mark."[79]

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[75] *See* 15 U.S.C. §§1125 (a), (c) (2018).

[76] Polaroid Corp. v. Polarad Elecs. Corp., 287 F.2d 492, 495 (2d Cir. 1961).

[77] *Id.*

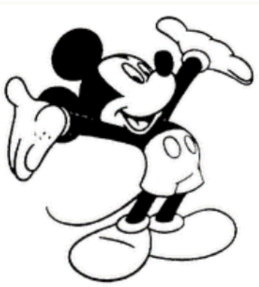
[78] *See* BEEBE, *supra* note 59, at 474.

[79] Louis Vuitton Malletier S.A. v. Haute Diggity Dog, LLC, 507 F.3d 252, 264-65 (4th Cir. 2007).

With this background in mind, Mickey Mouse is undeniably trademarked and thus merits indefinite protection. Both the Mickey Mouse name and image are highly distinctive, and it is nearly impossible for consumers to hear Mickey's name or see his image without making the association with the Disney brand. While trademark registration is not required to get protection, Disney has chosen to register many different versions of the Mickey Mouse mark with the U.S. Patent and Trademark Office (USPTO). For instance, Disney owns the word mark for the stylized words "Mickey Mouse,"[80] various marks featuring the more "classic" version of Mickey Mouse,[81] marks featuring the modern image of Mickey Mouse,[82] and even a mark featuring the evolution of Mickey Mouse over time.[83] As long as Disney does not abandon these marks and its other unregistered marks, and continues to use them in commerce, they will have indefinite trademark protection. Furthermore, Disney's claims to its various Mickey Mouse trademarks are bolstered by the fact that Disney has sued infringers over the Mickey Mouse mark several times and has been successful in court, providing a body of case law precedent for the strength of the Mickey Mouse mark as well.[84]

Registration No. 0,247,156

Registration No. 5,027,809



Registration No. 2,704,887

Registration No. 5,464,657

[80] MICKEY MOUSE, Registration No. 0,247,156.

[81] *See* Registration No. 5,027,809. Color is not claimed as a feature of the mark. The mark consists of a fanciful mouse.

[82] Registration No. 2,704,887.

[83] Color is not claimed as a feature of the mark, Registration No. 5,464,657.

[84] *See* Disney Enters. v. Away Disc., No. 07-1493 (DRD), 2010 WL 3372704, at *5 (D.P.R. Aug. 20, 2010).

III
THE PROBLEM

Professor Viva R. Moffat suggests that Mickey Mouse (and other characters)[85] have been afforded both copyright and trademark protection as a result of the expanding nature of copyright and trademark laws.[86] In her article *Overlapping Copyright and Trademark Protection: A Call for Concern and Action*, Professor Irene Calboli explains that dual protection is unsurprising given both trademark's and copyright's inherent emphasis on creativity.[87] To be granted copyright protection, the Copyright Act requires works to be "original." Courts have interpreted originality to mean that works must be independently created and contain a modicum of *creativity*.[88] A work lacking in creativity cannot receive copyright protection. Similarly, trademark law also subtly favors marks that are more creative in a different way. Under trademarks doctrine, marks that are "arbitrary,"[89] "fanciful,"[90] or "suggestive"[91] are considered inherently distinctive and do not require a showing of secondary meaning to be protected.[92] Such marks embody a creative element since they require the consumer to make an association between the mark and source that is not immediately obvious. Conversely, marks that are "descriptive"[93] (and less creative) do require a showing of secondary meaning in

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[85] *See* Irene Calboli, *Overlapping Copyright and Trademark Protection: A Call for Concern and Action*, 2014 ILL. L. REV. SLIP OPINIONS 25, 29 (2014) (explaining that other characters such as the Simpsons, Angry Birds, Star Wars, the Lord of the Rings, the Hobbit, and other Disney characters are also protected simultaneously by both trademark and copyright).

[86] *See* Moffat, *supra* note 13, at 1496 ("This Article posits that overlapping protection has arisen mostly by accretion, as a result of the expansion of intellectual property rights, rather than by design.").

[87] *See* Calboli, *supra* note 85, at 27-28.

[88] Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 346 (1991).

[89] BEEBE, *supra* note 59, at 38. (stating that "the term 'fanciful,' as a classifying concept, is usually applied to words invented solely for their use as trademarks"). Examples of fanciful marks include "Google" and "Acela."

[90] *Id.* ("When the same legal consequences attach to a common word, i.e., when it is applied in an unfamiliar way, the use is called 'arbitrary.'"). Examples of arbitrary marks include "Apple" for technology and "Camel" for cigarettes.

[91] Abercrombie & Fitch Co. v. Hunting World, Inc., 537 F.2d 4, 11 (2d Cir. 1976) ("A term is suggestive if it requires imagination, thought and perception to reach a conclusion as to the nature of goods."). An example of a suggestive mark is "Lyft" for a ride sharing app.

[92] *Abercrombie*, 537 F.2d at 9.

[93] *Id.* at 11 ("A term is descriptive if it forthwith conveys an immediate idea of the ingredients, qualities or characteristics of the goods."); for example, the mark "American Airlines" describes an airline that is American.

order to acquire distinctiveness. Moreover, marks that are "generic" (and by extension, completely uncreative) are ineligible for trademark protection.[94] In this sense, "even though copyright and trademark protection are different in scope and follow different rules, their normative foundations conceptually overlap in their aspects of originality (the *sine qua non* for copyright protection) and of distinctiveness (the *sine qua non* for trademark protection . . .)"[95] Further, trademark law's goals do not relate directly to innovation, simply from a business standpoint. Still, marketing professionals today must invest creativity in the process of creating a brand's image and designing a company's trademarks in order to find new ideas that have not already been used[96] so they can stand out from competitors and avoid the risk of being considered confusingly similar to other marks. Calboli argues that, due to this emphasis on creativity, the lines between copyright and trademark have blurred, "precisely with respect to creative elements that can be defined as both creative and distinctive—such as characters, graphical elements, pictures, video clips and songs."[97]

At first glance, overlapping protection is not inherently problematic. Some might argue that the greater coverage afforded to works by overlapping protection has led to more innovation on the copyright side and fewer search costs on the trademark side, leaving everyone better off overall. Furthermore, being protected by both the Copyright Act and the Lanham Act provides plaintiffs with additional possibilities of remedies in the event of infringement. As such, it is unsurprising that plaintiffs in infringement cases frequently advance both theories.[98]

But the counter to this argument is that allowing for dual protection and the possibility of a wide menu of remedies in the event of breach may be unfair to defendants. Additionally, it would seem that overlapping protection could be

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[94] *Id.* at 9 ("A generic term is one that refers, or has come to be understood as referring, to the genus of which the particular product is a species."); *see e.g.*, BEEBE, *supra* note 59, at 36 (stating that the word "escalator" had become generic (*citing* Haughton Elevator Co. v. Seeberger, 85 U.S.P.Q. 80 (1950)).

[95] Calboli, *supra* note 85, at 27.

[96] *See generally* Barton Beebe & Jeanne C. Fromer, *Are We Running Out of Trademarks? An Empirical Study of Trademark Depletion and Congestion*, 131 HARV. L. REV. 945, 947 (2018) (finding that evidence suggests that we are running out of trademarks which causes marketers to settle for second-best, less competitively effective marks).

[97] Calboli, *supra* note 85, at 27-28.

[98] *See* Wal-Mart Stores, Inc. v. Samara Bros., 529 U.S. 205, 208 (2000) (plaintiffs brought claims under copyright and trademark law for knock-off outfits sold by Wal-Mart).

particularly problematic and create uncertainty in the situation where copyright protection expires but trademark protection persists.

One of the Peter Rabbit illustrations at issue in Frederick Warne

Courts have gone back and forth on this issue over time. In 1979, the Second Circuit suggested that overlapping copyright and trademark protection was no cause for concern. In *Frederick Warne & Co. v. Book Sales, Inc.*, the court addressed the question of overlapping protection regarding an image of the famous children's story character, Peter Rabbit.[99] The plaintiff, the publisher for Beatrix Potter's *Peter Rabbit* books, argued that the defendant's newly published book, a collection of *Peter Rabbit* stories, which featured an image of Peter Rabbit found in Beatrix Potter's illustrations, infringed on its trademark. The defendant argued that he had done nothing wrong since the *Peter Rabbit* books and illustrations had fallen into the public domain before he had used them.[100] The court sided with the plaintiff, finding that, "[t]he fact that a copyrightable character or design has fallen into the public domain should not preclude protection under the trademark laws so long as it is shown to have acquired independent trademark significance, identifying in some way the source or sponsorship of the goods. . . . Because the nature of the property right conferred by copyright is significantly different from that of trademark, trademark protection should be able to co-exist, and possibly to overlap, with copyright protection without posing preemption difficulties."[101]

However, years later, in 2003, the Supreme Court seemed to reject this reasoning in *Dastar* and argued that granting trademark protection after a copyright has expired should not be allowed since it undermines the rationales behind copyright and disrupts the copyright bargain.[102] In *Dastar*, the plaintiff, 20th Century Fox, owned the copyright to a TV series based on a book written by President Eisenhower about Europe during World War II.[103] Fox inadvertently failed to renew its copyright in the TV series and, as such, the TV series copyright fell into the public domain. At that point, Dastar, the defendant, decided to slightly edit and use the public domain footage. Dastar sold it and presented its version as its own without

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[99] Frederick Warne & Co. v. Book Sales, Inc., 481 F. Supp. 1191, 1196 (S.D.N.Y. 1979).
[100] *Id.* at 1193-96.
[101] *Id.* at 1196.
[102] Dastar Corp. v. Twentieth Century Fox Film Corp., 539 U.S. 23, 34 (2003).
[103] *Id.* at 25-27.

any mention of Fox. Fox then sued Dastar for "reverse passing off"— the misrepresentation of another's goods as one's own—in violation of § 43(a) of the Lanham Act.[104] Lanham Act § 43(a) allows a mark holder to bring a civil action against one who uses an infringing mark in a way that "is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the *origin*, sponsorship, or approval *of his or her goods*, services, or commercial activities by another person" (emphasis added).[105] The court held that the "origin" of the goods in question was actually Dastar rather than Fox or even Eisenhower, since Dastar produced the product actually being sold to consumers.[106] By holding this way, the court was able to find that Dastar did not infringe on any trademark and also expressed its opposition towards considering an expired copyright holder to be an "origin" of the good at all. The court explained that, "allowing a cause of action under § 43(a) . . . would create a species of mutant copyright law that limits the public's federal right to copy and to use expired copyrights."[107] In other words, using trademark law to extend protection once a copyright has expired unfairly limits the public's right to use materials that should be considered part of the public domain.[108]

A prime example of this concern is Mickey Mouse. As previously mentioned, the original copyright for Mickey Mouse dates back to 1928 with the release of *Steamboat Willie*. Since then, Mickey Mouse has become trademarked, since it has acquired distinctiveness and has come to be a strong source indicator for Disney. When Mickey Mouse's copyright expires in 2023, this will put the *Steamboat Willie* version of Mickey Mouse into the public domain. At that point, everyone may use the version of *Steamboat Willie* Mickey Mouse in their artwork, stories, videos, social media profile pictures, etc. and Disney will have no recourse under copyright law.

However, mainstream public use of Mickey Mouse's image will certainly conflict with Disney's Mickey Mouse trademark. Perhaps because of this issue, Disney has preemptively done its best to incorporate the *Steamboat Willie* version of Mickey Mouse into the modern-day brand. They continue to show *Steamboat*

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[104] *Id.* at 27.
[105] 15 U.S.C. § 1125 (2018).
[106] *Dastar*, 539 U.S. at 31-38.
[107] *Id.* at 34 (internal quotation marks omitted).
[108] *Id.*

Willie on their website,[109] sell Steamboat Willie merchandise through their store,[110] make references to *Steamboat Willie* in other works,[111] and even use the iconic Steamboat Willie image as part of their logo for Disney Animation Studios.[112]

Steamboat Willie Mickey Mouse plush doll available for sale on the Disney shop website

Disney referencing Steamboat Willie *as the genie pretends to be Mickey Mouse in* Aladdin and the King of Thieves *(1996)*

Disney using Steamboat Willie Mickey Mouse as part of the Walt Disney Animation Studios logo

Due to these efforts, consumers are likely to assume that Disney endorsed any product featuring Steamboat Willie and will most certainly continue to associate such paraphernalia with the Disney brand for years to come. For this reason, it would seem that Disney has every right to sue users of the *Steamboat Willie* Mickey Mouse image under a trademark infringement theory.

Yet under the *Dastar* precedent, it seems that Disney would fail in this endeavor. The purpose of the copyright bargain is to allow works to eventually enter the public domain, and if trademark law were to persist here, it would inhibit the copyright bargain. Yet, it is also unclear as to why the rationale for copyright should prevail over the rationale for trademark protection. Surely, Disney has invested a large sum in using Mickey Mouse to build its brand and help consumers minimize search costs. This is precisely the kind of behavior that trademark law is usually

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[109] *Steamboat Willie*, DISNEY VIDEO, https://video.disney.com/watch/steamboat-willie-4ea9de5180b375f7476ada2c (last visited Jan. 23, 2019).

[110] See, e.g., *Mickey Mouse Knit Plush—Steamboat Willie*, SHOP DISNEY, https://www.shopdisney.com/mickey-mouse-knit-plush-steamboat-willie-15-400021021501.html (last visited Jan. 23, 2019) (featuring a plush Steamboat Willie doll that consumers can buy from the Disney online shop).

[111] *See Steamboat Willie*, FANDOM, https://disney.fandom.com/wiki/Steamboat_Willie (last visited Jan. 23, 2019); *see also* Tormagainst, *Aladdin and the King of Thieves—Mickey Mouse scene*, YOUTUBE.COM, https://www.youtube.com/watch?v=KUoUsPkjie0 (last visited June 14, 2019).

[112] *Steamboat Willie*, *supra* note 109.

meant to incentivize, and for which there is no protection end date. *Dastar* does not specifically address or comment on this reasoning.

As the Supreme Court did not provide any practical guidance on how to implement *Dastar*, overlapping protection is still quite an open and undecided area of law. Since many popular works, including Mickey Mouse, will enter the public domain within the next few years, it is clear that the Supreme Court or Congress needs to address the issue.

IV
SOLUTIONS

The remainder of this paper will explore some proposals of ways that Congress and/or the Supreme Court might address the issue, including: 1) amending the duration of protection in the Copyright Act or the Lanham Act, 2) allowing the works to fall into the public domain, 3) using false advertising law, and 4) creating stronger channeling doctrines.

A. Proposal #1: Amend the Lanham Act in order to impose a time limit on marks whose copyrights have expired

Until recently, Congress arguably chose to address the issue of overlapping protection through avoidance. Congress never set out clear instructions on how to handle expired copyrights that receive trademark protection, and the CTEA's 20 year delay of many characters' entry into the public domain effectively deferred the issue.[113] However, Professor Moffat argues that the CTEA did more than just delay a resolution of the issue and that it actually exacerbated the problem because it gave companies like Disney time for their trademarks to acquire secondary meaning, and thereby to become more powerful.[114] Certainly, during the past 20 year copyright freeze, Disney took advantage of Mickey Mouse's continued protection and undertook countless marketing,[115] branding, and legal initiatives to strengthen the Mickey Mouse trademark.[116]

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[113] Moffat, *supra* note 13, at 1507 n. 173.

[114] *Id.* at 1508 ("Disney used its copyright as leverage for getting trademark protection that it may not have been able to obtain without the benefits of copyright law.").

[115] *See, e.g.*, *About the Quest for Hidden Mickeys*, FIND MICKEYS, http://findmickeys.com/ (last visited Jan. 23, 2020) (explaining how Disney has hidden a number of hidden Mickey Mouse related images all around its theme parks and as Easter Eggs in its movies).

[116] *See generally* Joseph Greener, *If You Give a Mouse a Trademark: Disney's Monopoly on Trademarks in the Entertainment Industry*, 15 WAKE FOREST J. OF BUS. & INTELL. PROP. L. 598 (2015) (providing examples of Disney's efforts to protect its Mickey Mouse copyright and

For this reason, an additional extension of the copyright term would not be advisable, and perhaps Congress realized this since it chose not to extend the copyright term in 2019 when the CTEA protection expired for works from 1923. However, the issue of overlapping protection must still be addressed.

Instead of amending the Copyright Act and dealing with the issue through copyright law, Congress could address the issue through trademark law. One possible solution to the problem of overlapping protection would be to amend the Lanham Act by adding a section specifically addressing marks whose copyrights have expired. For example, a rule which places a time limit on such marks and allows a trademark to be enforced for an additional, fixed number of years past the expiration of its copyright, after which the trademark would expire as well, would allow characters like Mickey Mouse a period of time in which they could benefit from both copyright and trademark law individually without running into the risk of becoming a "mutant" eternal copyright.[117] This solution could be compatible with the copyright bargain, since the works would eventually enter the public domain. Additionally, it would also help to achieve some of the goals of trademark because it would give the company a period of time where the marks would be protected, and consumers could rely on the association of the mark with a particular source.

Yet, this compromise is not perfect, as it does not directly address the fact that under trademark theory, protection should be indefinite. In her article, *The Methuselah Factor: When Characters Outlive Their Copyrights*, Professor Leslie Kurtz argues that part of the difficulty with characters is that they do not fit neatly into trademark doctrine to begin with.[118] While one goal of trademarks is to identify the source of a good, in the case of characters, Kurtz argues that, "a character's ability to identify a single source may be no more than a convenient fiction."[119] Unlike logos, such as the Starbucks logo, which signifies that drinks bearing the logo come from the Starbucks Company, characters do not provide as clear of a source. Kurtz explains,

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trademark including suing or threatening to sue daycares with drawings of Mickey Mouse on the walls, street vendors selling unauthorized t-shirts with images of Mickey and Minnie Mouse, a New York bar called "Mickey's Mousetrap," and deadmau5 (pronounced "dead mouse"), a Canadian DJ who is famous for wearing a mouse-shaped helmet during concerts).

[117] Dastar Corp. v. Twentieth Century Fox Film Corp., 539 U.S. 23, 34 (2003).

[118] *See* Kurtz, *supra* note 19, at 443.

[119] *Id*. at 443.

> What is the source of a fictional character? Is it the author or publisher of a book; the director or producer of a film? What if a character appears in a book and a film? Is the source the book's author, the book's publisher, the film's director, or the film's producer? . . . There is a tendency to focus on the character itself, rather than on any information it provides about source or identification.[120]

Additionally, Kurtz argues that characters do not meet trademark's goal of minimizing search costs through signifying that goods bearing the mark are of consistent quality.[121] She explains, "[c]onsumers buy Teenage Mutant Ninja Turtles clothing or 'E.T. Phone Home' mugs not because the symbol indicates that the shirt is of a certain quality or the mug won't break, but because they want that picture or that phrase on their merchandise."[122]

Yet this critique could extend to trademarks generally. Consumers may buy a Nike t-shirt simply to display the Nike swoosh logo across their chest, with little thought to the quality of the shirt itself. In fact, some have criticized trademarks as creating "artificial product differentiation" since consumers are likely to pay more for a shirt with a popular logo than for a shirt of identical quality without one.[123]

Regardless, it is clear that characters do have some unique characteristics that other trademarks do not. Therefore, rather than broadly limiting the Lanham Act to restrict any mark whose copyright has expired, perhaps it makes sense to narrow the parameters and only place a time limit upon characters being used in logos or as part of the brand, whose copyright has expired. If, as Kurtz says, it is a stretch for characters to receive trademark protection in the first place, then placing a time limit just on characters might be less problematic under the Lanham Act.

B. Proposal #2: Allow the Characters to Fall Into the Public Domain

While Disney would certainly be upset, an additional plausible option to address the issue is simply to do nothing and to let copyrighted works fall into the public domain.

Kurtz argues that "[f]ictional characters help form the modern myths out of which we operate and are an important part of the cultural heritage on which an author can draw to create something new. They can encapsulate an idea, evoke an

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[120] *Id*. at 443-44.
[121] *Id*. at 444.
[122] *Id.* at 445.
[123] BEEBE, *supra* note 59, at 25.

emotion, or conjure up an image. When a fictional character has entered the public domain, there are strong policy reasons for keeping it there, thus allowing others to make use of it."[124] Keeping works in the public domain is the best way to adhere to the copyright bargain and to protect against monopolies. Additionally, as Professor Jessica Litman points out, "Mickey Mouse has enjoyed a long, and very lucrative, run. If it is time to close the show, it has more than paid back its investment."[125] Therefore, despite the outcry from Disney, it would not be horrific if Mickey Mouse were available for all to use.

In fact, Mickey Mouse would not be the first major character to fall into the public domain. Sherlock Holmes provides an illustrative example of an iconic fictional character that has fallen into the public domain without catastrophic consequences. Today, Sherlock Holmes books, movies, and TV shows continue to be written, borrowing the character from Arthur Conan Doyle's iconic series, and the consent of the Arthur Conan Doyle estate is not required.[126] However, it was not always clear that it would be this way.

The use of Sherlock Holmes was initially met with resistance. In *Klinger v. Conan Doyle Estate, Ltd.,* the Conan Doyle estate argued that Sherlock Holmes should not be in the public domain until the totality of the series had fallen into the public domain.[127] The Court disagreed and held that since most of the books were written prior to 1923, they were in the public domain.[128] However, they found that certain plot elements included in Sherlock Holmes short stories written after 1923, such as the existence of Dr. Watson's second wife, Dr. Watson's background as an athlete, and Sherlock Holmes' retirement from his detective agency, had not yet fallen into the public domain.[129] Therefore, these elements may not be used in modern adaptations until they, too, expire and enter the public domain.

Similar reasoning can be applied to Mickey Mouse. When the copyright expires for the *Steamboat Willie* version of Mickey Mouse, it will fall into the public

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[124] *See* Kurtz, *supra* note 19, at 441.

[125] Jessica Litman, *Mickey Mouse Emeritus: Character Protection and the Public Domain*, 11 U. MIAMI ENT. & SPORTS L. REV. 429, 431 (1994).

[126] Mike Masnick, *Sherlock Holmes and the Case of the Never Ending Copyright Dispute*, TECHDIRT (May 26, 2015, 8:12 AM), https://www.techdirt.com/articles/20150524/17521431095/sherlock-holmes-case-never-ending-copyright-dispute.shtml.

[127] Klinger v. Conan Doyle Estate, Ltd., 988 F. Supp. 2d 879, 888 (N.D. Ill. 2013).

[128] *Id*. at 890.

[129] *Id*.

domain. However, later versions of Mickey Mouse will be protected until their copyrights expire.

Yet, the analogy between Sherlock Holmes and Mickey Mouse is not perfect. While Doyle could only write so many books before he passed away, Disney, as a company, can (and has) continuously updated Mickey Mouse over time, slightly changing his appearance thus maintaining his relevance for new generations (and generating new copyrights in the process).[130] This also has interesting ramifications for trademarks.

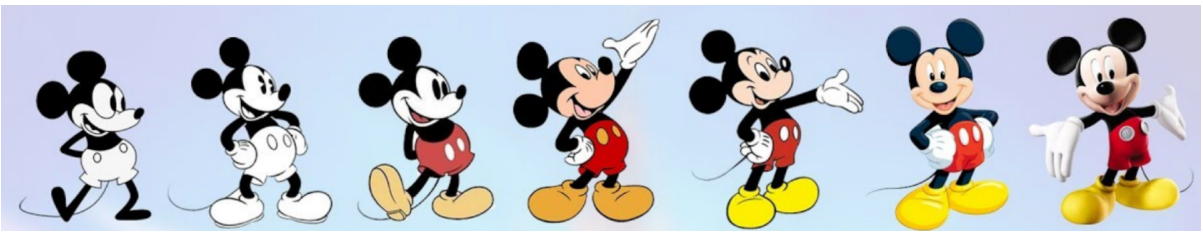

Illustration showing the progression of different versions of Mickey Mouse over time.

In trademark law, there is a concept called tacking, whereby trademarks, which are slightly updated over time, but are still recognized as creating "the same, continuing commercial impression," can be considered the same mark and refer back to the initial registration when determining the registration date.[131] Although tacking is mainly used to determine the date of registration, which is important when a trademark is contested, the idea that trademarks can develop over time yet essentially remain the same mark is particularly relevant here. If some sort of tacking logic is applied to Mickey Mouse, then even once a copyright expires, Mickey Mouse's trademark protection could effectively remain indefinite. However, the Supreme Court has noted that tacking only applies in "exceptionally narrow" circumstances.[132] Even without tacking, a company could have multiple trademarks in effect at any given time, as long as the marks remained in use in commerce and continued to be associated with the source.

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[130] *See* accompanying figure showing the progression of Mickey Mouse over time.

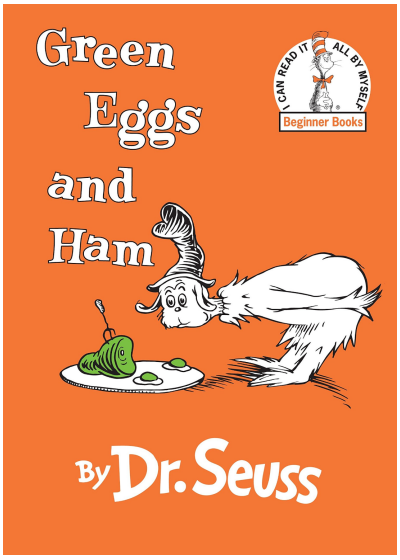
[131] Van Dyne-Crotty, Inc. v. Wear-Guard Corp., 926 F.2d 1156, 1159 (Fed. Cir. 1991) (*citing* Ilco Corp. v. Ideal Security Hardware Corp., 527 F.2d 1221, 1224 (C.C.P.A. 1976)); s*ee generally* Gideon Mark & Jacob Jacoby, *Continuing Commercial Impression: Applications and Measurement*, 10 INTELL. PROP. L. REV. 433 (2006).

[132] Hana Fin., Inc. v. Hana Bank, 135 S. Ct. 907, 910 (2015).

Yet the question still remains, if a copyright expires, practically speaking, how could we continue to enforce trademark rights without running into conflicts between the goals of the two intellectual property regimes?

The *Frederick Warne* court argued that the property rights afforded by trademark and copyright were significantly different[133] and therefore implied that the line could be drawn based on the way that a character was being used. For example, if a character were to be used in an artistic way, such as in a painting, movie, or book, that would clearly be a copyright use and would not be considered infringement after the work falls into the public domain. If, however, a mark is being used to identify its source, such as being placed as a logo and being sold on a lunchbox, then it is being used in the trademark sense, and in that situation, infringers could be liable for trademark infringement.

Professor Jane C. Ginsburg uses the example of the Cat in the Hat to describe this distinction.[134] She explains, "[t]he Cat, the character, stars in two eponymous children's stories," and "[t]he Cat, the brand . . . adorns the spines and front and back covers of the books in the Beginner Books 'I Can Read It All By Myself' series of children's books."[135] She continues: "When the Dr. Seuss books fall into the public domain, anyone may republish them, but the subsistence of trademark rights in the Cat as part of the trade dress of the Random House book series means that any unlicensed versions of that image of the Cat may not appear on the spines, back covers, or upper right hand corners of the front covers of those republications."[136] She analogizes the Cat in the Hat to Mickey Mouse and says that there is no reason why "Steamboat Willie, the brand, should [not] remain distinct from Steamboat Willie, the character."[137] However, this analogy between the



A book featuring the Cat in the Hat logo for the "I Can Read It All By Myself" Brand

[133] Frederick Warne & Co. v. Book Sales, Inc., 481 F. Supp. 1191, 1196 (S.D.N.Y. 1979).

[134] See Jane C. Ginsburg, *Intellectual Property as Seen by Barbie and Mickey: The Reciprocal Relationship of Copyright and Trademark Law*, 65 J. OF THE COPYRIGHT SOC'Y OF THE USA 1, 15-16 (2017).

[135] *Id.* at 15.

[136] *Id.* at 16.

[137] *Id.*

Cat in the Hat and Mickey Mouse is not perfect. The "I Can Read It All By Myself" series uses the Cat in the Hat logo in a very specific way, in predictable places on the spines and backs of books, whereas the Steamboat Willie mark manifests itself in different ways and is used in many different contexts.

While it is unclear if this difference would be material, practically speaking, Ginsburg's proposal still faces the objection that it can be confusing to draw the line between acceptable copyright uses of a character and unacceptable trademark uses. Surely the public is unlikely to know which versions of Mickey Mouse are in the public domain, and because Mickey Mouse has acquired an enormous amount of secondary meaning, even if an artist tries to use Mickey Mouse in a purely artistic and non-commercial sense, the public will likely still assume that Disney is involved. Furthermore, there are instances where this line will blur. For instance, what if a street artist makes a mural of Mickey Mouse, but then Disney decides to sell postcards of the mural? Would that be considered a copyright use of Mickey Mouse or a trademark use?

Kurtz argues that the best way to handle the confusion between copyright and trademark is through the use of disclaimers.[138] To prevent this confusion at the outset, Kurtz proposes that those who do not have trademark rights be required to visibly indicate "not an authorized use."[139] Alternatively, the trademark holder might be required to somehow indicate that something *is* a trademarked use. This solution is interesting and may craft a system, similar to the art world, where authenticity matters more than what is actually displayed in the work itself. An authentic, authorized Mickey Mouse lunch box could be worth much more than an unauthorized lunchbox. However, this system hinges on people reading and understanding disclaimers. If a company has a very discrete small logo, like the tiny polo man on Ralph Lauren polo shirts, for aesthetic reasons, it may not want to have to use space indicating that something is an authorized use. Perhaps these indications could be made through some sort of small symbol, like the ® or ™ signs. However, unlike the ® and ™ signs, the symbol used would have to be broadly understood by the general public, and building up that understanding would require time and money to educate.

While this solution certainly provides some food for thought as to how trademarks could be used in a world when copyrights expire, some might argue that it disregards the Supreme Court's decree in *Dastar* that trademarks not be used to extend protection once copyright expires. This is unsurprising since Kurtz's article

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[138] *See* Kurtz, *supra* note 19, at 446.
[139] *See id.*

was written prior to the *Dastar* opinion. But at the end of the day, *Dastar* is Supreme Court precedent, and therefore, it cannot be completely ignored when implementing a solution.

Of course, the courts *could* limit the holding of *Dastar* to the very specific facts of the case. For instance, one could say that the holding about avoiding mutant copyrights only applies in the limited situation of reverse passing off when someone accidentally forgets to renew a copyright. Reading *Dastar* in this way would remove a lot of its power, but that was probably not Justice Scalia's intention and may not be the wisest approach.[140] Alternatively, as we have seen in many Supreme Court cases, a future Supreme Court may take the line about "mutant copyrights" and say that it was merely dicta and not the holding. Only time will tell, and it will be up to the Supreme Court to maneuver out of past precedent, but until then, we can only guess at how *Dastar* should best be applied with the text that we have.

C. Proposal #3: Use false advertising law instead of trademark law in order to get around Dastar

Although *Dastar* does not permit the use of trademarks as a means of extending protection after copyrights expire, the *Dastar* opinion does leave room for the possibility of using false advertising law as a means of protection instead. At the end of the *Dastar* decision, the court explains that if a copied worked were used "in advertising or promotion, to give purchasers the impression that [it] was quite different" than the original that it copied "then . . . the respondents might have a cause of action . . . for misrepresentation under the 'misrepresents the nature, characteristics [or] qualities' provision of § 43(a)(1)(B)."[141] This refers to Lanham Act § 43(a)(1)(B), often called the false advertising prong,[142] which holds liable in a civil action "any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which in commercial advertising or promotion, misrepresents the *nature*, *characteristics*, *qualities*, or geographic origin of his or her or another person's goods, services, or commercial activities" (emphasis added). [143] As it has been interpreted, "nature, characteristics, and

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[140] *See generally* Mark McKenna, *Dastar's Next Stand*, 19 J. INTELL. PROP. L. 357 (2012) (discussing how best to interpret the *Dastar* opinion).

[141] Dastar Corp. v. Twentieth Century Fox Film Corp., 539 U.S. 23, 38 (2003).

[142] *See* ZS Assocs. v. Synygy, Inc., No. 10-4274, 2011 WL 2038513, at *28 (E.D. Pa. May 23, 2011).

[143] 15 U.S.C. § 1125(a)(1)(B) (2018).

qualities" refers to the nature of the good itself, rather than a question about the authorship or source of the good.[144]

As it applies to Mickey Mouse, this means that a false or misleading promotion made about Mickey Mouse's "nature, characteristics, or qualities" might qualify for a false advertising claim, but a claim about the author of Mickey Mouse would not. For instance, if a non-Disney entity was selling Mickey Mouse products and was advertising Mickey Mouse's tendency to be the villain, his superpower of teleportation, his connection to his girlfriend Daisy Duck, or his famous triangular shaped ears, any of these might be false advertising. However, Disney would not have a claim against a seller who simply sold Mickey Mouse paraphernalia without accreditation to Disney or who even took Disney gear and sold it under its own brand, since these are examples of passing off and reverse passing off, which are seemingly barred by *Dastar.*

To make matters more complicated, the requirements for false advertising are different from regular trademark protection. Rather than just needing to show a likelihood of confusion (necessary for a trademark infringement claim), to have a valid false advertising claim, a plaintiff must demonstrate that: "(1) the defendant's statements were false or misleading; (2) the statements deceived, or had the capacity to deceive, consumers; (3) the deception had a material effect on consumers' purchasing decision; (4) the misrepresented service affects interstate commerce; and (5) the plaintiff has been, or likely will be, injured as a result of the false or misleading statement."[145] These requirements mean that a plaintiff might not have a viable false advertising claim in a situation where they might have been able to sue for trademark infringement.

For example, although in the past Disney might have brought trademark claims against street vendors selling Mickey Mouse t-shirts,[146] under false advertising law, Disney might have difficulty showing that the deception had a material effect on consumers' purchasing decisions and that Disney was injured as a result of one street vendor selling a few shirts.

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[144] *ZS Assocs.*, 2011 WL 2038513, at *26.

[145] 44 AM. JUR. PROOF OF FACTS 3d 1, § 1 (1997); *see also* Skil Corp. v. Rockwell Int'l Corp., 375 F. Supp. 777, 783 (N.D. Ill. 1974).

[146] *See* Greener, *supra* note 116, at 607.

Lastly, a false advertising claim requires actual advertising or promotion.[147] Simply selling a Mickey Mouse product without making a promotional claim about it would be insufficient to trigger liability. Consequently, although false advertising law might be a workable tool for Disney in a post-*Dastar* world, it would actually only be able to be employed in very limited circumstances.

D. Proposal #4: Creating stronger channeling doctrines and implementing election at the outset

Perhaps the best way to prevent overlapping protection is to minimize overlap at the outset. In fact, there are efforts to minimize this overlap built into both trademark and copyright laws called "channeling doctrines." A channeling doctrine is a rule meant to police the boundaries of intellectual property and keep different works, so to speak, "in their lane."[148] For example, there is a rule that short phrases and words (like "McDonald's" or "Starbucks Coffee") cannot be copyrighted while they may be trademarked. [149] Additionally, copyright has an originality requirement that trademark protection does not require.[150] As such, some logos, which do not contain the requisite amount of originality, cannot claim copyright protection even though they would be able to get trademark protection. For example, Tommy Hilfiger submitted its logo for copyright registration but was rejected for not having enough originality.[151] As such, this logo could be trademarked but not copyrighted.[152] But, that would not apply to a more original logo like Mickey Mouse. It is clear that, despite the existence of these rules, clearly the current channeling doctrines have been insufficient in preventing overlapping protection.

Tommy Hilfiger logo which cannot be copyrighted due to a lack of originality

If Congress were to create stronger channeling doctrines, this might help to minimize overlap. For instance, if Congress were to decide that one could not

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[147] 44 AM. JUR. PROOF OF FACTS 3d 1, § 1 (1997) ("The contested representations must be: (1) commercial speech, (2) made for the purpose of influencing consumers to buy defendant's goods or services, and (3) disseminated sufficiently to the relevant purchasing public.").

[148] *See generally* Mark P. McKenna, *An Alternate Approach to Channeling?* 51 WM. & MARY L. REV. 873, 873-75 (2009).

[149] *See* Moffat, *supra* note 13, at 1505.

[150] *See id.* at 1505-06.

[151] *See* Review Board Letters Online, Tommy Hilfiger Flag, U.S. COPYRIGHT OFF., https://www.copyright.gov/rulings-filings/review-board/docs/tommy-hilfiger-flag.pdf.

[152] *See* Moffat, *supra* note 13, at 1505-06.

copyright logos or that characters could not be used as part of a trademark, this might minimize overlap going forward.

Alternatively, without reducing the overall number of compositions protected, the U.S. could return to a system of election, where applicants would have to choose at the outset whether to seek trademark or copyright protection on a work but could not pick both. Yet, practically speaking, this has its challenges. According to Professors Jeanne Fromer and Mark McKenna, "[a] number of considerations affect the viability and value of a doctrine of election, particularly the timing and form of election, creator choice, and the subject of election."[153] One does not actually need to register a copyright prior to enforcement, and trademark registration is not actually necessary at all.[154] Furthermore, trademark rights do not kick in until there is "use in the marketplace and distinctiveness established" which would likely happen at a different time from copyright registration.[155] For these reasons, election would have to be seriously reconsidered and framed in a way that would overcome these difficulties.

CONCLUSION

Walt Disney was famous for saying, "I only hope that we never lose sight of one thing—that it was all started by a mouse."[156] Whatever Congress or the Supreme Court decides, it seems like Mickey Mouse will once again be a trailblazer. In the meantime, courts will do their best to implement *Dastar* while the public benefits from the works entering the "new" public domain.

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[153] Jeanne C. Fromer & Mark P. McKenna, *Claiming Design*, 167 U. PA. L. REV. 123, 204-05 (2018).

[154] *Id.*

[155] *Id.*

[156] Kevin Fallon, *Mickey Mouse is 90 and this Disney Exhibit Celebrates Him Perfectly*, DAILY BEAST (Nov. 9, 2018, 4:38 AM), https://www.thedailybeast.com/mickey-mouse-is-90-and-this-disney-exhibit-celebrates-him-perfectly.

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NOTE

PATENT TERM EXTENSION AND THE ACTIVE INGREDIENT PROBLEM

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Patent term extension (PTE) is a statutorily-based mechanism to compensate inventors for patent term loss due to regulatory delay during the drug approval process at the United States Food and Drug Administration (FDA). In the context of pharmaceutical products, PTE is only available for the active ingredient of a drug formulation. Case law and interpretation of the relevant statutory text have clearly delineated the boundaries of what qualifies as an active ingredient in a chemical formulation for purposes of PTE. As therapeutics expand beyond simple chemical formulations into cell-based and gene therapy-based formulations, where a chemical compound is not the active ingredient, an interpretation of active ingredient for purposes of PTE is lacking. I term this shortcoming "the active ingredient problem." In the absence of applicable case law, it has become increasingly important to review FDA guidance and recommendations. Furthermore, the United States Patent and Trademark Office (USPTO) has offered limited indications of how it may interpret active ingredients in these scenarios. Moving forward, it will be essential for inventors to understand how these cutting-edge therapeutics will be protected and how their efforts will be compensated as a result of delays associated with the regulatory approval process. In this paper, I advocate the adoption of "treatment complex protocols" or TCPs, a novel framework for PTE for cellular and gene-based therapeutics. This framework

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moves away from considerations of an active ingredient and instead embraces the complexities of the production and development of cellular and gene-based therapies. Under this framework, PTE would be granted to a TCP, which is a complete protocol-based description of the inputs, modifications, and outputs required to develop these complex and clinically important therapeutics. Although TCPs are necessarily more complex than determinations of active ingredients for chemically based therapeutics, they have the potential to clarify this increasingly murky, yet clinically relevant, area of the law.

INTRODUCTION

The twenty-year patent term serves as a means of incentivizing inventors to create and innovate in exchange for a grant of a period of exclusivity during which they hold exclusive rights to exclude others from practicing the invention. The twenty-year term, however, often implies that the inventor can begin practicing her invention (and begin excluding others) as soon as the patent is granted. This is frequently not the case, especially for patents covering therapeutics that cannot be fully practiced (i.e., marketed and sold) until they have gone through a required regulatory approval process. In the United States, this approval is completed by the United States Food and Drug Administration (FDA). In cases where the invention could be practiced (i.e., marketed as a drug) but-for this delay, it seems sensible that the inventor should not bear the burden of the "lost" time of protection of the patent term. Patent term extension (PTE) is a statutory mechanism to deal with this precise issue: it permits the inventor to recoup at least a portion of the time that was spent approving the product and that resulted in a delay in commercial exploitation of the product.

PTE exists as a regulatory mechanism to compensate inventors for patent term loss due to unfair regulatory delay during the drug approval process by the FDA.[1] To ensure that inventors are not inappropriately recovering lost patent terms, PTE is only available for the active ingredient, which is, generally speaking, the component of the drug that is responsible for providing its pharmacological activity. Traditionally, this has been defined as a chemical compound in the drug formulation that, when administered to a patient, results in the drug's beneficial effects.[2] Case law and interpretation of the relevant statutory text have clearly delineated the boundaries of what qualifies as an active ingredient in a chemical formulation for PTE well beyond the traditional FDA definition. As therapeutics expand beyond simple chemical formulations into cell-based and gene therapy-based formulations (i.e., where the treatment is not comprised of a chemical compound), and a chemical compound is thus not the active ingredient, it is less clear precisely what the "active ingredient" is. An applicable interpretation of the active ingredient in complex therapeutics like cellular and gene-based therapies is lacking for purposes of PTE. Furthermore, the shortcomings of the PTE statute will not easily be ameliorated by

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[1] *See* 35 U.S.C. § 156 (2018); *see, e.g.*, Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 663 (1990) ("The [Patent] Act was designed to remedy . . . distortions," for instance when "the patentee would as a practical matter not be able to reap any financial rewards during the early years of the term while he was engaged in seeking [regulatory] approval.").

[2] *Active Ingredient*, FDA, https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms (last visited Apr. 6, 2020).

amending the statute or adding simple additional language. As I argue in this Note, simply amending the statute or modifying the statutory definitions almost certainly would not resolve what I described as "the active ingredient problem," and the question "what is an active ingredient in a cell-based or gene therapy-based formulation?" remains open and unanswered.

In the absence of extensive, applicable case law, it has become increasingly relevant to review FDA guidance and recommendations. Furthermore, the United States Patent and Trademark Office (USPTO) has offered limited insight with regards to the interpretation of active ingredients in cell-based therapeutics. Although the USPTO will likely not be granted any agency deference by courts,[3] this still provides an important step forward in understanding how these cutting-edge therapeutics will be protected and how inventors' innovations will be compensated as a result of delays associated with the regulatory approval process. In the meantime, appropriate claim construction that reflects the active ingredient contained in the FDA regulatory filing may alleviate some of the uncertainty while ensuring protection extensions for inventors.

In this paper, I argue that the statutory definition of "active ingredient" fails to work effectively in the context of novel therapeutics and, as a result, there exists a need for a novel framework. As a result, the concept of active ingredient for PTE should be revamped entirely with respect to novel therapeutics. In its place, I propose "treatment complex protocols," or "TCPs" which are a protocol-based collection of information that would include a holistic review of the treatment, its components, and input and output information related to the production of the clinical therapeutic. Although extending the active ingredient analysis may be cumbersome, the current

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[3] Courts have not yet recognized a basis for *Chevron* deference for the USPTO. *See, e.g.*, John M. Golden, *Working Without Chevron: The PTO as Prime Mover*, 65 DUKE L.J. 1657, 1659 (2016). The United States Court of Appeals for the Federal Circuit has held that "Congress has not vested the [USPTO] Commissioner with any general substantive rulemaking power." Merck & Co. v. Kessler, 80 F.3d 1543, 1550 (Fed. Cir. 1996). The United States Supreme Court has stated that *Chevron* only applies where Congress has delegated relevant authority (e.g., substantive rulemaking authority) and when the agency interpretation seeking deference was promulgated under that authority. United States v. Mead Corp., 533 U.S. 218, 226–27 (2001). The bid for adjudicatory deference is constantly being litigated: as recently as March 18, 2020, the Federal Circuit held that "even if § 315(c) [of the Patent Act] were ambiguous—which it is not—we would conclude in the alternative that on appeal the PTO's interpretation . . . is not deserving either of Chevron or Skidmore deference," reaffirming that Congress did not delegate substantive rulemaking authority to the agency. Facebook, Inc. v. Windy City Innovations, LLC, 2020 U.S. App. LEXIS 8522, at *67 (Fed. Cir. Mar. 18, 2020).

statutory definition of active ingredient fails to capture the complexities and nuances incident to novel therapeutics.

This paper begins with Section I introducing patent term extension, the FDA regulatory approval process, and the interplay between the two. Section II explores the current, albeit limited, case law and interpretation of the relevant statutory provisions pertaining to patent term extension and active ingredients for purposes of PTE. Section III describes in detail the paradigmatic shift we are observing in the types of therapeutics that have been approved by the FDA. This section will also describe how this shift will impact our understanding of incentivizing innovation, in addition to how it will impact regulatory procedures surrounding PTE. Section IV addresses suggestions for updating the current patent term extension and active ingredient framework, while also suggesting how inventors and patent drafters can operate in the current case law and statutory structure before concluding.

I
THE TUG-OF-WAR: PATENT TERM EXTENSION (PTE) AND THE UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL PROCESS

Patent term extension (PTE) is a means for an inventor to recover the portion of her patent term during the regulatory review process when she could not effectively practice her invention. Before describing PTE and the FDA regulatory process in more detail, it is important to remember an essential factor of the interplay between drug approval and patent term: it can take several years for a drug to be approved and to reach market, yet the patent protecting the drug or therapeutic may have been filed years earlier. The patent may have been filed at a time when the drug was still being developed, but before it was tested and approved and, thus, before it was ready to enter the market. As a result, the proverbial patent term clock would have been ticking well before the drug or therapeutic could be approved and, thus, enter the market.

A. Patent Term Extension and 35 U.S.C. § 156

The provisions governing patent term restoration/extension are found in 35 U.S.C. § 156 (Extension of patent term) of the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman").[4] Patent term extension does not apply broadly for all types of all patents: it only applies to patents covering human drug products, medical devices, food additives, color additives, and animal drug

[4] 35 U.S.C. § 156 (2018).

products.[5] A patent in one of the prescribed areas of protection, regardless of whether it claims a product, method, or method of manufacture, according to the statute, "shall" receive an extension on its term provided that 1) the patent term has not expired prior to the application for extension having been submitted,[6] 2) the patent term has not been extended previously,[7] and 3) the application is submitted in accordance with several additional procedural requirements.[8] These requirements include the identity of the approved product and the federal statute under which regulatory review occurred,[9] the identity of the patent for which extension is being sought,[10] a brief description of activities undertaken by the applicant during the applicable regulatory review period,[11] and other information used for determining the eligibility of the patent for extension[12] or that the Director may require.[13]

The option to extend a patent term is not *carte blanche* for the inventor to unfairly extend her patent term indefinitely. Section 156 contains provisions on calculating periods of regulatory review[14] for products that are new drugs, antibiotics, or human biological products;[15] food additives and color additives;[16] medical devices;[17] animal drugs;[18] and veterinary biological products.[19] In each of these situations, the total period of extension may not exceed five years.[20]

Furthermore, § 156(c)(3) states an important exception to term extension: the total patent term cannot exceed 14 years after the product's approval date, and if it does, that product is not eligible for patent term extension.[21] This is a statutory

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[5] *Id.* §§ 156(a), (f).
[6] *Id.* § 156(a)(1).
[7] *Id.* § 156(a)(2).
[8] *Id.* § 156(a)(3).
[9] *Id.* § 156(d)(1)(A).
[10] *Id.* § 156(d)(1)(B).
[11] *Id.* § 156(d)(1)(D).
[12] *Id.* § 156(d)(1)(E).
[13] *Id.*
[14] *Id.* § 156(g).
[15] *Id.* § 156(g)(1).
[16] *Id.* § 156(g)(2).
[17] *Id.* § 156(g)(3).
[18] *Id.* § 156(g)(4).
[19] *Id.* § 156(g)(5); Note that each of the foregoing, with the exception of the provision in § 156(g)(1), lies beyond the scope of clinical therapeutics and will not be covered further in this Note.
[20] *Id.* § 156(g)(6)(A)–(B).
[21] *Id.* § 156(c)(3); *Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program*, FDA, https://www.fda.gov/drugs/cder-small-business-industry-assistance-

protection to ensure that the inventor is not extending her term well beyond the normal twenty-year term of protection. It is important to note that both the 14 year total and the five-year cap apply together: that is, if 14 years from the approval date is a shorter period than a five-year period added after the patent expires, the earlier of the two dates, here the 14 years from the approval date, is the maximum extension permitted. This also applies if the five-year total cap ends earlier than 14 years after the approval date.[22]

Taken together, the determination that a patent is eligible for extension may be made by the Director solely by what is contained in the application for extension.[23] If the application is eligible under § 156(a)(1) and compliant with the application content requirements found in §156(d)(1)–(4), then the extension shall be granted for a term prescribed in § 156(c).[24] Section 156(b) governs rights derived from extended patents and will be addressed fully in Section II.

B. The Patent Term Extension Regulations: 37 C.F.R., Subpart F and "Active Ingredients"

The relevant regulations interpreting the patent term extension statute can be found in 37 C.F.R., Subpart F—Adjustment and Extension of Patent Term, sections 1.710–1.791.[25] Many of the regulations in this section cover important procedural requirements related to a PTE application, including its contents (section 1.740) and the duty of disclosure in patent term extension proceedings (section 1.765). The regulations in sections 1.775–1.779 cover how to calculate the term extension for all products covered by PTE (including human drugs, antibiotic drugs, or human biological products;[26] food additives or color additives;[27] medical devices;[28] animal drug products;[29] and veterinary biological products[30]).

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sbia/small-business-assistance-frequently-asked-questions-patent-term-restoration-program (last visited Mar. 15, 2020).

[22] § 156(c); *Frequently Asked Questions*, *supra* note 21.

[23] 35 U.S.C. § 156(e)(1).

[24] *Id.*

[25] 37 C.F.R. §§ 1.701–1.791 (2020). Note that §§ 1.701–1.705 covers patent term adjustment (PTA), which deals with delay during examination at the USPTO. PTA is covered by 35 U.S.C. § 154. Together PTA and PTE are the two mechanisms for recovering term time that may be "lost" due to either agency or regulatory delay.

[26] *Id.* § 1.775.

[27] *Id.* § 1.776.

[28] *Id.* § 1.777.

[29] *Id.* § 1.778.

[30] *Id.* § 1.779.

Section 1.710—Patents Subject to the Extension of Patent Term includes two important and relevant provisions. The first, section 1.710(b), sets forth the language in § 156(f)(2) defining the term "active ingredient."[31] The second, section 1.710(a), states that "[a] patent is eligible for extension of the patent term if the patent claims a product as defined in paragraph (b) of this section, either alone or in combination with other ingredients that read on a composition that received permission for commercial marketing or use, or a method of using such a product, or a method of manufacturing such a product . . ."[32] There are two important requirements included in this subsection: 1) the patent must claim the product (i.e., the "active ingredient" as defined in § 156(f)(2) and section 1.170(b)); and 2) that claimed product must read on a composition that received permission for commercial marketing or use. Taken together, the two subparts of the regulation mean that a patent is eligible for extension if it claims a product (i.e., "active ingredient") that has received permission for commercial marketing or use (i.e., FDA approval).

Section 1.720 also provides an essential interpretation of the statute, setting forth the conditions for extension of the patent term.[33] First, the patent must claim a product or method of using or manufacturing the product as defined in section 1.710.[34] Second, the term of the patent must not have been previously extended (except for an extension issued pursuant to sections 1.701, 1.760, or 1.790).[35] Third, an application must be submitted in compliance with section 1.740.[36] Fourth and finally, the product must have been subject to a regulatory review period prior to its commercial marketing or use,[37] and the product must have actually received permission for commercial marketing or use.[38] Importantly, the permission for the commercial marketing or use of the product must be the *first* received permission for the commercial marketing or use under the provision of law that the regulatory review occurred.[39] No other patent term can have been extended for the same

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[31] 35 U.S.C. § 156(f)(2); 37 C.F.R. § 1.710(b).
[32] 37 C.F.R. § 1.710(a).
[33] *Id.* § 1.720.
[34] *Id.* § 1.720(a).
[35] *Id.* § 1.720(b).
[36] *Id.* § 1.720(c).
[37] *Id.* § 1.720(d).
[38] *Id.* § 1.720(e).
[39] *Id.* § 1.720(e)(1).

regulatory review period for the product.[40] There are also additional procedural requirements.[41]

C. A Brief Primer on the United States Food and Drug Administration (FDA) Regulatory Approval Process

The United States Food and Drug Administration (FDA) describes a five-step Drug Development Process that begins with Discovery and Development (Step 1), where research for new drugs begins in the laboratory setting.[42] During this stage, basic research is performed, compounds are identified, and potential future clinical applications may begin to take shape.[43] This represents the earliest stages of research, and many of the potentially interesting therapeutics that are studied do not make it past this stage.

Step 2 focuses on preclinical research. At this point, potential drugs undergo testing, both in the laboratory and in animal models, with the aim of elucidating information about the safety of the compounds; if the compound has high levels of toxicity, for example, it will not be a viable lead compound for further development into a potential therapeutic.[44] This stage is also the point when researchers submit an Investigational New Drug (IND) application to the FDA, which includes important information regarding testing in humans, the hallmark of Step 3.[45]

Step 3 focuses on clinical research. During this stage, drugs are tested on actual persons, and the outputs are safety and efficacy.[46] In other words, the clinical research has to show that the candidate therapeutic is safe and that it works in the way it is supposed to work. The clinical testing phase includes Phase I trials, which are studies of approximately 20–80 healthy volunteers focusing on the safety and

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[40] *Id.* § 1.720(h).

[41] *See id.* § 1.720(f)–(g). For further information on additional procedural requirements, as well as relevant case law for many of the rules and regulations surrounding patent term extension, see MPEP, Chapter 2700 (9th ed. Jan. 2018).

[42] *The Drug Development Process*, FDA, https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process (last visited Mar. 15, 2020); *U.S. Food and Drug Administration Drug Approval Process*, FDA, https://www.fda.gov/media/82381/download (last visited Mar. 15, 2020).

[43] *Step 1: Discovery and Development*, FDA, https://www.fda.gov/patients/drug-development-process/step-1-discovery-and-development (last visited Mar. 15, 2020).

[44] *Step 2: Preclinical Research*, FDA, https://www.fda.gov/patients/drug-development-process/step-2-preclinical-research (last visited Mar. 15, 2020).

[45] *Id.*

[46] *Step 3: Clinical Research*, FDA, https://www.fda.gov/patients/drug-development-process/step-3-clinical-research (last visited Mar. 15, 2020).

side effects of the compound of interest.[47] Phase II trials are larger and focus instead on efficacy.[48] The main goal of a Phase II study is to collect data to determine whether there is a difference in the treatment of affected individuals given the treatment and affected individuals who are administered a placebo.[49] Phase III studies are even larger than Phase II trials, often containing thousands of patients.[50] These studies focus on understanding safety and efficacy in more detail while studying different populations (e.g., different ages) and appropriate dosages.[51]

Once the data are collected, the process moves onto Stage 4, which is FDA review.[52] During this phase, the New Drug Application (NDA), containing all the data collected from the animal and human testing, pharmacological information, and manufacturing information, is filed by the investigators and reviewed by the FDA. The FDA considers information pertaining to proper labeling and inspects drug manufacturing facilities during this stage. Importantly, it is at this point where "regulatory delay" becomes an important factor relative to patent term and where inventors can "lose" part of their patent term. At this point, the application can be approved, or a response letter may be issued requesting more information or changes to the application. The IND and NDA periods, together, comprise the "regulatory review period" that the patent term extension statute uses as the basis for calculating the length of the extension of the patent term.[53] Finally, during Step 5: post-

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[47] *Id.*

[48] *Id.*

[49] *Id.*

[50] *Id.*

[51] *Id.*

[52] *Step 4: FDA Drug Review*, FDA, https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review (last visited Mar. 15, 2020).

[53] 35 U.S.C. § 156(g); Note that multiple INDs and NDAs can serve as the basis for multiple PTE applications. Although this lies outside the scope of this Note, this is an important practical consideration for applications for and grants of patent term extension. In short, if more than one NDA is approved on the same day, it appears that there may be more than one first received permission for commercial marketing under section 156(a)(5)(A). Often a product is covered by more than one patent, and INDs and NDAs can also cover more than one patent. As a result, the possibility emerges where an applicant can mix-and-match regulatory review periods for a particular product or patent. For example, if a product is covered by three patents and those patents are covered by two INDs (A and B) and two NDAs (C and D), it could be possible for the applicant to allege four regulatory review periods, as long as C and D were approved on the same day. The result is period 1: AC, period 2: AD, period 3: BC, and period 4: BD. Although an inventor cannot receive more than one extension on the same patent, § 156 (a)(2), there is nothing in the statute about more than one PTE per *product*. Furthermore, the regulations envision such a setup in 37 C.F.R. section 1.785 (Multiple applications for extension of term of the same patent or of different patents for the same regulatory review period for a product). Importantly, the regulation sets forth

marketing safety monitoring, all drugs and devices are regularly monitored by the FDA for safety.[54] This monitoring usually takes place through the submission of safety reports from drug manufacturers to the FDA.

In summary, and for the purposes of this paper, there are two important takeaways with regards to the FDA approval process. First, the process for approval by the FDA is neither quick nor speedy; in fact, the average time to receive approval for a new drug is twelve years.[55] This fact alone underscores why inventors feel PTE is an essential incentive to continue innovating in the space of therapeutics that require regulatory approval. Second, the drug development process clearly illustrates the tension between the patent system and the regulatory approval process, which will be explored further in the following subsection.

D. The Intersection (and Challenges) Between the Patent System and FDA Regulatory Approval

Generally speaking, a drug producer will be unable to market her drug until it is approved, which comes at the end of Step 4, described in the previous subsection. The important, innovative, and influential work that inventors will want to protect with a patent, however, begins much earlier, often even as early as Step 1. The time from the filing of the patent until the end of Step 4, then, represents a time when the inventor is unable to market her drug. This is the precise time that PTE aims to recover.[56]

A hypothetical example clearly illustrates the concept, and it is not difficult to see that the extension of the term may not (and in fact, almost certainly *will* not) recover all of the time lost to regulatory review. Suppose that an inventor files a patent two years after discovering a potential compound, but immediately before entering Step 2 of the drug development stage, which focuses on preclinical research (see Figure 1). The patent clock begins to run, and the twenty-year term has begun, even though the inventor cannot yet begin to practice (i.e., market) her invention as a clinical therapeutic. At this stage, all the inventor can do is exclude others from

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procedural requirements for selecting the final patent to receive the PTE grant, but it does not discuss the possibility of having more than one first permitted commercial marketing and *different* regulatory review periods for the same patent or product.

[54] *FDA Post-Market Drug Safety Monitoring*, FDA, https://www.fda.gov/patients/drug-development-process/step-5-fda-post-market-drug-safety-monitoring (last visited Mar. 15, 2020).

[55] Gail A. van Norman, *Drugs, Devices, and the FDA: Part I: An Overview of Approval Process for Drugs*, 1 JACC: BASIC TO TRANSLATIONAL SCI. 170, 170 (Apr. 2016).

[56] Note that PTE does not recover the Step 1–Step 4 time, but just the time lost to regulatory delay, per section 156 and the promulgated regulations.

practicing the invention, but she can neither sell nor market the drug. Suppose, again, that the regulatory review period takes twelve years, and that the inventor, as a result, is unable to practice her invention for 14 years after the patent term has begun (that is, Steps 2 through 4 in the FDA approval process take 14 years total). The inventor has a remaining six years on her patent term. This hardly seems a fair compensation in light of the twenty-year patent term that an inventor may expect at the outset of filing a patent. Even in this situation, though, the inventor can only recover up to the shorter of five years total extension or 14 years after the approval date of the therapeutic.[57]

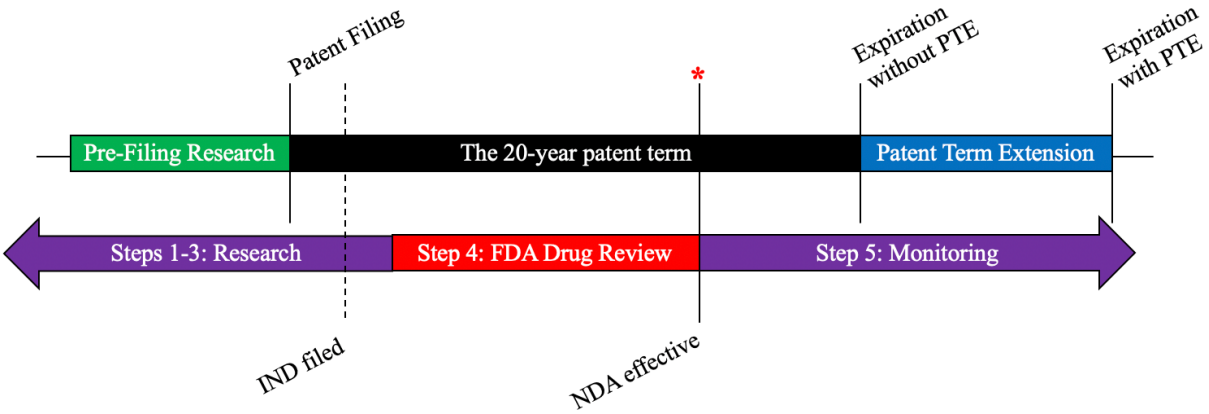

FIGURE 1: A Comparison of the Patent Term and the FDA Drug Approval Process. This example illustrates how the FDA approval process of a drug affects the patent term. In this example, the inventor cannot market her drug until the NDA is effective, which is marked by a red asterisk. The inventor may have filed the patent many years before (at some stage during the research process); this filing will have started the 20-year patent term clock. Patent term extension serves as a way to recover a portion of the term when the inventor could not market her invention because it was not yet approved. In particular, the period of recovery is based on the regulatory review period, or the period from when the IND is effective until the NDA is approved. Note: the times here are approximate and are not drawn to scale, particularly with regards to Steps 1–3, which can last many years before FDA drug review (Step 4) begins. The top bar represents the patent term, and the bottom bar represents the FDA regulatory process.

The statutory framework, interpreted in the context of the FDA approvals process, sheds important light on the balance at play between the goals of patent law (i.e., promoting, and then protecting, innovation) and the mandates and goals of regulatory approvals (i.e., promotion of public health and safety and ensuring that pharmaceutical products are safe and effective before being marketed and sold). It is not clear that the incentives on either side win: although the full patent term may be truncated as a result of the regulatory review process, the patent term extension statute allows for the recovery of only some of that term. On the other hand, the

[57] 35 U.S.C. § 156(g)(6).

regulatory process is allowed to proceed without external pressure from inventors who, in the absence of the statute, may otherwise feel that there is little reason to innovate in this particular space because of the perceived decreased in patent term.

II
PHARMACEUTICAL ACTIVE INGREDIENTS, *PFIZER V. DR. REDDY'S*, AND 35 U.S.C. § 156

Section 156(f)(2) defines a "drug product" as the "active ingredient of . . . a new drug, antibiotic drug, or human biological product . . . or a new animal drug or veterinary biological product . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient."[58] The importance

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[58] *Id.* §§ 156(f)(2)(A)–(B). It should be noted that the terms "drug," "antibiotic drug," and "human biological product" are used as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, *et seq.*) and in the Public Health Service Act (42 U.S.C. § 201, *et seq.*).

The term "drug" is defined in 21 U.S.C. § 321(g)(1) as follows:

> (1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

The term "antibiotic drug" is defined in 21 U.S.C. § 321(jj) as follows:

> The term "antibiotic drug" means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

The term "biological product" is defined in 42 U.S.C. § 262(i)(1) as follows:

> (1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic

and relative limitations of this definition become apparent when considering the limited applicable case law in this area, § 156(b) of the PTE statute, and the changing nature of therapeutics (See Section III).

Under § 156(b), patent rights during the extended period apply, in the case of product patents, to any use approved for the product,[59] for method patents, only to any use claimed by the patent and approved for the product,[60] and for method of manufacture patents, only to the method of manufacturing as used to make the approved product.[61] Of particular interest to active ingredients and novel therapeutics is § 156(b)(1), pertaining to product patents, which includes extension for only the approved product.[62] An analysis of the statute shows that the approved product, under § 156(f)(1)(A) is defined, for purposes of the statute, as a "drug product."[63] Under § 156(f)(2), a "drug product" is "the active ingredient of . . . a new drug, antibiotic drug, or human biological product . . . or a new animal drug or veterinary biological product . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient."[64] Therefore, patent term extension for a drug product only covers the approved active ingredient. Although "active ingredient" is not directly defined, the fact that it "includ[es] any salt or ester,"[65] implies that the statutory framework is constructed primarily for application to chemical compounds and active ingredients that are chemically based. As clinical therapeutics evolve and cell-based and gene therapy-based therapeutics continue to play an increasingly important role in clinical treatment, the definition of "active ingredient" will need to be expanded, or at the very least, adjusted. Right now, the statutory definition that focuses on chemical formulations simply does not provide enough definitional coverage to clearly elucidate what is or will be considered an "active ingredient" for purposes of patent term extension.

Interpretations of the statute in case law have provided limited guidance in terms of applying this framework outside of the context of chemical compounds. A leading case in the area of patent term extension and active ingredient interpretation

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compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

[59] 35 U.S.C. § 156(b)(1).

[60] *Id.* § 156(b)(2).

[61] *Id.* § 156(b)(3)(A); § 156(b)(3)(B) includes a separate requirement that the product must have been subject to a regulatory review period as described in § 156(g)(1), (4), and (5).

[62] *Id.* §156(b)(1).

[63] *Id.* § 156(f)(1)(A).

[64] *Id.* § 156(f)(2).

[65] *Id.* § 156(f).

is *Pfizer, Inc. v. Dr. Reddy's Laboratories, Ltd*.[66] In this case, the United States Court of Appeals for the Federal Circuit asked whether patent term extension applies to all salts of a molecule covered by the patent or only to the particular salt covered by the patent. The majority held that PTE applies to all salts because of the provision in § 156(f) that states that the active ingredient, "includ[es] any salt . . . of the active ingredient."[67]

Pfizer held a patent (Patent No. 4,572,909; the '909 patent) claiming "certain dihydropyridine compounds and their acid additional salts," including amlodipine and its salts.[68] Importantly, Pfizer had obtained federal registration on a drug product with amlodipine (a dihydropyridine compound) as the active ingredient, but only as the besylate salt formulation.[69] Dr. Reddy's Laboratories, a producer of generics, filed a new drug application that would permit them to market the amlodipine maleate formulation of the drug.[70] Interestingly, Dr. Reddy's conceded that the '909 patent covered both amlodipine besylate and amlodipine maleate, but argued that the patent term extension only covered amlodipine besylate because that was what Pfizer had pursued in its regulatory proceedings due to the ease of tableting that particular formulation.[71]

The Court determined that the active ingredient for purposes of patent term extension was amlodipine, and therefore, it did not matter whether it was administered as the besylate or maleate salt,[72] particularly in light of the provision in § 156(f) that states that active ingredients include salts and esters of the active ingredient. As a result, the term extension for the '909 patent could not be limited only to the besylate formulation, and Dr. Reddy's could not produce the maleate version of the drug during the extended period of protection.[73] However, in a dissenting opinion, Judge Mayer emphasized that the majority inappropriately excluded § 156(a)(4) from its interpretation, which provides that eligibility for patent term extension requires that the product must "ha[ve] been subject to a regulatory review period before its commercial marketing or use."[74] In the dissent's view, this means that the only product eligible for patent term extension was amlodipine

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[66] Pfizer, Inc. v. Dr. Reddy's Labs., Ltd., 359 F.3d 1361 (Fed. Cir. 2004).
[67] *Id.* at 1366–67; 35 U.S.C. § 156(f).
[68] *Pfizer*, 359 F.3d at 1363.
[69] *Id.*
[70] *Id.* at 1364.
[71] *Id.* at 1363–64.
[72] *Id.* at 1366.
[73] *See id.* at 1366–67.
[74] *Id.* at 1367 (Mayer, J., dissenting); 35 U.S.C. § 156(a)(4).

besylate and neither amlodipine alone nor amlodipine maleate; after all, neither amlodipine alone nor amlodipine maleate were subject to regulatory review. The dissent would have Dr. Reddy's Laboratories beginning to produce amlodipine maleate during the extension that Pfizer had received and would consider the extension as covering amlodipine besylate alone.

The debate between the majority and dissenting opinions in this case illustrates the potential real-world and market effects of defining an active ingredient in one way or another. Although there may be no difference in treatment, efficacy, administration, or formulation with differing active ingredient salts (in *Dr. Reddy's*, between amlodipine maleate and amlodipine besylate), restricting the active ingredient definition would permit competitors to potentially alter (and impinge upon) the inventor's ability to exclude. Under the dissent's approach, incentives for drug development could begin to suffer. Inventors could be placed in a squeeze between losing portions of the patent term to regulatory review when they cannot market their yet-to-be approved drug, and having their term extension eroded by competitors who are able to begin production and marketing on an equivalent—albeit slightly different—formulation before the full extended term has elapsed. The majority opinion, on the other hand, is more patentee-friendly in that it permits a patent holder to claim exclusivity, in some way, over variants of the same active ingredient, rather than in only one specified chemical compound.

Dr. Reddy's has played an important role in interpreting the active ingredient provision of § 156, and the case remains good law, but its interpretation remains limited to therapeutics that are comprised of chemical compounds. In addition to *Dr. Reddy's*, there has been a string of other cases that are relevant to the interpretation of "product" and "active ingredient" for purposes of PTE. In *Ortho-McNeil Pharmaceutical v. Lupin Pharmaceuticals*,[75] the Federal Circuit held that the approval of an enantiomer[76] qualifies as the first permitted commercial marketing or

[75] Ortho-McNeil Pharm. v. Lupin Pharms., 603 F.3d 1377 (Fed. Cir. 2010).

[76] Enantiomers are pairs of molecules that are mirror images of each other. The traditional example to explain enantiomers are left and right hands—they are mirror images of each other and cannot be superimposed. Different enantiomers of the same molecule can have vastly different clinical effects. Thalidomide, a drug that was used to treat morning sickness in pregnant women, resulted in 10,000 infants born with limb malformation. *See generally Molecule of the Week Archive: Thalidomide*, AM. CHEMICAL SOC'Y (Sept. 1, 2014), https://www.acs.org/content/acs/en/molecule-of-the-week/archive/t/thalidomide.html. The culprit was determined to be only one of the two enantiomers. Blaschke, Kraft, Fickentscher & Köhler, *Chromatographic Separation of Racemic Thalidomide and Teratogenic Activity of Its Enantiomers*, 29 ARZNEIMITTELFORSCHUNG 1640 (1979). Additional research has come out that illustrates that the enantiomers interconvert in vivo, suggesting that the enantiomeric explanation

use of the product when the racemate[77] had been previously approved. The underlying rationale is that the enantiomer is a different drug product than the racemic mixture and, thus, it required its own regulatory approval before marketing and use.[78] In *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*,[79] the Federal Circuit held that claims to a metabolite were not eligible for patent term extension because the metabolite was not part of the active ingredient that is present in the formulation administered to the patient.[80] Taken together, these cases illustrate that a salt or ester of an active ingredient is eligible for patent term extension, a metabolite is not, and an enantiomer is, at least in cases where the racemic mixture has already received approval. While these are all important developments in the law, none provides instructive guidance for dealing with therapeutics that are not chemically based.

An additional case, *PhotoCure ASA v. Kappos*[81] may, however, be of limited instructive value in considering how to deal with the active ingredient problem. The Federal Circuit held that "product," for purposes of patent term extension, means the product subject to regulatory approval, not the active ingredient of the formulation.[82] Under this approach, then, it may be important to understand the approved product rather than what may be an "active ingredient." Interestingly, the approved product often *is* the active ingredient, and even in cases of complex therapeutics that are not chemically based, this distinction may still prove insufficient. Taken together with the previously discussed case law, however, the application to and coverage of these cases do not cover novel therapeutics that are not comprised of chemical compounds.

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for limb malformation is possibly more complex than previously thought. Etsuko Tokunaga, Takeshi Yamamoto, Emi Ito & Norio Shibata, *Understanding the Thalidomide Chirality in Biological Processes by the Self-Disproportionation of Enantiomers*, 8 NATURE SCI. REPS., Article Number 17131 (2018).

[77] A racemate is a mixture that contains both enantiomers, or mirror-image, non-superimposable molecules. To continue the "hand example," a racemic mixture of hands would contain both right hands and left hands. *See supra* note 76.

[78] *Ortho-McNeil Pharm.*, 603 F.3d 1381.

[79] Hoechst-Roussel Pharms., Inc. v. Lehman, 109 F.3d 756 (Fed. Cir. 1997).

[80] *Id.* at 759 n.3 (stating that the patent term extension defines "product" as "active ingredient" of a drug that receives FDA approval, and that for purposes of patent term extension, this particular active ingredient must be present in the drug when it is administered to the patient).

[81] PhotoCure ASA v. Kappos, 603 F.3d 1372 (Fed. Cir. 2010).

[82] *Id.* at 1376–77.

The developed caselaw thus ultimately remains limited at best and inapplicable at worst.[83]

III
CHANGING THERAPEUTICS

As Section II described and established, the current case law and statutory interpretation frameworks do not factor in the myriad advances in technology and therapeutics that have been developed in recent years. In short, the current framework for determining the active ingredient of a pharmaceutical or therapeutic product for purposes of patent term extension is not easily applied beyond chemical compounds and salt formulations. Yet, there are many novel, exciting, and valuable therapies focused on cellular and gene therapy-based products that involve genetic engineering and patient-tailored formulations.[84]

A. Active Ingredients in Currently Approved Cellular and Gene-Based Therapeutics

To begin to understand how patent term extension can be calculated for "active ingredients" of cellular and gene-based therapies, it is first important to ask what the active ingredients of those treatments are according to the FDA and those marketing these products. In other words, why does the current framework not apply to these therapeutics, and how *might* it apply? It is only then that we can begin to understand how to develop a more applicable framework.

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[83] There is an additional case in this area of jurisprudence that tackles similar themes, although it was issued prior to any of the cases discussed in text. In *Glaxo Operations UK Ltd. v. Quigg*, the Court held that a patentee was entitled to a grant of patent term extension for an ester of a compound which was therapeutically active and effective when orally administered even though two of the salt formulations of the compound had already been approved by the FDA. Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392 (Fed. Cir. 1990). Relying on the plain language of the statute, the Court focused on the fact that the formulation in question was an ester, and "product"/"active ingredient" in § 156 of the statute includes esters.

[84] Personalized medicine is a growing area of clinical therapeutics. Sunil Mathur & Joseph Sutton, *Personalized Medicine Could Transform Healthcare*, 7 BIOMEDICAL REPS., 3, 3 (2017). In some sense, personalized medicine is fueling (or at least contributing to) the active ingredient problem—as treatments for individual patients become more patient-specific and patient-tailored, a treatment for the same disease or condition can take on different genetic, molecular, and compositional characteristics that make them harder to define as a homogenous genus.

The FDA currently has seventeen approved cellular and gene therapy-based products,[85] which pales in comparison to the 20,000+ FDA products approved for marketing, nearly all of which contain chemical compounds as active ingredients.[86] Remarkably, eight of the sixteen approved cellular and gene-therapy based products are for cord blood.[87] Cord blood, or blood that has been isolated from an umbilical cord, is a rich source of stem cells. Stem cells have a high degree of plasticity, meaning that, under appropriate conditions, they can be transformed into many types of cells in the body and thus, have a high potential for reparative and therapeutic benefit. In particular, cord blood is especially valuable for patients suffering from various types of blood cancers.[88] Cord blood can be used for "immunologic reconstitution," which is the establishment of a new population of healthy and non-cancerous blood cells and blood components in the previously affected patient.

In the particular case of the cord blood products, the active ingredient of the formulation is listed as hematopoietic progenitor cells expressing CD34 (CD34+ cells).[89] In other words, the active ingredient is a stem cell (i.e., a full cell) that expresses a particular protein on its surface. Although this may sound specific to the non-specialist, there is an important consideration to be made regarding CD34: it is found on *all* hematopoietic stem cells,[90] meaning that it is not as specific an identifier as one may perhaps expect. At this point, a comparison to a chemical compound is in order: for chemically based therapeutics, the active ingredient is comprised of a homogenous mixture of synthesized or isolated compound. There is, or should be, nothing more, and nothing less. In the case of cellular therapeutics, this is not the

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[85] *Approved Cellular and Gene Therapy Products*, FDA, https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products (last visited Mar. 16, 2020).

[86] *Id.*; *Fact Sheet: FDA at a Glance*, FDA, https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance (last visited Mar. 16, 2020).

[87] *Approved Cellular and Gene Therapy Products*, *supra* note 85.

[88] *See, e.g.*, Justyna Ogonek, Mateja Kralj Juric, Sakhila Ghimire, Pavankumar Reddy Varanasi, Ernst Holler, Hildegard Greinix & Eva Weissinger, *Immune Reconstitution after Allogenic Hematopoietic Stem Cell Transplantation*, 7 FRONTIERS IN IMMUNOLOGY, 1 (2016).

[89] FDA-approved products in this group are Allocord, Ducord, Clevecord, Hemacord, Cord Blood (Clinimmune Labs), Lifesouth Cord Blood, and Bloodworks Cord Blood. *Approved Cellular and Gene Therapy Products*, *supra* note 85.

[90] CD34 is a glycophosphoprotein that is expressed on the surface of early-stage developmental cells (i.e., stem cells) that will develop and differentiate into the various types of cells that comprise blood. It is unsurprising, then, that it is found in cord blood, since cord blood is rich in stem cells that are capable of constituting the entire complement of blood (e.g., red blood cells, white blood cells, etc.); *see, e.g.*, D.S. Krause, M.J. Fackler, C.I. Civin & W.S. May, *CD34: Structure, Biology, and Clinical Utility*, 87 BLOOD, 1 (1996).

case. In fact, some of the therapeutics are comprised of complex, heterogeneous mixtures, or are comprised of more than one "active ingredient" or component, which will be illustrated in the following discussion.

1. Autologous and Allogenic Cell-Based Therapeutics

The remaining seventeen FDA approved cellular and gene therapy-based products can be grouped into several classes. The first class contains products with listed active ingredients that contain autologous cells, or cells that have been harvested from the patient and will be readministered to the same patient after undergoing some modification or reprogramming. Interestingly, and in almost all cases, the FDA-listed active ingredients are *lists* rather than *individual components*. As the examples will illustrate, this immediately calls into question the applicability of the "active ingredient" definition in § 156 to these types of therapies.

Matrix-applied characterized autologous cultured chondrocytes (MACI)[91] have been approved for cartilage repairs and defects of the knee. The active ingredient is listed as 1) autologous cultured chondrocytes (collagen-producing cells harvested from, and then readministered to, the patient), and 2) porcine (i.e., derived from a pig) Type I/III collagen. The patient's own cells are embedded on a collagen matrix (the porcine collagen), which is then implanted into the patient's knee.[92] The patient's cartilage cells regenerate on the matrix and repair tissue that may have been damaged by injury or another condition.[93]

Also belonging to this class is Laviv (Azficel-T), which has been approved for the improvement of the appearance of moderate to severe nasolabial fold wrinkles (i.e., the wrinkles/folds that extend from the bottom of the nose to the corners of the mouth, commonly referred to as smile lines) in adults, and interestingly, an active ingredient is not listed.[94] Instead, the FDA filing notes that it includes autologous skin cells.[95] This class also contains Provenge, a treatment for prostate cancer. The active ingredient of Provenge is autologous peripheral blood

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[91] *See The MACI Story*, MACI, https://www.maci.com/healthcare-professionals/the-maci-story/index.html (last visited Mar. 16, 2020).

[92] *How MACI Works*, MACI, https://www.maci.com/patients/how-maci-works/the-maci-procedure.html?gclid=EAIaIQobChMIgLCfn9765wIVAT0MCh0CBQWZEAAYASABEgJdxPD_BwE (last visited Mar. 16, 2020).

[93] *Id.*

[94] *Approved Cellular and Gene Therapy Products*, *supra* note 85.

[95] *Id.*

cells,[96] including a particular class of immune cells, called antigen presenting cells, as well as an immune cell activator.

A subset of this class includes Gintuit, a topical scaffold application for use in mucogingival (i.e., oral) wound treatment. The active ingredient is listed as allogenic keratinocytes, allogenic dermal fibroblasts, and bovine Type I collagen. Although the cells in this formulation are allogenic, meaning that they are isolated from a compatible donor, instead of autologous, meaning they are isolated from the patient directly, Gintuit still falls into the class of cell-based therapeutics.

This class also contains Yescarta® and Kymriah™, the two chimeric antigen receptor T- cell (CAR T-cells) treatments. T-cells are a particular type of immune cell that are primarily responsible for mediating our bodies' responses against foreign "invaders," including bacteria, viruses, and even self-cells that have begun to exhibit signs and patterns of becoming pre-cancerous. CAR T-cell treatments involve isolating a particular set of T-cells from a cancer patient, reprogramming the cells to target the cancerous cells, and then reintroducing the cells to the patient in the hopes that the reprogrammed cells specifically target the cancerous cells while leaving non-cancerous cells intact.[97]

The goal of CAR T-cell therapy is to treat cancer using a patient's own immune system.[98] Interestingly, both Yescarta® and Kymriah™ list an engineered T-cell as the active ingredient (axicabtagene ciloleucel for Yescarta® and

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[96] Peripheral blood is blood that is circulating through a living organism and that is not sequestered in the lymphatic system, spleen, liver, bone marrow, or other organ.

[97] *See, e.g.*, Androulla N. Miliotou & Lefkothea C. Papadopoulou, *CAR T-cell Therapy: A New Era in Cancer Immunotherapy*, 19 CURRENT PHARM. BIOTECHNOLOGY, 5 (2018).

[98] Some have described CAR T-cell therapies as heralding a "new era" of cancer treatments. *See, e.g.*, *id.*; Rimjhim Mohanty, Chitran Roy Chowdhury, Soloman Arega, Prakriti Sen, Pooja Ganguly & Niladri Ganguly, *CAR T Cell Therapy: A New Era for Cancer Treatment*, 42 ONCOLOGY REPS., 2183, 2183 (2019). In a CAR T-cell therapy, a patient's T lymphocytes, a class of immune cells (e.g., white blood cells) that are responsible for detecting and destroying foreign invaders, are reprogramed to target cancerous cells. Interestingly, T-cells can also play a role in detecting internal invaders (i.e., cells that are no longer growing and dividing properly—cancer cells). In a CAR T-cell therapy, T-cells are engineered to express a chimeric antigen receptor (CAR). A CAR is a surface receptor that has been engineered to recognize and target the previously described "internal invaders" (i.e., cancer cells), while leaving normally growing and reproducing cells intact. The process involves isolating the cells from the patient, reprogramming them, growing them in cell culture in the lab, and readministering them to the patient. *NCI Dictionary of Cancer Terms: CAR T-cell Therapy*, NAT'L CANCER INST., https://www.cancer.gov/publications/dictionaries/cancer-terms/def/car-t-cell-therapy (last visited Mar. 16, 2020).

tisagenlecleucel for Kymriah™). Personalized treatments such as this are interesting to explore when considering active ingredients and patent term extension: if one developed ten CAR T-cell treatments for ten different patients, the cells in each of the ten treatments would be individualized to each patient and thus different from the other nine. How, then, can a treatment that is personalized to each patient have a consistent active ingredient? The patent term extension application for Yescarta® highlights this issue and provides an important case study in this area, emphasizing the need for the law to catch up quickly. Since the application has introduced particularly interesting issues with regards to active ingredients in the context of patent term extension, and given the importance of and recent attention given to CAR T-cell therapies, I will return to the Yescarta® patent term extension application and subsequent follow up as a case study in subsection III.C.

2. Gene Therapy-Based Therapeutics

Another class of approved therapeutics are gene therapy-based therapeutics. Gene therapy is any treatment that seeks to modify the recipient's DNA with the aim of ameliorating a genetic mutation or defect.[99] To more fully understand gene therapies, it is important to first understand the central dogma of molecular biology, which, in brief, states that the DNA in our cells contains information that is translated into a functional protein through an intermediate molecule called mRNA.[100] If there is a problem with the source material (the DNA), then there will likely be a problem with the functional protein. Gene therapy aims to correct this type of underlying issue by replacing the non-functional or malfunctioning DNA with the correct information.

This class of FDA approved products includes Imlygic and Andexxa. Imlygic, which lists talimogene laherparpvec (genetically modified attenuated Herpes

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[99] *What is Gene Therapy?*, NIH, https://ghr.nlm.nih.gov/primer/therapy/genetherapy (last visited Mar. 16, 2020).

[100] The central dogma of molecular biology, in its simplest formulation, describes information flow in a living organism. In the central dogma, DNA can be thought of as a blueprint that contains all the information required for an organism to grow, develop, and maintain itself. The information in DNA encodes proteins, which are the actual cellular components that carry out biochemical processes encoded in DNA. RNA acts as an intermediary molecule between DNA and proteins. The central dogma describes the flow of information from DNA to RNA to protein. It also states that information cannot be transferred from one protein to another protein or from a protein to DNA or RNA. This is (more or less and for purposes of this discussion) a one-way street. *See, e.g.*, Francis Crick, *Central Dogma of Molecular Biology*, 227 NATURE 561 (1970). The actual situation is far more complex than described here, but the central dogma represents a central tenet of molecular biology and information flow and transfer in living systems.

Simplex Virus-1) as its active ingredient, is an oncolytic viral therapy.[101] This means it uses tumor-targeted viruses to fight cancer. Andexxa, which lists its active ingredient as a genetically modified variant of human factor Xa, is a coagulation factor, which can be used in patients with blood-clotting disorders.[102] Interestingly, Luxturna, an adeno-associated virus (AAV) vector-based gene therapy used in the treatment of Leber congenital amaurosis,[103] does not have any listed active ingredient.

Gene therapy-based therapeutics are also beginning to test the applicability of our current active ingredient framework in ways different from cell-based therapeutics. An important factor with regards to gene therapies are their composition: a gene-based therapeutic must contain the genetic material that is to be delivered to the recipient as well as a vector, or carrier. In the case of gene therapies, the carrier is a viral capsid[104] which encapsulates the genetic material to be delivered to the recipient patient. As a result, an emerging question in this area is whether the active ingredient is or should be considered the genetic information alone or the genetic information coupled with the viral vector, which could be considered part of the delivery or drug formulation. Including the vector as part of the formulation, instead of as part of the active ingredient, could prevent controversy in terms of infringement, given that similar or identical vectors are often used for the administration of vastly different therapeutics with varying targets.[105]

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[101] Oncolytic viral therapies use lytic viruses that are targeted to tumors. Lytic viruses have the ability to lyse, or destroy, particular cells. *See, e.g.*, *Oncolytic Virus Therapy: Using Tumor-Targeting Viruses to Treat Cancer*, NAT'L CANCER INST., https://www.cancer.gov/news-events/cancer-currents-blog/2018/oncolytic-viruses-to-treat-cancer (last visited Mar. 16, 2020).

[102] *Approved Cellular and Gene Therapy Products*, *supra* note 85.

[103] Leber congenital amaurosis is an eye disorder that results in severe visual impairment from infancy. In addition to vision problems, patients with the disorder may have other vision problems including sensitivity to light, involuntary movement of the eyes, and extreme farsightedness. *Leber Congenital Amaurosis*, NIH, https://ghr.nlm.nih.gov/condition/leber-congenital-amaurosis (last visited Mar. 16, 2020).

[104] A viral capsid can be thought of as a shell comprised of proteins that surround and protect the viral genetic material. *See, e.g.*, W.H. Roos, I.L. Ivanovska, A. Evilevitch & G.J.L. Wuite, *Viral Capsids: Mechanical Characteristics, Genome Packing and Delivery Mechanisms*, 64 CELLULAR AND MOLECULAR LIFE SCIS. 1484, 1484 (2007).

[105] In January 2020, the FDA issued Draft Guidance for Industry entitled, *Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations*. In the guidance, the FDA proposes the following. First, two gene therapy products expressing different transgenes and having or using different vectors will be considered different drugs. Next, two gene therapy products expressing different transgenes but having or using the same vector will also be considered different drugs. Finally, gene therapy products having or using vectors from different

B. Defining the Active Ingredient Problem in Light of Current Therapeutics

The awkwardness and cumbersome nature of describing active ingredients as "engineered T-cells" or "allogenic keratinocytes, allogenic dermal fibroblasts, and bovine Type I collagen" suggests that the basic approach to identifying active ingredients in pharmaceutical formulations has already begun to show cracks. How can a full cell, which is far more complex than an individual chemical compound, and of which there is a great degree of cell-to-cell variability, be considered an "active ingredient"? In fact, a major benefit of chemical compound-based therapeutics is that, with appropriate manufacture, testing, and monitoring, patients can be certain that the active ingredient they receive when taking a particular therapeutic is identical from dose to dose: there is not, and in fact, *must* not be any variability from dose to dose or manufacture to manufacture. In other words, all patients receive the same exact treatment.

In cell-based therapies, however, this framework breaks down, and new approaches are needed. Many cell-based therapies are *centered* on the fact that each patient can be treated individually with the hopes of being able to specifically use the patient's reprogrammed cells to better combat the patient's ailment with decreased chances of negative side effects, tissue rejection, or unsuccessful treatment. CAR T-cell therapies, for example, operate under the assumption that the engineered T-cell will be *specific* to each patient and that these patient-specific cells will be reprogrammed in a particular way that results in a patient-targeted therapy. Thus, when describing active ingredients in cell-based therapeutics, a major difference is that the active ingredient will, at some level, *differ* from patient to patient. How then can an active ingredient be adequately described in light of this therapeutic heterogeneity?

This development in clinical therapeutics, broadly speaking, represents a paradigmatic shift in terms of how treatments are developed, administered, and considered successful; the shift does not, however, only affect clinicians and patients, but also inventors, regulators, manufacturers, and distributors.

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viral classes will be considered different drugs, even if they include the same transgene. Determinations of whether two vectors are the same will be made on a case-by-case basis, and minor differences in transgenes and vectors will not count as actual differences between two transgenes or two vectors. The FDA will receive comments on this proposed Guidance until July 28, 2020. *Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations*, FDA, (Jan. 2020) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/interpreting-sameness-gene-therapy-products-under-orphan-drug-regulations (last visited May 17, 2020).

C. The Yescarta® CAR T-Cell Therapy Case Study

The active ingredient problem is not imaginary; in fact, we are already seeing the challenges of active ingredient determinations in novel therapeutics. Recent PTE applications have revealed the challenges surrounding active ingredients in cell-based therapeutics and emphasize the need for a clearer framework as we move forward.

Yescarta®, a CAR T-cell cancer therapy used to treat B-cell lymphoma, is a prime example that illustrates the difficulties surrounding the definition of "active ingredient" in light of these novel cell-based therapies. The 2017 10-K SEC filing for Gilead, the parent company that produces Yescarta®,[106] included information that it had a pending patent term extension application for United States Patent Number 7,741,465 (the '465 Patent) filed to recover part of the patent term for Yescarta® that had been lost as a result of the regulatory review period.[107] A further investigation revealed that a patent term extension application for the '465 patent had initially been filed on December 14, 2017,[108] and the USPTO issued a "Requirement for Information" on April 3, 2018[109] requesting a further elaboration of the active ingredient of the CAR T-cell therapy. The letter also stated that an active ingredient had not yet been disclosed:

> Clearly, the lymphocytes differ from patient to patient since the drug is designed for each particular patient. Each patient will have its own unique lymphocyte cells therefore the active ingrediant [sic] cannot be the cells obtained from the patient. The antibody that is expressed on the cell surface is also not an active ingrediant [sic] because it has not been defined in the Application as filed.[110]

Although a Request for Information is not a binding regulation from the USPTO, it suggests that patent examiners are already struggling with exactly how

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[106] Gilead exclusively licenses a patent from Cabaret for Yescarta® in the oncology field. *Cabaret Biotech Files Lawsuit Against Gilead Over Yescarta Drug*, BLOOMBERGLAW (Sept. 16, 2019, 4:45 PM) https://news.bloomberglaw.com/pharma-and-life-sciences/cabaret-biotech-files-lawsuit-against-gilead-over-yescarta-drug.

[107] Gilead, Annual Report (Form 10-K), available at https://www.sec.gov/Archives/edgar/data/882095/000088209518000008/a2017form10-k.htm (2017).

[108] Application for Patent Term Extension, U.S. Patent No. 7,741,465 (filed Dec. 15, 2017).

[109] Requirement for information sent under 37 C.F.R. 1.750, U.S. Patent No. 7,741,465 (Apr. 3, 2018).

[110] *Id.*

to evaluate what active ingredients are or should be in the context of cellular therapeutics. Interestingly, this PTO communication also emphasizes two important concerns, one of which has been previously highlighted in this Note: 1) many of these therapeutics are not as homogenous in their composition as chemical-based therapeutics are, and the heterogeneous solution cannot be an active ingredient, and 2) additional aspects of the drug formulation that are not defined in the regulatory filings cannot be considered the active ingredient.

In a letter from the USPTO to the FDA dated August 7, 2018,[111] the USPTO further stated the challenge they faced:

> Applicant is seeking to extend [the '465 Patent] based on the regulatory review and approval of YESCARTA® (axicabtagene ciloleucel), where the product is comprised of non-disclosed components of lymphocytes, differs from patient to patient, and is produced with a non-disclosed vector type expressing non-disclosed chimeric DNA. Applicant has failed to provide a sufficient detailed disclosure of the product such that the Office can determine compliance with the eligibility requirements of 35 U.S.C. § 156, because no specific elements which form the product are disclosed. It is therefore concluded, in order to determine the rights that will be derived from the extension . . .
>
> [that] the information provided is not adequate for the Office to determine eligibility of YESCARTA® (axicabtagene ciloleucel).[112]

Despite the FDA's and applicant's response on June 19, 2018,[113] the USPTO remained unconvinced. In a seemingly unconventional response, the USPTO presented the FDA with information gathered "through its own diligence,"[114] including "the sequence and chemical identity of YESCARTA®" obtained "through information submitted to the World Health Organization to establish a generic name for YESCARTA® (axicabtagene ciloleucel) under the International Nonproprietary Name (INN) conventions . . ."[115] In short, the USPTO "requested that FDA confirm

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[111] Second letter to regulating agency to determine regulatory review period, U.S. Patent No. 7,741,465 (Aug. 7, 2018).

[112] *Id.*

[113] Transaction for FDA Determination of Regulatory Review Period, U.S. Patent No. 7,741,465 (June 19, 2019).

[114] Second letter to regulating agency, *supra* note 111.

[115] *Id.*; International Nonproprietary Name (INN) conventions are rules that, according to the World Health Organization (WHO), "facilitate the identification of pharmaceutical substances or

that the vector and sequence disclosed in the attached information from the World Health Organization does describe the approved YESCARTA® (axicabtagene ciloleucel) product."[116]

The FDA accepted this information and moved forward with its determination of the regulatory review period as required by § 156(d)(2)(A),[117] making a final regulatory review period determination, pursuant to notice and comment procedures,[118] on December 26, 2019.[119] As of May 17, 2020, no PTE had been granted for Yescarta®, but the process was fully underway, even despite its unconventional history and the novel situation it presented. In some sense, it appears that the question of a homogenous active ingredient was skirted in the communications between the USPTO and the FDA, as the USPTO provided to the FDA what it would consider appropriate for furthering the inter-agency communications for determining patent term extension. Although the situation has not been resolved (i.e., the PTE has not yet been granted), the above process provides important information on what concerns the USPTO has and how they may be overcome.

IV
POTENTIAL SOLUTIONS

Although the USPTO may have shed some light on what it accepts as appropriate information for fulfilling the requirements of 35 U.S.C. § 156, there are two important lessons to acknowledge. First, the Yescarta® case study represents a single data point, and further efforts to obtain PTE on cellular and gene-based therapeutics may be instructive in elucidating how the USPTO and the FDA may continue to navigate this new terrain. Second, just because the USPTO has provided a way forward, it does not preclude the possibility of additional, less challenging and novel paths forward for PTE on these novel classes of therapeutics. The remainder of this Note explores some of these potential paths forward, addressing the benefits and potential drawbacks associated with each.

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active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name." *Essential Medicines and Health Products: International Nonproprietary Names*, WHO, https://www.who.int/medicines/services/inn/en/ (last visited Mar. 16, 2020).

[116] Second letter to regulating agency, *supra* note 111.

[117] *Id.*; 35 U.S.C. § 156(d)(2)(A).

[118] Transaction for FDA Determination, *supra* note 113; Determination of Regulatory Review Period for Purposes of Patent Extension; YESCARTA, 84 Fed. Reg. 18,055 (Apr. 29, 2019).

[119] FDA Final Eligibility Letter, U.S. Patent No. 7,741,465 (Dec. 26, 2019).

A. Monoclonal Antibody-Based Therapeutics and the Sameness Analysis

Monoclonal antibody-based therapeutics are affected by many of the same challenges that affect cellular and gene-based therapies. For example, antibodies are more analogous to cellular and gene-therapies, in that they are, at least on a molecular scale, large and complex.[120] Furthermore, there have been challenges with defining the active ingredient[121] and how to determine whether such complex molecules are the "same" or "different."[122] Finally, clinical formulations may exhibit non-clinically relevant batch-to-batch variation that results in a slightly different antibody composition, but that, importantly, does not affect drug function or efficacy. A central question surrounding antibody-based treatments is what precisely counts as the "same" given the inherent variability between production batches and the lack of homogeneity within production batches.

In April 2014, the FDA issued a Guidance for Industry, entitled *Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations*.[123] In its Guidance, the FDA turned to the "sameness" analysis found in the FDA Orphan Drug regulations.[124] Under these regulations, an antibody-containing drug is the same as another antibody-containing drug if it "contains the same principal molecular structural features (but not necessarily all of the same structural features) and is intended for the same use as a previously approved drug . . . ."[125] An antibody-containing therapeutic is "different" from an approved antibody-containing therapeutic if it is either demonstrated that 1) it is chemically or structurally distinct from an approved orphan drug, or 2) it is "clinically superior" to the approved orphan

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[120] It is important to note an essential difference between antibodies and cellular and gene-based therapeutics: while antibodies are macromolecules, neither cellular therapeutics nor gene-based therapeutics are.

[121] *See* Malgotzata Kesik-Brodacka, *Progress in Biopharmaceutical Development*, 63 BIOTECHNOLOGY AND APPLIED BIOCHEMISTRY, 306, 306–07 (2018).

[122] *See id.*

[123] *Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations*, FDA (Apr. 2014) https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Interpreting-Sameness-of-Monoclonal-Antibody-Products-Under-the-Orphan-Drug-Regulations.pdf (last visited Mar. 16, 2020).

[124] *See Orphan Drug Regulations: Regulatory History*, FDA, https://www.fda.gov/industry/designating-orphan-product-drugs-and-biological-products/orphan-drug-regulations-regulatory-history (last visited Mar. 16, 2020).

[125] 21 C.F.R § 316.3(b)(14)(ii).

drug.[126] The sameness analysis focuses on two separate aspects of the therapeutic that are directly relevant to antibody-based therapeutics: structure and efficacy.

In its Guidance, the FDA acknowledges "diversity" that results from the antibody production process—something which is also seen particularly in cellular therapeutics—and states that, "[b]ecause of the many processes involved in generating antibody diversity, it is unlikely that independently derived monoclonal antibodies with the same antigen specificity will have identical . . . sequences."[127]

Currently, there is a "sameness analysis" for other types of drugs that is used for purposes of determining whether a drug is different from an approved orphan drug.[128]

- Two protein drugs are considered the same if the differences are due to post-translational events or minor differences in amino acid sequences (antibodies fit in this bin).
- Two polysaccharide drugs are considered the same if they have identical saccharide repeating units, even if there are a different number of repeating units.
- Two polynucleotide drugs are considered the same if they contain identical sequences of purine and pyrimidine bases bound to an identical sugar backbone.
- Vaccines for the same indication are considered the same unless the subsequent drug is clinically superior.

These classes illustrate an important point: none of them relies on the determination of an active ingredient that is chemically based. It then seems reasonable to consider developing a sameness analysis for cellular and gene-based therapies. For example, two CAR T-cell therapies could be considered the same because they are defined as an autologous treatment aimed at treating a particular

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[126] An orphan drug is a pharmaceutical that is commercially underdeveloped because it has limited potential for profitability. These drugs are often used for treatment in rare diseases. *See, e.g.*, *Designating an Orphan Product: Drugs and Biological Products*, FDA, https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products (last visited Mar. 16, 2020); *NCI Dictionary of Cancer Terms: Orphan Drug*, NAT'L CANCER INST., https://www.cancer.gov/publications/dictionaries/cancer-terms/def/orphan-drug (last visited Mar. 16, 2020). For more information on orphan drugs and their uses, see *List of FDA Orphan Drugs*, NIH, https://rarediseases.info.nih.gov/diseases/fda-orphan-drugs (last visited Mar. 16, 2020).

[127] *Interpreting Sameness of Monoclonal Antibody Products*, *supra* note 123, at 2–3.

[128] *Id.*

type of cancer. Another example could be that two cell-based therapies are considered the same because they contain the same types of cells targeted to fight the same disease, even if the cell has been programmed to be patient-specific. In the context of gene therapies, two therapeutics could be considered the same if they contain the same genetic material, targeting the same disease, enclosed in the same capsid. Or perhaps two gene therapies could be considered the same if they contain the same capsid and target the same underlying genetic condition.[129] What is important is not that a sameness analysis be developed here; in fact, developing a sameness analysis would require investigations and efforts that lie beyond the scope of this Note. Furthermore, just because two cells do the same thing does not necessarily mean they should be clinically defined as the "same." What should be the focus, however, is that a sameness analysis *could* be developed for cellular and gene therapies, and this could potentially help to solve the active ingredient problem.

B. FDA Guidance on Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use

A second FDA guidance, entitled *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use*,[130] issued in 2017, may also be relevant in solving the active ingredient problem. This Guidance focuses on the regulation and proper use of human cells and tissues, and it focuses on two standards: minimal manipulation and homologous use.

The concept of minimal manipulation will likely fail to be applicable in the current framework, since minimal manipulation has been defined to include various types of processing that do "not alter the relevant biological characteristics of cells or tissues."[131] That is precisely what is being done, to the benefit of the patient, in something like a CAR T-cell therapy or in any of the approved allogenic therapies.[132]

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[129] See *Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations*, *supra* note 105.

[130] *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use*, FDA (2017), https://www.fda.gov/media/124138/download (last visited Mar. 16, 2020).

[131] *Id.*

[132] Kazuo Yano, Alessondra T. Speidel & Masayuki Yamato, *Four Food and Drug Administration Draft Guidance Documents and the REGROW Act: A Litmus Test for Future Changes in Human Cell- and Tissue-Based Products Regulatory Policy in the United States?*, 12 J. TISSUE ENGINEERING & REGENERATIVE MED., 1579, 1581 (2018).

The concept of homologous use, however, could be extremely helpful. Homologous use for tissue products requires that the product repairs, reconstructs, replaces, or supplements the recipient's cells or tissues with tissue product that performs "*the same basic function or functions in the recipient as in the donor*"[133] (or presumably in the case of an autologous treatment, the same basic function or functions in the recipient after reintroduction of the modified tissue or cell). This standard, endorsed by the FDA in its guidance, could be particularly instrumental in ameliorating the active ingredient problem. A "homologous use" approach could be used, under which two cellular-based or gene-based therapeutics are the same if each "repair[s], reconstruct[s], replace[s], [or] supplement[s] . . . a recipient's cells or tissues . . . with [cells] that perform[] *the same basic function or functions in the recipient as in the donor*." [134] This overcomes the issue of defining the active ingredient for purposes of PTE; instead, the inquiry relies on whether two compared therapies perform the same basic function before and after donation or before and after isolation, modification, and reintroduction (in the case of autologous treatments).

There are, however, drawbacks to importing a "homologous use" standard from the FDA Guidance, because vastly different products could be used for similar treatments. This could lead to a definition that casts too broad a net and that ensnares too many unrelated products for purposes of PTE. This could confound some of the clear delineations that already exist surrounding various types of therapeutics and their clinical applications.

C. Proposed Statutory Changes

At the very least, § 156's definition of active ingredients is currently too narrow, only focusing on chemical compositions and salts and esters of those compositions. An additional mechanism for solving the active ingredient problem, and one that could incorporate some of the above-discussed solutions, is amending the statute to more clearly define "active ingredient" in light of the discussed novel cellular and gene-based therapeutics. "Amendment" in and of itself should not be viewed as a monolithic change to the statute; in fact, there are many paths the amendment could take, several of which are addressed below.

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[133] *Id.* at 1584 (emphasis added).
[134] *Id.* (emphasis added).

1. A New Framework for Cellular Therapeutics and Gene Therapies

First, the statute could be amended to adopt a novel definition or standard for active ingredients that applies to all novel cellular therapeutics and gene therapies. This amendment could incorporate the homologous use standard or a therapeutic-specific sameness analysis. Assuming that this approach to amending the statute keeps the current framework in place for chemically based compounds, clear lines of delineation could help direct particular therapies into particular bins. A caveat of this approach is that if different therapeutics have different treatments (real or perceived) of PTE, it could skew how a PTE applicant seeks to define her drug, and, in particularly extreme circumstances, could negatively affect particular areas of innovation. A more easily extended patent term for a cellular therapeutic could, for example, push innovation further into this realm, but there is also the concern that it could stifle innovation by increasing patent term unfairly for innovators. Determining the true effect would require an empirical analysis, but it is at least clear that the lever works both ways: if there is a particular innovative space that Congress feels *should* be incentivized, building in these sorts of incentives could lead to desired outcomes (e.g., more innovation surrounding novel cellular therapeutics as a result of favorable PTE treatment for these inventions).

2. Fixing the Problem Once and For All? Abolishing the Active Ingredient Approach for Novel Therapeutics

To this point, I have advocated what may seem like deliberate and careful changes to the statute and its interpretation that could help to ameliorate the active ingredient problem. The final suggestion is the most drastic, but, perhaps also the most promising in fixing the active ingredient problem—abolishing the concept of active ingredient altogether with regards to more complex, non-chemical-compound-based therapeutics. Here I advocate an entirely novel framework that leaves intact the current PTE structure for chemically based therapeutics but that introduces a completely separate and novel approach for cellular and gene therapy-based products.

I propose using "treatment complex protocols" instead of "active ingredients" for purposes of defining what is protected by PTE for cellular and gene-based therapeutics. A treatment complex protocol, or TCP, would be a complete compilation of the input (e.g., cells isolated from a patient), the precise modification or reprogramming that is performed (e.g., laboratory and clinical procedures), and the output (e.g., the reprogrammed autologous cells that are introduced back into the patient, and perhaps even the method of reintroduction). Instead of focusing on an active ingredient, the analysis would focus on a holistic review of what the treatment

is and how it is developed for the particular patient. Two products would then be the same if they had the same input, the same modifications, and the same output, while not being concerned with the heterologous nature of the actual therapeutic contents, or with the result of treatment (since clinical results cannot always be anticipated in all patients *a priori*).

The applicability of this framework is broad and alleviates challenges related to the definition of active ingredient for complex, non-chemically based pharmacological products. Not only would it apply to cellular-based therapeutics, but it would also apply to gene therapies, with a slight tweak: input of the TCP could be considered a combination of the DNA, the capsid carrier, and the target of treatment (i.e., the disease).

The concept of TCPs are beneficial for another reason: it seems that the current system largely works for chemically based therapeutics, but does not for more molecularly complex products. Considering TCPs only for these more complex products will allow the current setup to remain for chemical formulations; after all, there is little reason to reinvent the wheel, at least in circumstances where the wheel functions sufficiently well.

One potential challenge to TCPs relates to the administrability of a fairly complex system such as this. That is, how would inputs, modifications, and outputs be defined? Although fully fleshing out definitions would be the work of the legislature, the FDA, and USPTO, I make the following recommendations:

- Inputs should be defined as the starting material used in the treatment. For example, in MACI, described in Section III, the input would be chondrocytes isolated from the patient and the porcine collagen matrix.
- Modifications should be defined as what happens to the input in order to take that starting material and transform it into the clinical therapeutic (i.e., the output). In the case of MACI, the modifications would, generally speaking, be the specific conditions of culturing the chondrocytes and the procedure that incorporates them into the matrix that will eventually be implanted in the patient's knee.
- Outputs should be defined as the modified input (i.e., what will be used in the clinical treatment and what will be administered to the patient). In the case of MACI, the output would be the matrix-applied cultured chondrocytes that could be reintroduced into the patient for repairing cartilaginous injuries or defects of the knee. It is also possible to consider the method of administration of treatment as part of the output

(e.g., arthroscopic surgery to implant matrix-applied autologous cultured chondrocytes).

TCPs would solve the active ingredient problem of PTE in at least three major ways. First, TCPs completely do away with having to consider what the active ingredient of a complex formulation is while providing a useful comparative mechanism to describe the product. Since determining the active ingredient of a complex therapeutic could be unworkable, this is an attractive benefit of TCPs and could lessen the administrative burden attached to deciphering what the active ingredient is in a cellular or gene therapy formulation and what precisely is protected for purposes of PTE.

Second, TCPs are better tailored to the complexities of cellular and gene-based therapeutics. As I argue above, the current PTE active ingredient determination falls immensely short with cellular and gene therapy-based products. With this change, PTE would not be granted on an "active ingredient" but on a "TCP," which represents the input, modification, and output. Admittedly, a TCP, in practice, could be a lengthy written document that could invite questions of similarities and differences between TCPs in later litigation, but, at least as a first pass, it would be a better way of handling complex therapeutics for purposes of PTE. Concerns of additional paperwork and related administrative challenges could be addressed through instituting procedural requirements (for example, TCPs cannot be longer than 1,500 words).

Finally, TCPs could have an effect on encouraging innovation in the area of complex therapeutics. Although there does not seem to be any shortage of innovation in this space at this time, it is possible that uncertainties surrounding PTE for cell-based and gene-based therapies could chill innovation: if an inventor is not sure whether she can capitalize on that extension without immense administrative burdens, she may decide it is not worth it at all to develop a therapeutic that may only have five years of protection after the product is approved and can enter the market.

In summary, it seems as though a bifurcated approach to PTE may have arrived with the advent of non-chemically based therapeutics. TCPs could represent the way forward and could provide for a smoother path to PTE for cell-based and gene-based therapies.

D. Patent Claim Drafting

Statutory changes require immense effort on the part of advocates, buy-in from Congressional representatives and senators, and sufficient political will and

motivation to make the change. As a result, these changes happen slowly and (perhaps) methodically. In the meantime, what can inventors and PTE applicants do to ensure they capture the extended term with relative ease, similar to their peers developing chemically based drugs?

The answer may lie in patent claim drafting. Accurate description of an active ingredient in both a patent application and a regulatory filing is extremely important. In fact, under 37 C.F.R. Section 1.710, a patent up for PTE must claim the product/active ingredient, and the claimed product must read on a composition that received permission for commercial marketing or use.[135] As a result, careful claim drafting may clear the path for PTE in what may be an otherwise challenging landscape. Unfortunately, however, this still does not solve the core problem of what precisely the active ingredient is in a cell-based or gene therapy-based formulation. In fact, the Yescarta® case study suggests that even careful claim drafting can still lead to inter-agency strife as each party attempts to parse out precisely what the active ingredient is in a complex formulation. Interestingly, TCPs would help to overcome this challenge, in addition to those spelled out in the previous subsection.

In short, legislative change takes time and immense effort, but sometimes technology cannot wait for the law to change. Thus, careful claiming of the approved (or more likely, to-be-approved product) could increase the likelihood of a patent term extension grant because patent term extension only extends to approved products (i.e., the active ingredient), and approved uses of the product that must be claimed in the patent under the statute and regulations.

CONCLUSION

We are currently experiencing an immense growth in the types and number of novel therapeutics that are available, and the legal framework that describes drug products as compound-based is beginning to show cracks. Cellular and gene therapy-based therapeutics are changing the clinical landscape and are playing an increased role in treatment and management of diseases.

In short, a new framework, i.e., one that is not rooted in the world of chemical-based therapeutics, is needed to ensure adequate patent term protection and to appropriately incentivize innovation. The regulatory process is an essential part of developing and approving a drug, but if we are not careful, the measures put in place for safety and efficacy may erode the very incentives that encourage innovation in the first instance.

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[135] 37 C.F.R. §§ 1.710, 1.720.