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NOTES

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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 and only online 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.

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NEW YORK UNIVERSITY

JOURNAL OF INTELLECTUAL PROPERTY AND ENTERTAINMENT LAW

PREFACE

Intellectual property law continually grapples with questions of economic incentives and public policy more broadly. The authors in this issue challenge readers to consider the relationship between intellectual property and the general public in both the law's substance and procedure.

First, Professor Srividhya Ragavan directly questions the purported public interest aims in patent law, arguing that a trend towards a rights-based approach undermines the public benefit. Professor Ragavan's insights reach the fundamental bases of American patent law, including incentives' effects on innovation. Later in the issue, Doran Satanove poignantly displays the importance of Professor Ragavan's inquiry, as he looks to patent law for solutions to the existing medical research landscape and improvement of the general welfare.

Beyond the substance and underlying philosophy of patent law, procedure in patent examination and litigation raises significant questions about the law's relationship to the public and the common good. Professor Joanna Shepherd examines inter partes review in relation to Hatch-Waxman litigation, and seeks to strike a better balance between encouraging innovation and providing the public with access to generic drugs. Our interview with Anne Hassett, Executive Director of NYU's Engelberg Center on Innovation Law & Policy, complements Professor Shepherd's research by providing an overview of the latest conversations and debates involving jury trials in patent cases. At the heart of this discourse lies a concern about the competence of lay jurors in matters of science and patent law.

Finally, Nicole Lieberman expands the issue's scope by offering a compelling argument for reexamining the copyright infringement analysis in music cases. Her recommendations would bear a significant, immediate impact on the music industry, opening new creative avenues for artists and expanding the general public's music library.

I hope that you find this issue stimulating and informative. On behalf of the 2016-2017 *JIPEL* board, thank you for reading.

Sincerely,

Thomas C. Merante
Editor-in-Chief
NYU Journal of Intellectual Property & Entertainment Law

NEW YORK UNIVERSITY

JOURNAL OF INTELLECTUAL PROPERTY AND ENTERTAINMENT LAW

VOLUME 6 FALL 2016 NUMBER 1

INTERVIEW
TRIAL BY JURY OF PATENT CASES SYMPOSIUM

ANNE HASSETT & JULIAN PYMENTO

In this interview, Anne Hassett, the Executive Director of NYU School of Law's Engelberg Center on Innovation Law & Policy, discusses her experience conceiving and bringing to fruition the Trial by Jury of Patent Cases Symposium. The conference was co-hosted by NYU School of Law's Engelberg Center and the Civil Jury Project on September 30, 2016. Distinguished federal jurists, academics, and practitioners discussed whether the 7th Amendment guarantees a right to a jury trial in patent cases and analyzed, in presentations and roundtable discussions, current issues and trends in how patent jury trials are conducted. Given her rich and varied background in the patent law sphere, Anne Hassett also discusses her own views on the matters brought up in the symposium, including the observations and experiences that shape her perspective on patent jury trials.

Anne Hassett joined NYU School of Law's Engelberg Center on Innovation Law and Policy following a distinguished 30-year career as a trial lawyer in complex business litigation, and in particular, intellectual property litigation. Anne most recently was a senior partner in the patent litigation practice at Goodwin Procter LLP and previously a partner in the intellectual property practice at Kirkland & Ellis LLP. Anne received her BS summa cum laude in chemistry from SUNY Albany, AM in chemistry from Harvard University, and JD cum laude from U.C. Hastings College of the Law. Anne was editor-in-chief of the Hastings Law Review and named to the Order of the Coif and the Thurston Society. She is currently President-Elect and serves on the board of the New York Intellectual Property Law Association (NYIPLA), is Board Liaison to the NYIPLA's Legislative Action Committee, and is a member of the Honorable William C. Conner Inn of Court. Anne is Of Counsel to Amster, Rothstein, & Ebenstein, LLP. Anne is also a research scholar at NYU School of Law, with a particular interest in how diversity enhances innovation.

Julian Pymento is a student at NYU School of Law graduating in May 2017 and the Senior Notes Editor for the NYU Journal of Intellectual Property and Entertainment Law. Julian has focused his studies on patent law and was co-chair for the Patent Committee of the Intellectual Property and Entertainment Law Society. Julian received both his BS and MS in Electrical Engineering from New York University Polytechnic School of Engineering and a minor in Business Studies from New York University Stern School of Business.

* * *

JP: Thank you for taking the time to speak with us. Before we get your views on the symposium topics, what was the inspiration behind Trial by Jury of Patent Cases, the choice of panels, and the order in which they were presented?

AH: So it was multivariate as you might expect. The question of what is the best way to handle deciding patent issues in litigation is something that is of interest to several of us at the Center – for me, because I've spent many years working in the area, and in particular, Rochelle Dreyfuss, and Jeanne Fromer are also involved in looking at some of these issues, and other people as well. This issue has been of interest to us for a while, and then the Civil Jury Project approached us about doing a program on why civil jury trials are decreasing and what can be done about it. So it seemed like a good opportunity for the two of us to put our resources together. Just to give you a sense of how long it takes to get these things, we probably started talking to

the Civil Jury Project, maybe February or March 2016 for a program that was at the end of September.

As for the choice of panels – when the Engelberg Center co-directors talked about the proposal to do this program, the co-directors had a number of ideas about what were important components of the question. And so a lot of the framing of the panel questions came out of that brainstorming discussion that we had. And then we proposed to Steve Susman of the Civil Jury Project our ideas for the framework. He and I also met to talk about what kinds of questions we thought would be of value, and then we put all this together and came out with a plan to fundamentally look at the issue of the 7th Amendment and whether there is, in fact, a constitutional right to jury trial in patent cases – and what parts of a jury trial might be protected by that right and which parts might not be.

And so we concluded that question should probably be the starting point of the conference, so everybody would have the same point of reference and be on the same page as we moved forward with the discussion for the day. So then we went to the judges' perspective, because judges are the practical funnel for everything in patent litigation. Getting their perspective on things was, I think, the next most important thing. And then after that we had the scholars look at their issues, and then the practitioners. Why the practitioners last? Because they're the ones who have to deal with all the attitudes of everybody else, including their clients. So it seemed reasonable for them to have a very broad sense of the overall discussion to frame what they were going to talk about and to be responding, in part, to issues that earlier panels were questioning. So the program would follow an iterative thought process.

JP: A theme throughout the symposium was an increased onus on advocates and judges to make jury trials more efficient, for example, by appointing an impartial technical advisor to the judge and allowing technological demonstrations in the courtroom. Do you agree with this assessment or do you find any potential problems with these approaches?

AH: I'm going to quibble with the question a bit here. I'm not sure that I agree that the two things you cite in the question, impartial technical advisers to the judge and technological demonstrations in the courtroom, necessarily make trials more efficient. I agree that there certainly is an interest in making trials more efficient. That is, using your time wisely and making sure that, as an advocate, you're pushing the arguments that really matter and not just every argument that's in the briefs. You want to make sure that those points are in the record to be dealt with but you may not want to present every single one of those at trial because that likely won't make things more

efficient. Efficiency is about how much time you use and how well you use it, whereas avoiding confusion and making it possible for the trier of fact to understand what is important may take more time.

For example, I think technological demonstrations in the courtroom can be very useful for the trier of fact, and depending on what the advocates propose to do, I would say most cases, you get permission to present them. I'm not aware of there being a time when we wanted to use, in my own trial practice, either through demonstration or a video, a way to explain and show how the technology worked, where it was not allowed.

Now the question of an impartial technical adviser to the judge – that is fraught with a lot of issues, so let's talk a little bit about that. It may or may not make the case more efficient. Under the Federal Rules of Evidence, an impartial technical advisor can be appointed, and some judges, in fact, routinely have someone appointed who is available to them to use as a technical advisor. But most of the judges that I know and that I've spoken to at the program are very careful to say that they only want to use a technical advisor as someone to whom they could go and say, "Is this how that wiring diagram should be understood?" Or if I'm writing my opinion, and I'm putting in a picture of something from the patent that I am using to help explain my decision, "Technically, is this correct? Are the electrical ions are flowing in the right direction?" I think most judges are very reluctant and wary of using technical advisors in a fashion that says, "Tell me what the answer is" to how the law applies to the technological facts. Having technical advisors can make the judge's decision making process more efficient. But it mostly means that there is a greater opportunity for the judge to be able to really evaluate what he or she is hearing from the experts on either side because these are advocates. Advocates can sometime emphasize certain things over others because that is better for their case. But advocacy can sometimes give a view of things that needs to be balanced, and judges' access to their own technical advisors can be a way for these impartial technical advisors to be very useful.

So I agree that there are a number of techniques that advocates can use to make the process more helpful, but whether they make it more efficient is another question.

JP: Certain courts such as the Eastern District of Texas and the District of Delaware already have the lion's share of patent jury trials. Might those advances in courtroom procedure lend further to the problem of forum shopping in the jurisdictions which do adopt such measures? And if so, is this downside outweighed by the benefits?

AH: Well, there are some assumptions implicit in the question, so let's just talk about those first. One is a concern about having a lot of cases go to only a few courts – is that a bad thing? That's actually an interesting question. One might say, and I'm not taking a position – just pointing out the assumptions built in there – that courts that handle a lot of these cases may have a better system to manage them. They can have a faster learning curve for any particular case, and they may be bolder, sitting down with the advocates and saying, "You know, let me tell you X, Y, and Z." They may be able to give more direction to the parties than other judges who don't have as many of these cases and may feel more intimidated by the process. So you have to think about this, whether in chambers with the parties before the case gets to trial, whether more experienced judges in patent-savvy courts are better able to signal to the parties news they may not want to hear, but news that they need to know so they can reconsider their assessments of whether they should go to trial, and what they should present at trial. So what I'm trying to focus on is that judges who handle patent cases infrequently, and I think this was suggested by some of the judges on the panel, can be somewhat intimidated by the process, just as jurors are going to be intimidated by the process because jurors only do this once. And the more you do it, the more comfortable you feel, and therefore, perhaps the more frank you may be in communicating things to the parties that they should know and should take into account. So that's some food for thought on the assumption in the question.

Why are people forum shopping? They are looking for a perceived advantage – whether it's true or not, whether they really have that advantage is another question. We don't have a lot of empirical data to back up these perceived advantages that people bank on when they are making these forum selections.

I think to the extent that any district court can develop more effective ways to get the cases ready for trial and to help the parties appreciate what arguments are better for them to move forward with than others, and to the extent that the court respects the technology and allows the parties to have an opportunity to present it, that's a very positive development. To my mind, such a court would make an excellent venue for a patent trial.

Of course, if the advocates want to do an animation or demonstration to explain the technology, it's on the parties to make it technically correct. Judges should be evaluating whether it should be permitted in terms of how helpful it may be for the jury, not on whether it might prolong the trial.

Just as an aside, there's a whole issue about demonstrations and animations, which can become very problematic in jury trials. You want your demonstration to be

in evidence in the jury room, and not just something that the jury sees in the court room and then doesn't have a chance to look at again. So you have to be very careful when you make these things to be sure that every piece of it is correct. And then, you want to be able to freeze a frame and say, "Okay, that's the document I want to introduce – that picture of that frozen frame – as an independent piece of evidence to go into record." The jury needs a way to have it during their deliberations, and that's a can of worms on how you to accomplish that.

Bottom line is you're never going to stop people from doing venue shopping. So really the issue is how we can make our courts the best at handling patent trials. And if people are picking a court because it's the best, I don't think that's bad.

JP: Shifting gears a little bit, in her opening address, the Honorable Judge O'Malley described herself as an unabashed believer in juries: a jury's competence, their good faith efforts, and their importance in patent trials. Taking all the speakers in sum, do you think that there was a majority dynamic in one direction or the other?

AH: I would say that the overwhelming dynamic, certainly from the judges, was that juries can do it. They can decide the issues they are presented with, and they can do it well. I would say this group was more pro-jury on the whole than you might have found twenty years ago, or even ten years ago, or that you may find among certain other judges who are not very pro-jury. One of the questions that Scott Hemphill asked the judge's panel was, "When you're sitting in a jury trial, do you agree with the juries and the results that they come to in the patent cases?" And what was interesting is that, at one level, the judges all said "Yes," but then they all kind of said, "You know, we don't listen the same way so it's not the same as if we were making the decision." So you have to recognize that there's a little bit of a tension there. They're saying, on one hand, that the juries get it right, but then that they didn't really listen with the same degree of scrutiny that they would have if they were at a bench trial.

Then I think there's another piece of this. They didn't come out explicitly and say this, but I think it's definitely a component that undergirds why judges these days are much more open to juries in patent cases: There is this a fear of the law becoming too elite. So if you have decisions about important things – and everybody I think agrees that what affects innovation is important to society – if you have those decisions being made by a smaller and smaller group of people who are the cognoscenti, the ones who "know," the law becomes very elite and removed from everybody else. I think that even though some people might say, "I'm not sure the juries always get it quite right," those same people might say they would rather have

the process involve the public than have it become the domain of just the experts. That's an attitude that I think is very strongly held these days.

The last thing I'll say is that one problem in evaluating what juries do is that it's kind of a black box. Judges, in their opinions at bench trials, have to explain their reasoning piece by piece by piece. But it is rare that jury verdicts break down how the jury has evaluated each piece of the case and so we don't necessarily have as good a read on their analysis.

JP: There were a number of statistics presented by the symposium participants, particularly from Professor Lemley, one of which showed that the number of jury trials in patent cases have risen since the 1970s. Among reasons given for this phenomenon are the trend shift of litigation conducted by IP boutiques to general practice firms and the 1982 formation of the Federal Circuit. Which way do you think these developments cut and to what extent do these explanations suffice?

AH: Certainly the number of patent cases tried to juries has changed tremendously. Kimberly Moore wrote a very interesting article, which is dated now, but contains a very good analysis for a certain period of time. One of things she points out is that in the late sixties and early seventies, the number of patent cases going to juries was two to five percent – something like that. Twenty years later, it was like fifty-two percent going to juries. That's a huge change. So the evidence, as you can see from the statistics we presented at the conference, shows that jury trials are more common than bench trials in patent cases. I don't think anyone has demonstrated empirically the "why."

I kind of lived through some of this change. When I came out of law school in 1985, I was interested in being a trial lawyer. Yes, I had a technical background, and a lot of people said I should do patent litigation. But I wasn't interested in it then because those cases rarely went to trial, certainly not jury trials, and jury trial were what I wanted to do. So I did other kinds of complex business litigation for almost fifteen years and got lots of jury trial experience. Then I had to try a criminal defense case for which we had to do present technical evidence – scientific evidence in a court. Long story short, that was my first opportunity, as a trial lawyer, to present scientific evidence to a jury and I decided, "Wow, that's really a lot of fun!" So I started looking around for how I could do that more. I knew it wouldn't come up come up more than once every fifteen years in the federal white collar criminal defense practice I was in at the time. I saw there are two places you could go to: product liability and patent litigation. That's how I decided switch to patent litigation. I went to a boutique patent practice firm and kind of knocked on the door and said,

"Would you take me in and teach me patent law?" There was already this phenomenon of general practice firms having identified how lucrative an IP practice could be and blending their IP teams with people having a lot of trial experience. The boutiques were also looking for people with trial experience because they could see this is what clients were now looking for.

By the time I was making this practice switch, the move to more patent jury trials was well underway. General practice firms had identified how much opportunity there was and started moving into this area and bringing in the focus of litigators, which was a very different perspective from what the predominantly prosecution-oriented lawyers who handled the boutique practice had. So my personal speculation is that the increase in jury trials in patent cases came because general practice firms identified IP practice as a kind of ore that could be mined, and brought the perspective that they had to treat these like regular trials. And quite honestly, from my talking to judges, it seems a lot of the judges thought, "Thank you!" When these cases were going to trial before that, many judges felt that the cases were just impossible to understand because it was very rare for people from the patent prosecution boutiques to be trying to make the technology and the law something that the average person could understand. They treated explanations to the judge like their explanations to the patent examiners at the USPTO. Many practitioners coming from the patent prosecution world didn't want juries because they figured, "It was hard enough to get the judge to understand. How do I get twelve jurors?" I don't know what to call that phenomenon. But honestly I think that's what happened. So I agree the trend shift does have a big impact. But why did that trend shift take place? I think it's because general practice firms were looking for places to expand, and not because we concluded that our system should have more jury trials in patent cases. It was more like general practice firms thought, "Here's an area of practice we can take up,' and then when litigation partners look at the cases, they applied their skills and that's what led to those changes. In my view, the formation of the Federal Circuit was not important to this trend shift.

JP: Jury trials may tend towards certain biases, for example, tilts toward the patentee and possibly pro-American companies versus foreign corporations. Is jury bias something that should be worried about?

AH: I think certain biases that really exist. The statistics seem to bear it out that if you compare judge bench trial resolutions versus jury trial resolutions in patent cases you find that, overall, patent holders tend to win more often before juries when they are the ones who bring the lawsuits. And why is that? There are a couple of factors. I think juries often feel like litigation is a tough process and so you're not

going to bring that case unless you're really sure you are right. And they give credibility to the party who brings the lawsuit, so there's that component. And actually what's interesting, if you look at the statistics that Kimberly Moore talks about in her article, when the alleged infringer brings the action through a declaratory judgment action, they tend to win more often before juries than judges, which credits the notion that jurors are biased in favor of the party that sues, inferring that if you take the time to go to court, you must really believe in the strength of your case.

There's a second component to juror bias: There is an evidentiary advantage to the patent holder in assessing patent validity. I think a lot of jurors believe the Patent Office does a good job and so they give the patentee credit for that. The presumption of validity and the high standard of clear and convincing evidence to overcome patent validity – that's a tough standard to meet! I think juries are impressed by those standards. And you can compare that with bench trials – the patentee-plaintiffs' win rate on bench trials tends to be higher than the alleged infringers' win rate – might be 53% to 47%, or something like that, whereas for jury trials, it's even higher: About 65% in favor of the patentee-plaintiffs. But the patentee win rate is lower in bench trials than in jury trials, and it's lower in a way that you cannot explain by anything other than bias differences. And so one thing I would infer is that this difference occurs in part because judges judge cases all the time. That's their business. I think that, with experience, judges are less intimidated by patent cases and become bolder in their willingness to conclude that the U.S Patent Office was wrong and the standard for invalidating a patent has been met, and because they have the opportunity to judge these types of cases over and over again, they get better at applying a standard of evidence. I think experienced judges are less overwhelmed by the standards of evidence they have to apply to technical facts. But jurors are only doing deciding a patent case once. And I think their lack of experience handling such cases makes it harder for them to say, "Sorry, the U.S. Patent Office was wrong when it granted this patent."

JP: Moving to the idea of specialization – by mere virtue of the existence of voir dire, isn't that a de facto "special" jury that may not be representative of their community? And if so, does that mean that the creation of "special" juries comprised of individuals deemed ordinarily skilled in the art is not too far flung?

AH: Well, there's a huge leap! It's a provocative question, but I don't think you literally mean a "special jury." There's a huge leap between a special jury of technical experts and the actual voir dire process. The actual voir dire process is "Okay, we're going to call in everybody from the venire and then figure out who among those people are the ones who we think cannot be impartial." You're not specializing in

anything except in the ability to be impartial: to not have any obvious prejudice in favor of one party or the other. Of course, a lot of prejudices we know we are not really getting at very well in the voir dire process. But voir dire is very different from selecting persons of ordinary skill in the art. That's like saying we're only going to have engineers, chemists, or coders, and nobody else, as jurors for any particular case. And it assumes that those "specialized" jurors lack biases about the technical field. They won't. There are attitudes and assumptions and biases about scientific matters, too, just as in other things. You can't expect that a "special jury" of microbiologists will be impartial on points in microbiology – you're going to find scientific biases apart from the evidentiary biases we discussed before. Some people will say, "Oh no, CRISPR method is the right way." Some people will say, "No, this other method is better." And so you're not necessarily getting a better set of decision makers. So that's a problem: The notion that, "Oh, just get these experts and they'll all be able to agree." You might find you have more disagreement among them because they have their own biases about science.

That being said, it certainly was common to have people experienced in a commercial field assist judges in 18th-century England. Let's say you came to the court in that era with an admiralty case. What was the judge going to do? He'd likely say, "I don't understand this stuff. Here's a bunch of folks who are admiralty experts. Go sort it out with them and come back and let me know what they figured out about these five things." So there's some logic to think that, at least in commercial cases, there may be value in letting the commercial community sort it out. But this is subject to the same concern, of course, that we spoke about earlier, which is letting elites make decisions and excluding the public from participating in those decisions when the public may be affected – I really don't want to do that.

So I'll say one more thing. This is a personal view. Since the America Invents Act was implemented, we have IPRs. You don't have to be involved in a district court litigation to file an IPR, but if you are involved in a court litigation and file an IPR in time, you may well find that the judge will grant a stay on the district court action, hoping the Patent Office [PTAB] will resolve the issue of patent validity. So that is de facto giving us something that I think people wouldn't swallow if we just proposed it flat out: Having the Patent Office resolve the validity issues, leaving infringement for the district courts. You could say, "Gee, that sounds like what those judges were doing in the admiralty situation, telling the experts to deal with these questions and come back with the answers." My personal view is that we ought to be looking more carefully at whether that division of issues is a good pro-innovation way for our system to function, perhaps to always have validity issues go back to a special court like the PTAB, and let the general public decide infringement issues – perhaps that's

the question that the society in general should be involved in. Whether that solves the concerns about elitism, I don't know. But I think it's something that's worth considering.

JP: So, as you mentioned, a highlight of PTAB proceedings is adjudication by specialized administrative law judges. Why may specialized judges be okay while specialized juries are not in district courts?

AH: Well, so if we just deal historically with how IPRs came to be part of the AIA, there was something called inter partes reexamination that the Patent Office had previously set up hoping to provide a forum for the people who fashioned and implemented the patent system to help make the decisions in reviewing validity. And that process wasn't being used very often. I think they analyzed a few reasons why it might have been infrequently used, and they really wanted to change that. That was a big reason why the AIA implemented the PTAB with IPRs and PGRs. There was a strong interest on the part of the people who were pushing that reform to make our system more like the European patent courts where none of these issues are jury issues. The PTAB brought in specialized judges to focus on questions of validity, which was what the Patent Office was really all about. And so, the goal was to bring in people to be judges and not examiners – you know their basic job function is very different – we could develop a system that would be more harmonious with the rest of the world. Whether it's the best solution, I can't say yet, but I think it offers a lot of advantages because it enable having technological experts judge patent validity and it allows the public to decide the questions of infringement and what innovation can go forward.

And I think one of the advantages of the way the PTAB is set up is that you have three judges, not just one, so there's an opportunity similar to the kind that happens in a jury, which is that people with different points of view can challenge each other. And I think that PTAB judges generally feel comfortable challenging each other, so that's a good thing. And in my view, it's better than a bench trial in district court where the poor judge – it's all on him or her. That can be very difficult. I think it's very difficult for a single person operating alone to get these decisions right. Willfulness – or questions of inequitable conduct – those might be jury issues along with infringement. So yes, I think it's something we should explore much more.

JP: On one side the 7th Amendment favors instituting jury trials for civil cases. However, on another side are practitioners, who prefer greater consistency in court outcomes, which is less feasible with jury trials. Is there a sense of whether one policy should weigh more heavily than the other?

AH: I'm going to interpret what you're saying to mean that, because bench trials produce opinions supported by fact and legal principles, we can better discern principles of law from them and apply them whereas jury verdicts – well, all we know is that's what the jury did. And what that jury verdict means for other cases, might be very hard to discern. So jury results provide less consistency in our understanding of the law and make it harder to advise your clients. Our conference did not explore the process that advocates go through to advise their clients before they decide to go forward with a jury trial – the legal and technical evaluations, the asymmetries of information, the estimations made for clients.

My personal view is that, because I care about the law, I'd like to encourage things that make the law more consistent and more apparent. The advantage of having judicial opinions is that it puts reasoning out there that can be studied and applied or criticized for failing to take into proper account facts or law, and it makes the law more apparent. Whether you are citizens – potential jurors – or judges, lawyers, or law students, everybody can look at that and try to understand it, which is not true with jury verdicts. In the case of juries, all you know is their decision; exactly what they relied on is very hard to appreciate. Even if you interview jurors afterwards, you're not necessarily getting anything that's very useful for the next case.

I suppose the benefit that, in the case of jury trials, post-trial motions may generate a post-trial opinion by the judge granting or denying the JMOL and therefore providing an analysis of why there is or is not enough to support a jury verdict, which would help explicate the principles that the judge views as important and relevant in that case. It's tough. I believe firmly in the notion that we don't want this to be a law of the elite. And yet, you want law that you can understand and apply, and that has consistency. So I guess I'm waffling but probably a little bit more in favor of having judicial decisions rather than black box jury verdicts.

JP: To close, during the symposium, an overarching theme was the dichotomy of patent exceptionalism and American exceptionalism. Patent exceptionalists argue that jury trials are inappropriate for patent cases because the issues are too complex and American exceptionalism stresses the importance of juries even in complex cases. With the passage of the AIA, PTAB proceedings, and other shifts in patent law, do you see the direction of our nation's patent law structure shifting towards one view or the other?

AH: Well, certainly if I look at the proposed patent reforms that are on the radar screen today, I don't see anything that is anti-jury. So I think they are all jury-neutral.

And actually in some ways, they are geared towards making patent cases fit the same standards that a lot of other litigations must meet, like the standards of *Iqbal* and *Twombly*: "Throw out that Form 18! You should be like everybody else, patent people!" And the judges, when they decided *eBay*, said to the patent bar, "Why should prevailing patentees always get injunctions? You should go make your injunction case like everybody prevailing party." So to a certain extent, there's actually a move against patent exceptionalism, and I think that's a good thing. Part of this is because I don't agree with the attitude that ordinary people cannot decide patent issues. They can, if you, as the advocate, present them the facts and the law in the right way. You have a big responsibility as advocates to understand, for decision makers, which components of law matter, which facts matter, and how you can present the facts so that the jurors get it visually and orally. Always, advocates need to present information so every juror has the opportunity to understand. I know it can be done because I've seen it happen. I believe that jurors can make these decisions so long as we advocates teach them the right way.

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DISRUPTING THE BALANCE: THE CONFLICT BETWEEN HATCH-WAXMAN AND INTER PARTES REVIEW

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Since the enactment of the America Invents Act, inter partes review has been a new pathway for challenging patents. This administrative proceeding at the Patent Trial and Appeal Board has had a pro-challenger bias. IPR proceedings apply a lower standard of proof than federal district courts, use the anti-patentee claim construction standard of broadest reasonable construction, and lack the Article III standing requirement of district court litigation. This Article explains how these differences create great uncertainty in pharmaceutical patents, and what could be done to restore the balance that was created in the Hatch-Waxman Act.

Pharmaceutical patents have their own alternative litigation pathways with the Hatch-Waxman Act, passed by Congress over three decades ago, and the recent Biologics Price Competition and Innovation Act. Both balance between stimulating innovation from brand companies who hold patents and facilitating market entry from generic companies who challenge the patents. Hatch-Waxman and BPCIA litigation occur in the federal district courts, which have significantly lower patent invalidation rates than IPR proceedings. The Article argues that this uncertainty in patent rights will harm pharmaceutical innovation by decreasing incentives. Pharmaceutical companies will not spend the billions of dollars needed to research, develop, and bring a drug to market if patent validity in IPR proceedings is uncertain. In the end, the author proposes several reforms for Congress to enact that can reduce the disparities between IPR proceedings and Hatch-Waxman litigation so the balance between patent holders and patent challengers is restored.

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INTRODUCTION

Inter partes review (IPR), a new pathway for challenging patents, is threatening the nature of competition in the pharmaceutical industry, drug innovation, and consumers' access to life-improving drugs. Since its creation under the America Invents Act (AIA) in 2012,[1] this new administrative proceeding has produced noticeably anti-patent results. Whereas patents challenged in district court are invalidated in less than 40% of cases,[2] and patents challenged in the administrative predecessors of IPR were invalidated in less than one-third of cases, IPRs have resulted in patent invalidations in a shocking 70% of cases.[3] Moreover, the IPR process has been exploited by entities that would never be granted standing in traditional patent litigation—hedge funds betting against a company, then filing an IPR challenge in hopes of crashing the stock and profiting from the bet.[4]

Unfortunately, in recent decisions, courts have recognized the anti-patentee bias of IPR, yet punted to Congress the job of amending the provisions. In *Cuozzo Speed Technologies v. Lee* (*Cuozzo*) in June 2016, the U.S. Supreme Court found

[1] Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

[2] *Cf.* PRICEWATERHOUSECOOPERS, 2016 PATENT LITIGATION STUDY: ARE WE AT AN INFLECTION POINT? 9 fig.11 (2016), https://www.pwc.com/us/en/forensic-services/publications/assets/2016-pwc-patent-litigation-study.pdf.

[3] U.S. PAT. & TRADEMARK OFF., PATENT TRIAL AND APPEAL BOARD UPDATE 10 (2016), https://www.uspto.gov/sites/default/files/documents/2016-6-30%20PTAB.pdf.

[4] *See* discussion *infra* Part V.

that an anti-patentee claim construction standard in IPR "increases the possibility that the examiner will find the claim too broad (and deny it),"[5] yet concluded that only Congress could mandate a specific standard.[6] Similarly, in *Merck & Cie v. Gnosis* in April 2016, the U.S. Court of Appeals for the Federal Circuit determined that an anti-patentee standard of review for IPR decisions "is seemingly inconsistent with the purpose and content of the AIA,"[7] yet decided that "the question is one for Congress."[8] On the standing issue, the Patent Trial and Appeal Board (PTAB) concluded in 2015 that, under the AIA language created by Congress, hedge funds cannot be excluded from IPR proceedings.[9]

Congress generally intended IPR to improve patent quality by providing a more efficient pathway to challenge patents of dubious quality. Because IPR is available for patents in any industry, for pharmaceutical patents, IPR offers an alternative to the litigation pathway that Congress specifically created over three decades ago in the Hatch-Waxman Act. With Hatch-Waxman, Congress sought to achieve a delicate balance between stimulating innovation from brand companies who hold patents and facilitating market entry from generic companies who challenge the patents. By all accounts, Hatch-Waxman has successfully achieved these goals. Generic drugs now account for 89% of drugs dispensed,[10] yet brand companies still invest significantly in R&D, which accounts for over 90% of the spending on the clinical trials necessary to bring new drugs to market.[11]

Unfortunately, IPR proceedings that culminate in a PTAB trial differ significantly from Hatch-Waxman litigation that occurs in federal district court. The PTAB applies a lower standard of proof for invalidity than do district courts in Hatch-Waxman litigation. It is also easier to meet the standard of proof in a PTAB trial because there is a more lenient claim construction standard and a substantially limited ability to amend patent claims. Moreover, on appeal, PTAB decisions in IPR proceedings are given more deference than lower district court decisions. Finally,

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[5] *See* Cuozzo Speed Tech. LLC v. Lee (*Cuozzo*), 136 S. Ct. 2131, 2145 (2016).

[6] *Id.* at 2144.

[7] *See* Merck & Cie v. Gnosis S.P.A., 820 F.3d 432 (Fed. Cir. 2016).

[8] *Id.* at 2 (majority opinion).

[9] *See* Coal. for Affordable Drugs VI LLC v. Celgene Corp. (*Celgene*), Nos. IPR2015-01092, IPR2015-01096, IPR2015-01102, IPR2015-01103 and IPR2015-01169, at 3 (P.T.A.B. Sept. 25, 2015). Though they may be excluded from appellate review under Article III.

[10] *See* IMS INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SPENDING IN THE U.S., A REVIEW OF 2015 AND OUTLOOK TO 2020, 46 (2016), http://www.imshealth.com/en/thought-leadership/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020#form.

[11] *See* PHRMA, 2016 PROFILE BIOPHARMACEUTICAL RESEARCH INDUSTRY 1, 35 (2016), http://phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf.

while patent challengers in district court must establish sufficient Article III standing, IPR proceedings do not have a standing requirement, allowing any member of the public other than the patent owner to initiate an IPR challenge. These inconsistencies have led to the significantly different patent invalidation rates in PTAB trials compared to rates in district court litigation.

It is imperative that Congress reduce the disparities between IPR proceedings and Hatch-Waxman litigation. The high patent invalidation rate in IPR proceedings creates significant uncertainty in pharmaceutical intellectual property rights. Uncertain patent rights will, in turn, lead to less innovation in the pharmaceutical industry. Drug companies will not spend the billions of dollars it typically costs to bring a new drug to market when they cannot be certain if the patents for that drug can withstand IPR proceedings that are clearly stacked against them. And if IPR causes drug innovation to decline, a significant body of research predicts that consumers' health outcomes will suffer as a result.

This Article proceeds as follows. Section II begins with a general discussion of the pharmaceutical market, explaining the nature of competition between brand and generic drugs and the importance of brand drug innovation. Section III explains the regulatory frameworks that Congress established to balance the interests of brand patent holders with generic patent challengers, focusing on the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act. Section IV describes administrative pathways available for patent challenges; it discusses both IPR's predecessors and the changes introduced with IPR under the AIA. Section V explains the critical differences between district court litigation in Hatch-Waxman litigation and IPR proceedings that give rise to the pro-challenger bias in IPR. Section VI proposes several reforms that Congress could institute to align IPR with Hatch-Waxman and restore the delicate balance between stimulating innovation and encouraging generic entry. Section VII concludes the Article.

I
UNDERSTANDING THE PHARMACEUTICAL MARKET

A. The Nature of Competition between Brand and Generic Drugs

Over the past several decades, the nature of competition in the pharmaceutical industry and the relative market shares of brand and generic companies have changed dramatically. The generic industry exploded after the 1984 Hatch-Waxman Act—discussed in greater detail in Section III—created various regulatory shortcuts and litigation incentives to spur the introduction of generic alternatives to brand name drugs. The generic industry was further assisted by drug substitution laws in

every state that allowed, or sometimes required, pharmacists to automatically substitute a generic equivalent drug when a patient presents a prescription for a brand drug. These regulatory changes have allowed generics to capture significant market share from brand companies. As shown in Figure 1, generics' market share has steadily increased from only 19% of drugs dispensed in 1984 to nearly 89% in 2015.

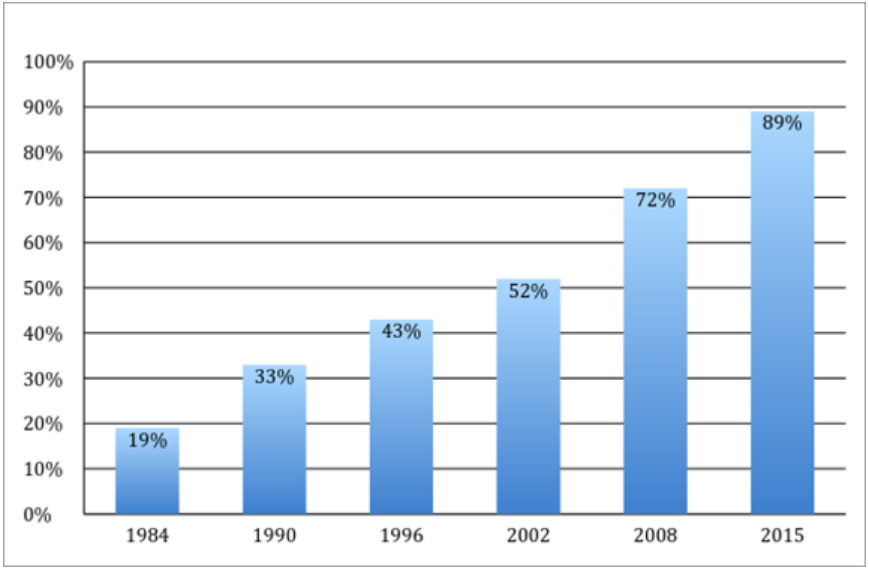

Figure 1: Growth in Generics' Share of Pharmaceutical Market[12]

The success of generic drugs can be attributed entirely to their lower prices. When a brand drug's patent expires, generics initially enter the market at a price that is, on average, 50% less than their branded counterpart.[13] As months pass and more generics enter the market, the generic price eventually drops to 80% of the pre-expiry brand drug's price. Generic companies are able to charge these lower prices while earning substantial profits because they face significantly lower costs than brand drug companies. In contrast to brand companies that spend an average of $2.6 billion on R&D and the FDA approval process, bringing a new generic drug to market costs

[12] *See* U.S. GOV'T ACCOUNTABILITY OFF. GAO-12-371R, DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE 2 (2012), http://www.gao.gov/assets/590/588064.pdf; *see also* IMS INSTITUTE FOR HEALTHCARE INFORMATICS, *supra* note 10, at 46; PHRMA, CHARTPACK: BIOPHARMACEUTICALS IN PERSPECTIVE 56 (2015), http://www.phrma.org/sites/default/files/pdf/chartpack-2015.pdf.

[13] *See* IMS INSTITUTE FOR HEALTHCARE INFORMATION, PRICE DECLINES AFTER BRANDED MEDICINES LOSE EXCLUSIVITY IN THE U.S. 3 (2016), http://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/Price_Declines_after_Branded_Medicines_Lose_Exclusivity.pdf.

only $1 to $2 million.[14] In addition, whereas brand companies spend millions of dollars marketing their drugs to physicians and patients,[15] generic companies typically spend very little on marketing. Because generics are automatically substituted for brand prescriptions at the pharmacy, generics can free-ride on the marketing efforts of brand companies and rely on automatic substitution laws for a large chunk of their sales. With these significantly lower costs, generic companies can afford to charge a lower price for their drugs and still earn impressive profits.

A significant number of existing brand drug customers switch to the lower-priced generics as they enter the market, swiftly eroding brand drugs' market share. As shown in Figure 2, upon market entry, generics now routinely capture over 70% of the brand drug's market share within only three months of generic entry. In contrast, as recently as 1999, generics captured less than 40% of the market within three months. Within twelve months, generics now capture over 80% of the brand drug's market share, whereas in 1999, they only captured slightly over 50%.

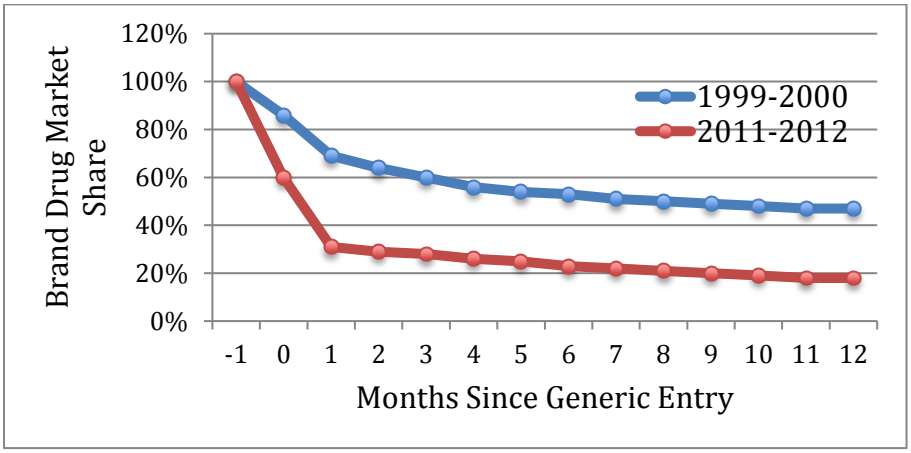

Figure 2: Generic Erosion of Brand Drug Market Share[16]

[14] *See* OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH & HUMAN SERVS., EXPANDING THE USE OF GENERIC DRUGS (Dec. 1, 2010), http://aspe.hhs.gov/basic-report/expanding-use-generic-drugs#11; *see also* Henry Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, 8 GEO. PUB. POL'Y REV. 7, 13 (2003) ("Generic firms can file an Abbreviated New Drug Application (ANDA), a process that takes only a few years and typically costs a few million dollars.").

[15] Brand companies spent between $103 million and $249 million on the top-ten most heavily advertised drugs in 2014 alone. *See* Beth Snyder Bulik, *The Top-10 Most Advertised Prescription Drug Brands*, FIERCEPHARMA, http://www.fiercepharmamarketing.com/special-reports/top-10-most-advertised-prescription-drug-brands (last visited Nov. 1, 2016).

[16] *See* Henry Grabowski, Genia Long & Richard Mortimer, *Recent Trends in Brand-Name and Generic Drug Competition*, 17 J. MED ECON. 207, 211-12 (2014).

The expansion of the generic industry has produced significant savings for consumers; in the last decade alone, generic drugs have saved the healthcare system nearly $1.7 trillion dollars.[17] However, it has also raised concerns about brand companies' ability to develop innovative new drugs. Brand drugs experience a significant drop in sales after generics enter the market and erode brand market share. For instance, in 1984 new brand drugs experienced a 12% decrease in net sales as a result of generic entry (a decrease which took place during the first decade after the enactment of the Hatch-Waxman Act).[18] And the expansion of generic drugs since then has further reduced brand sales. Brand drugs' average lifetime sales are now lower than they were in the early 1990s.[19] In fact, just two in ten brand drugs now earn profits sufficient to cover the average R&D costs required to bring new drugs to market.[20] Moreover, between 2012 and 2018, it is estimated that brand drug companies will lose almost $150 billion in sales because of patent expirations and generic entry.[21]

B. The Importance of Brand Drug Innovation

Unfortunately, reductions in brand drugs' profitability limits companies' ability and incentive to engage in the expensive R&D necessary to develop innovative new products. Drug companies will not spend millions (or potentially billions) of dollars to develop new drugs if they cannot recoup (and earn an acceptable return on) the costs of said development. Moreover, since only 20% of marketed brand drugs will ever earn enough sales to cover their development costs, the sales of these successful drugs must not just recoup their own costs; they must also cover the costs of the other 80% of approved drugs that generate losses for drug makers.[22]

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[17] *See* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 12, at 2; *see also* Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.* (2015), http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

[18] *See* U.S. CONG. BUDGET OFF., HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 38 (1998), https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf.

[19] *See* PHRMA, *supra* note 12, at 44.

[20] *Id.* at 43.

[21] *See* PRICEWATERHOUSECOOPERS, FROM VISION TO DECISION PHARMA 2020, at 6 (2012), http://www.pwc.com/gx/en/pharma-life-sciences/pharma2020/assets/pwc-pharma-success-strategies.pdf.

[22] *See* John A. Vernon, Joseph Golec & Joseph A. DiMasi, *Drug Development Costs When Financial Risk is Measured Using the Fama-French Three-Factor Model*, 19 HEALTH ECON. 1002, 1004 (2010).

Less R&D spending by brand companies will result in less innovation throughout the pharmaceutical industry. Brand drug companies are largely responsible for pharmaceutical innovation.[23] Since 2000, brand companies have spent over half a trillion dollars on R&D,[24] and they currently account for over 90% of the spending on the clinical trials necessary to bring new drugs to market.[25] Because of this spending, over 550 new drugs have been approved by the FDA since 2000,[26] and another 7,000 are currently in development globally.[27] Yet brand companies' R&D efforts and innovation are directly tied to their profitability. Numerous studies have found that policies that increase pharmaceutical profitability lead to increases in new clinical trials, new molecular entities, and new drug offerings.[28] Other studies have found that policies that reduce expected profitability lead to decreases in R&D spending.[29] Thus, reductions in brand drug profitability over the long term could very well lead to less R&D and less innovation in the pharmaceutical market.

A reduction in innovation will jeopardize the significant health advances that innovation achieves. Empirical estimates of the benefits of pharmaceutical innovation indicate that each new drug brought to market saves 11,200 life-years *each year*.[30] Another study finds that the health improvements from each new drug

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[23] *See, e.g.*, Kenneth Kaitin, Natalie Bryant & Louis Lasagna, *The Role of the Research-Based Pharmaceutical Industry in Medical Progress in the United States*, 33 J. OF CLINICAL PHARMACOLOGY 412, 414 (1993) (92% of new drugs are discovered by private branded companies).

[24] *See* PHRMA, *supra* note 12, at 46-47.

[25] *Id.* at 35.

[26] *Id.* at 20.

[27] *Id.* at 47.

[28] *See* Mark Duggan & Scott Morton, *The Distortionary Effects of Government Procurement: Evidence from Medicaid Prescription Drug Purchasing*, 121 Q. J. ECON. 1, 5 (2006); *see also* Amy Finkelstein, *Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry*, 119 Q. J. ECON. 527, 540 (2004); Daron Acemoglu & Joshua Linn, *Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry*, 119 Q. J. ECON. 1049, 1053 (2004).

[29] *See* Joseph Golec, Shantaram Hegde & John A. Vernon, *Pharmaceutical R&D Spending and Threats of Price Regulation*, 45 J. OF FINANCIAL & QUANTITATIVE ANALYSIS 239, 240-41 (2010); *see also* Frank R. Lichtenberg, *Public Policy and Innovation in the U.S. Pharmaceutical Industry*, *in* PUBLIC POL'Y AND THE ECON. OF ENTREPRENEURSHIP (Douglas Holtz-Eakin & Harvey S. Rosen eds., 2004).

[30] *See* Frank R. Lichtenberg, *Pharmaceutical Innovation, Mortality Reduction, and Economic Growth* 1 (Columbia U. & Nat'l Bureau of Econ. Res., Conf. Presentation on The Econ. Value of Med. Res., Working Paper No. 6569, 1998), http://www.nber.org/papers/w6569.

can eliminate $19 billion in lost wages by preventing lost work due to illness.[31] Moreover, because new, effective drugs reduce medical spending on doctor visits, hospitalizations, and other medical procedures, data shows that for every additional dollar spent on new drugs, total medical spending decreases by more than seven dollars.[32] Brand companies, and the profit incentives that motivate them, are largely responsible for pharmaceutical innovation. Thus, actions that reduce brand profitability could have long-term negative effects on consumer health and health care spending.

II
REGULATORY FRAMEWORKS BALANCING DRUG INNOVATION WITH GENERIC AVAILABILITY

Understanding the importance of stimulating innovation while encouraging generic entry, Congress created two regulatory frameworks that balanced the interests of brand patent holders with generic patent challengers. The Hatch-Waxman Act applies to traditional drugs, while the Biologics Price Competition and Innovation Act covers the new pathway for follow-on biologic drugs. This section discusses both regulations in turn.

A. The Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, was designed to balance the benefits of pharmaceutical innovation with consumers' needs for affordable drugs.[33] With Hatch-Waxman, Congress recognized that drug companies will only have the incentive to innovate if they can earn sufficient profits during the patent period to recover the exorbitant costs of researching and developing the drug, obtaining FDA approval, and marketing the drug to physicians and patients. However, while preserving incentives for "brand-name" innovations, Hatch-Waxman also encourages companies to create bioequivalent drugs—generics—that copy these

[31] *See* Craig Garthwaite, *The Economic Benefits of Pharmaceutical Innovations: The Case of Cox-2 Inhibitors*, 4 APPLIED ECON. 116, 118 (2012).

[32] *See* Frank R. Lichtenberg, *Benefits and Costs of Newer Drugs: An Update*, 28 MANAGERIAL & DECISION ECON. 485, 485 (2007).

[33] Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585. (1984).

branded drugs and enter the market at a lower price as soon as the patents expire on the innovator drugs.[34]

Hatch-Waxman includes various provisions designed to incentivize innovation by brand drug companies. First, to help companies recover the costs of bringing a drug to market, Hatch-Waxman allows for an extension of the patent term lost because of delays attributable to the FDA approval process. It establishes a period of *patent restoration*, which extends a covered drug's patent length by up to five years (to a maximum of fourteen years) for half of the brand drug's clinical testing period and all time spent securing FDA approval.[35] In addition to patent term restoration, Hatch-Waxman confers on brand drugs five years of *data exclusivity*. Data exclusivity prohibits the FDA from receiving a generic application that relies on the brand drug's safety and efficacy data. Protection from early generic filings helps to ensure that brand drug manufacturers have an adequate opportunity to recoup research, development and marketing costs.[36]

But in exchange for these new protections for brand drug manufacturers, Hatch-Waxman created various incentives for other companies to produce and market cheaper, generic drugs. First, to spur the introduction of low-cost generics, Hatch-Waxman created the Abbreviated New Drug Application ("ANDA") process that allows a generic that demonstrates bioequivalence to rely on *previously submitted* brand drug safety and efficacy data.[37] Prior to Hatch-Waxman, generics were required to submit their own original safety and efficacy data, often duplicating the brand drugs' tests. The new, greatly truncated process enables generics to quickly enter the market after brand patent expiration and to bring new drugs to market at a cost of only $1 to $2 million, compared to an average of $2.6 billion for brand drugs.[38] Moreover, Hatch-Waxman also immunizes generic companies from patent infringement liability for uses of the brand drug prior to expiration that are reasonably related to the filing of an FDA application.[39]

Second, Hatch-Waxman actively incentivizes generic companies to challenge the validity of brand patents before they expire by creating a pathway for such

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[34] *See* Margo Bagley, *Patent Term Restoration and Non-Patent Exclusivity in the U.S., in* PHARMACEUTICAL INNOVATION, COMPETITION, AND PAT. L. 111, 114-15 (Josef Drexel & Nari Lee eds., 2013).

[35] 21 U.S.C. § 355(c)(3)(E)(ii) (2012).

[36] *Id*.

[37] 21 U.S.C. § 355(j) (2012).

[38] *See* OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, *supra* note 14; *see also* Henry Grabowski, *supra* note 14.

[39] 35 U.S.C. § 271(e).

challenges and by offering a lucrative incentive to the first generic manufacturer to do so. Under a "Paragraph IV" challenge, a generic manufacturer submits an ANDA certifying that either the brand drug patent is invalid or unenforceable, or the generic drug will not infringe on the listed brand patent. As an incentive for filing Paragraph IV challenges, for the first generic that files a challenge and wins, Hatch-Waxman grants a 180-day exclusivity period during which the FDA will not approve any other generic versions of the drug. During this period, the first generic is the only generic on the market, and it can earn substantial profits by shadow pricing, or pricing slightly under the innovator's price.[40] As a result of this lucrative incentive, Paragraph IV challenges have exploded in recent years: although only 9% of drugs facing generic entry in 1995 were challenged, 81% of drugs facing generic entry in 2012 were challenged.[41] Moreover, Paragraph IV challenges are occurring earlier in the lives of brand drugs. Brand drugs that experienced their first generic entry in 1995 faced their first Paragraph IV challenge 18.7 years after original launch. By comparison, drugs facing the first generic entry in 2012 saw only 6.9 years between market launch and the first Paragraph IV challenge.[42]

Thus, Congress designed the Hatch-Waxman Act to strike a delicate balance between promoting brand innovation and facilitating generic entry. By granting brand drugs a period of patent restoration and data exclusivity, the Act recognized that brand innovators must earn a sufficient return on their R&D costs for innovation to occur. Yet, by streamlining the generic approval process, incentivizing generic challenge of brand patents and providing a litigation pathway for such challenges as discussed below, the Act also sought to increase generic availability and lower drug prices. By all accounts, Hatch-Waxman has successfully achieved these twin goals; generics now account for 89% of drugs dispensed,[43] yet brand companies still invest significantly in R&D, accounting for over 90% of the spending on clinical trials.[44]

B. The Biologics Price Competition and Innovation Act

Congress reconfirmed its intentions to balance brand innovation with the entry of cheaper, follow-on alternatives in 2009 with the Biologics Price Competition and

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[40] *See, e.g.*, U.S. DEP'T HEALTH & HUM. SERVS., GUIDANCE FOR INDUSTRY: 180-DAY GENERIC DRUG EXCLUSIVITY UNDER THE HATCH-WAXMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (1998), http://www.fda.gov/downloads/Drugs/.../Guidances/ucm079342.pdf.

[41] *See* Grabowski, Long & Mortimer, *supra* note 16, at 207.

[42] *Id.*

[43] *See* IMS INSTITUTE FOR HEALTHCARE INFORMATICS, *supra* note 10, at 46.

[44] *See* PHRMA, *supra* note 11, at 35.

Innovation Act (BPCIA).[45] The BPCIA deals with biologic drugs that distinguish themselves from traditional drugs by their origins: biologics derive from living organisms, typically proteins; though occasionally include toxins, blood, viruses or allergens.[46] These medications are far more complex than traditional medicines; whereas a traditional drug might contain between a few dozen to a hundred atoms per molecule, a biologic's complicated proteins can include several thousand atoms per molecule.[47] Because of this complexity, biologics are significantly more expensive to manufacture than traditional drugs. The average cost of a biologic drug is twenty-two times greater than a traditional drug, making them prohibitively expensive for many consumers.[48]

Fortunately, Congress recognized the need for cheaper, follow-on substitutes for biologic drugs—or biosimilars (the generic counterpart of biologic drugs). With the BPCIA, it achieved a compromise between biologics and biosimilars patterned after Hatch-Waxman's regulatory scheme for traditional drugs. First, the BPCIA created an expedited biosimilar approval pathway—analogous to Hatch-Waxman's approval pathway for generic drugs—under which a proposed biologic substitute does not have to demonstrate bioequivalence, but merely biosimilarity, to a reference product.[49] A product approved as biosimilar may further be deemed "interchangeable" with another biologic if its manufacturer can demonstrate that switching between the reference biologic and the proposed substitute presents no additional risk in safety or efficacy for consumers.[50] Similar to Hatch-Waxman's 180-day generic exclusivity window, the first biosimilar deemed interchangeable receives an exclusivity window as well.[51]

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[45] 42 U.S.C. § 262(i)(2)(B) (2012).

[46] *See* Jason Kanter & Robin Feldman, *Understanding & Incentivizing Biosimilars*, 58 HASTINGS L.J. 57, 59 (2012) (citing 42 U.S.C. § 262(i)(I) (2006)).

[47] *See, e.g.*, Joan Kerber-Walker, *Small Molecules, Large Biologics, and the Biosimilar Debate*, ARIZ. BIOINDUSTRY ASSOC. (Feb. 18, 2013), http://www.azbio.org/small-molecules-large-biologics-and-the-biosimilar-debate.

[48] *See* Anthony D. So & Samuel L. Katz, *Biologics Boondoggle*, N.Y. TIMES (Mar. 7, 2010), http://www.nytimes.com/2010/03/08/opinion/08so.html?_r=0.

[49] *See* 42 U.S.C. § 262(i)(2)(B) (2012); *see also* Zachary Brennan, *FDA Likely to Require Substantial Clinical Data for Interchangeable Biosimilars*, LAWYERS SAY (Jan. 12, 2016), http://www.raps.org/Regulatory-Focus/News/2016/01/12/23887/FDA-Likely-to-Require-Substantial-Clinical-Data-for-Interchangeable-Biosimilars-Lawyers-Say/ (noting that the FDA is still determining what pre-clinical and clinical data will be required for approval).

[50] 42 U.S.C. § 262(i)(3) (2012).

[51] Kanter & Feldman, *supra* note 46, at 69-72 (citing 42 U.S.C. § 262(i)(I) (2006)).

However, the BPCIA also recognizes the importance of protecting the original biologic's patent period to encourage biologic innovation. Innovative biologics—the biologic equivalent of brand drugs—receive twelve years of marketing exclusivity during which the FDA cannot approve a biosimilar substitute. [52] The BPCIA also confers four years of data exclusivity on innovative biologics during which a biosimilar is not permitted to use a reference drug's safety information to file an abbreviated application for FDA approval.[53]

Thus, like Hatch-Waxman's balance between protecting brand innovation and encouraging generic entry, the BPCIA protects biologics' patent terms while incentivizing biosimilar entry in the market.

C. Legal Challenges to Patents under Hatch-Waxman and BPCIA

Both Hatch-Waxman and the BPCIA establish frameworks for patent challenges that further balance the competing interests of brand and generic drug manufacturers. As noted above, when an ANDA applicant makes a Paragraph IV certification that the brand patent is either invalid, unenforceable or would not be infringed by the generic drug, Hatch-Waxman provides a structure for resolving the dispute.[54] First, the ANDA filer must give notice to the brand patent holder of the Paragraph IV certification. Hatch-Waxman makes the filing of an ANDA with a Paragraph IV certification an act of patent infringement even though no direct infringement has occurred. Thus, in contrast to many other industries in which the patent holder cannot sue for infringement until an infringing product has been produced and sold, the brand patent holder can bring suit against a generic rival before the infringing product is brought to market.[55] Moreover, the ANDA filer can resolve the patent dispute in court before exposing itself to patent infringement damages for bringing the challenged product to market. If the brand company does

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[52] 42 U.S.C. § 262(k)(7)(A); *see, e.g.*, Elizabeth Richardson et al., *Biosimilars*, HEALTH AFF. (Oct. 10, 2013), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=100.

[53] 42 U.S.C. § 262(k)(7)(B) (2012).

[54] *See, e.g.*, Bagley, *supra* note 34.

[55] *See* Lang v. Pacific Marine & Supply Co., 895 F.2d 761 (Fed. Cir. 1990) (noting that in other industries, it is possible to seek a declaratory judgment prior to the good entering the market); *see also* 35 U.S.C. § 271(a) (noting that it is also an infringement to merely offer to sell the invention even if the sale is not completed). *Compare* 35 U.S.C. § 271(e)(2) ("It shall be an act of infringement to submit—(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . ."), *with* 35 U.S.C. § 271(a) ("[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent therefor, infringes the patent.").

not sue for patent infringement within forty-five days of receiving notice of the Paragraph IV certification, the FDA may approve the ANDA and the ANDA filer can file for declaratory judgment of patent invalidity or noninfringement. If the brand company does sue for patent infringement within the forty-five days, the FDA is stayed from approving the generic ANDA until the generic company prevails in court or reaches a settlement, the brand patent expires, or a thirty-month stay expires. If the generic company wins at trial or reaches a favorable settlement, it receives a 180-day exclusivity period during which the FDA will not approve any other generic versions of the drug.

Similarly, the BPCIA creates a framework for patent challenges of biologic drugs that balances the interests of original biologics and biosimilars.[56] First, the biosimilar applicant must give notice to the biologic manufacturer that it plans to market a competing product, and it must provide access to the biosimilar application and relevant manufacturing details. Similar to a Paragraph IV filing under Hatch-Waxman, the BPCIA creates an artificial act of infringement that enables the original biologic manufacturer to bring a claim for patent infringement against a biosimilar manufacturer. If it chooses to bring an infringement claim, the original biologic manufacturer may provide to the biosimilar applicant a list of all patents it believes are infringed. The parties may then decide to exchange statements describing why each patent will or will not be infringed and negotiate as to which patents will be subject to the patent infringement action in the first round of litigation.[57] Unlike Hatch-Waxman, the BPCIA does not provide a stay of FDA approval during the course of patent litigation. However, by requiring the biosimilar applicant to give 180 days' notice before going to market, the BPCIA does provide an opportunity for biologic manufacturers to seek a preliminary injunction against an "at-risk" launch (i.e., a launch while patent litigation is ongoing and there is a risk of incurring patent infringement damages) of the biosimilar. Furthermore, to encourage biosimilar development and patent challenges, the BPCIA grants an exclusivity period to the

[56] *See, e.g.*, Jacob Sherkow, *Litigating Patented Medicines: Courts and the PTO* 8 (2015), http://law.stanford.edu/wpcontent/uploads/sites/default/files/event/862753/media/slspublic/Litigating%20Patented%20Medicines%20-%20Courts%20and%20the%20PTO.pdf; Louis Fogel & Peter Hanna, *The Biosimilar Regulatory Pathway and the Patent Dance* 1-2 (2014), https://jenner.com/system/assets/publications/13837/original/The_Biosimilar_Regulatory_Pathway_and_the_Patent_Dance.pdf?1420753075.

[57] Amgen Inc. v. Sandoz Inc., 794 F.3d 1347, 1360 (Fed. Cir. 2015) (holding that notice of commercial marketing is only effective after FDA approval of the biosimilar application and that the information exchange process is optional).

first interchangeable biosimilar that wins a patent dispute or is not sued for infringement.[58]

Thus, Hatch-Waxman and the BPCIA encourage generic and biosimilar manufacturers to challenge patents with a regulatory "bounty" system that provides a lucrative incentive for follow-on drug development and patent challenges. At the same time, they protect brand and biologic patent holders from generic/biosimilar competition in the marketplace until after a patent dispute has been resolved. Moreover, brand patent holders are afforded additional protections because federal district court is the venue for Hatch-Waxman and BPCIA patent challenges. The court presumes patents are valid unless a patent challenger can show invalidity by clear and convincing evidence. In addition, the court interprets patent claims using the "ordinary and customary meaning" standard, making invalidation less likely than under the more lenient standard used in administrative proceedings.[59]

III
ADMINISTRATIVE PROCEEDINGS FOR PATENT CHALLENGES

A. Pre-IPR Proceedings

In addition to the litigation frameworks created under Hatch-Waxman and the BPCIA, patents can also be challenged in administrative proceedings. Congress has long recognized that imperfections exist in the U.S. Patent and Trademark Office (PTO) examination and issuance process and that some issued patents may require reexamination.[60] In creating an administrative pathway for patent reexamination, Congress intended to reduce both the number of doubtful patents and the cost of patent litigation.[61] This "second look" allows the PTO to withdraw improperly

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[58] *See* 42 U.S.C. § 262(k)(6) (2012) (noting that exclusivity extends until the earliest of: (i) one year after the first commercial marketing of the first-approved interchangeable biosimilar; (ii) eighteen months after a final court decision or the dismissal of a suit against the first interchangeable biosimilar; (iii) forty-two months after the approval of the first interchangeable biologic if patent litigation is still ongoing; or (iv) eighteen months after the approval of the first interchangeable biosimilar if the applicant has not been sued).

[59] *See, e.g.*, Phillips v. AWH Corp., 415 F.3d 1303, 1312-18 (Fed. Cir. 2005) (en banc).

[60] *See, e.g.*, Wayne B. Paugh, *The Betrayal of Patent Reexamination: An Alternative to Litigation, Not a Supplement*, 19 FED. CIR. B.J. 177, 181-88 (2009).

[61] *See* Patlex Corp. v. Mossinghoff, 758 F.2d 594, 602 (Fed. Cir.), *aff'd in part, rev'd on other grounds*, 771 F.2d 480 (1985); H.R. REP. NO. 107-120, at 3 (2001) ("The 1980 reexamination statute was enacted with the intent of achieving three principal benefits. It is noted that the reexamination of patents by the PTO would: (i) settle validity disputes more quickly and less expensively than litigation; (ii) allow courts to refer patent validity questions to an agency with

granted patents, thereby correcting its previous errors at a much lower cost than litigation. Indeed, Congress predicted that the administrative reexamination of doubtful patents would:

> permit efficient resolution of questions about the validity of issued patents without recourse to expensive and lengthy infringement litigation. This, in turn, will promote industrial innovation by assuring the kind of certainty about patent validity which is a necessary ingredient of sound investment decisions. . . . A new patent reexamination procedure is needed to permit the owner of a patent to have the validity of his patent tested in the Patent Office where the most expert opinions exist and at a much reduced cost. Patent office reexamination will greatly reduce, if not end, the threat of legal costs being used to 'blackmail' such holders into allowing patent infringements or being forced to license their patents for nominal fees.[62]

Prior to the AIA in 2012, these administrative reexamination proceedings took place exclusively before the PTO. Ex parte reexamination, created by the 1980 Bayh-Dole Act, allows anyone, including the patent owner, to request reexamination of a patent.[63] The request can be made at any time during the life of a patent, but the reexamination is limited to issues of obviousness and novelty on the basis of prior art consisting of patents or printed publications.[64] The party requesting the reexamination submits prior art to the PTO that it believes calls into question the obviousness or novelty of the patent. The PTO will grant the petition and order an ex parte reexamination if the petition raises a "substantial new question of patentability."[65]

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expertise in both the patent law and technology; and (iii) reinforce investor confidence in the certainty of patent rights by affording an opportunity to review patents of doubtful validity.").

[62] H.R. REP. NO. 96-1307, pt. 1, at 3-4 (1980), *as reprinted in* 1980 U.S.C.C.A.N. 6460, 6463.

[63] *See, e.g.*, Bayh-Dole Act, Pub. L. No. 96-517, ch. 30, § 302, 94 Stat. 3015, 3015 (1980) (codified at 35 U.S.C. § 302 (2012)) ("Any person at any time may file a re-quest for reexamination by the Office of any claim of a patent on the basis of any prior art cited . . . .").

[64] 37 C.F.R. § 1.552 (2014); U.S. PAT. & TRADEMARK OFF., MPEP § 2258 (9th ed. Rev. Mar. 2014) [hereinafter MPEP].

[65] 35 U.S.C. § 303(a) (2012).

If the ex parte reexamination is granted, it involves only the patent owner and the PTO; any third-party petitioners are excluded from the process.[66] The reexamination advances much like the original examination of the patent application: none of the patent claims are presumed valid and the PTO uses the broadest reasonable construction to interpret the claims.[67] Because this broad construction standard is more likely to interpret claims as invalid, patent owners are allowed to amend their claims to narrow their scope and avoid invalidation of the patent.[68]

Ex parte reexamination has never gained popularity because, as critics claim, it does not allow any third-party participation beyond the initial reexamination request.[69] In response to concerns of its underutilization, Congress enacted an alternative reexamination procedure in 1999: inter partes reexamination.[70] Although similar to ex parte reexamination in almost every way, inter partes reexamination could not be initiated by the patent owner,[71] and it allowed substantial involvement of third parties in the reexamination process.[72] The two procedures existed side-by-side until inter partes reexamination was replaced by the new administrative procedure established by the AIA in 2012.

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[66] 37 C.F.R. § 1.550(g) (2014) ("The active participation of the ex parte reexamination requester ends with the [grant of the petition for reexamination], and no further submissions on behalf of the reexamination requester will be acknowledged or considered.").

[67] MPEP § 2111 ("During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.'").

[68] Douglas Duff, Comment, *The Reexamination Power of Patent Infringers and the Forgotten Inventor*, 41 CAP. U. L. REV. 693, 710 (2013) ("[R]eexamination affords the patent owner a chance to narrow the scope of the claims to avoid being invalidated based on subsequently discovered prior art.").

[69] Shannon M. Casey, *The Patent Reexamination Reform Act of 1994: A New Era of Third Party Participation*, 2 J. INTELL. PROP. L. 559 (1995); Marvin Motsenbocker, *Proposal to Change the Patent Reexamination Statute to Eliminate Unnecessary Litigation*, 27 J. MARSHALL L. REV. 887, 898 (1994); Gregor N. Neff, *Patent Reexamination—Valuable, But Flawed: Recommendations for Change*, 68 J. PAT. & TRADEMARK OFF. SOC'Y 575 (1986).

[70] American Inventors Protection Act of 1999, Pub. L. No. 106-113, 113 Stat. 1501 (codified in relevant part in 35 U.S.C. §§ 311-318 (2006)) (repealed 2012).

[71] Patent owners cannot request inter partes reexaminations of their patents because there would be no third party to participate. *See* 35 U.S.C. § 311(a) (2012).

[72] 35 U.S.C. §§ 311-318 (2012).

B. Inter Partes Review

The AIA, perhaps the most significant reform to the patent system in sixty years,[73] created several new procedures for reexamining the validity of patents.[74] A primary goal of the AIA was to provide a swifter resolution to patent reexaminations than the pre-AIA procedures.[75] Congress had grown increasingly concerned that reexaminations were "too lengthy and unwieldy to actually serve as an alternative to litigation when users are confronted with patents of dubious validity."[76] The average length of an ex parte reexamination proceeding in 2012 was about 27.9 months,[77] and the average length of an inter partes reexamination was thirty-six months.[78] In contrast, the average length of patent litigation in the courts prior to the AIA was 27.36 months.[79] Thus, the existing reexamination procedures were unable to offer a quicker resolution to patent disputes than litigation. To remedy this, Congress intended the AIA "to establish a more efficient and streamlined patent system." [80]

Congress also sought, with the AIA, to "improve patent quality and limit unnecessary and counterproductive litigation costs."[81] On the one hand, Congress recognized the importance of challenging weak patents because "patents of dubious probity only invite legal challenges that divert money and other resources from more productive purposes, purposes such as raising venture capital, commercializing

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[73] Andrei Iancu & Ben Haber, *Post-Issuance Proceedings in the America Invents Act*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 476, 476 (2011).

[74] Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. at 299-305 (2011)(setting forth procedures for IPR).

[75] *See generally* Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 FED. CIR. BAR J. 539, 599-604 (2012) (summarizing legislative history); H.R. REP. NO. 112-98, at 45 (2011).

[76] Sen. Patrick Leahy, *Senate Begins Debate on Leahy-Smith America Invents Act*, PRESS RELEASE (Sept. 6, 2011), http://www.leahy.senate.gov/press/senate-begins-debate-on-leahy-smith-america-invents-act.

[77] U.S. PAT. & TRADEMARK OFF., EX PARTE REEXAMINATION FILING DATA, at 1 (Sept. 30, 2012), http://www.uspto.gov/sites/default/files/documents/ex_parte_historical_stats_roll_up_EOY2014.pdf.

[78] *See* PRICEWATERHOUSECOOPERS, 2011 PATENT LITIGATION STUDY: PATENT LITIGATION TRENDS AS THE 'AMERICA INVENTS ACT' BECOMES LAW 28 (2011) https://www.pwc.com/us/en/forensic-services/publications/assets/2011-patent-litigation-study.pdf.

[79] *Id.* at 28 (reporting the average time to trial as 2.28 years, or 27.36 months).

[80] H.R. REP. NO. 112-98, at 40 (2011).

[81] *Id.*

inventions and creating jobs."[82] Yet it also accepted that provisions under the pre-AIA reexamination procedures had threatened strong patents by making the reexaminations "too easy to initiate and used to harass legitimate patent owners."[83] Indeed, combating patent-assertion entities, pejoratively known as "patent trolls," was cited as a primary goal of the AIA.[84] Thus, to balance the role of patent owners and challengers, Congress transformed post-issuance proceedings "from an examinational to an adjudicative proceeding."[85] The new "mini-trials," it was believed, would more fairly balance the role of patent holders and patent challengers in a manner similar to litigation.[86]

Two of the new administrative procedures created by the AIA—covered business method review and post-grant review—are not the focus of this Article. Covered business method review applies only to business method patents within financial services, making it largely irrelevant to the pharmaceutical industry. Post-grant review, which allows an invalidity challenge on any grounds during the first nine months of a patent,[87] applies only to patents issued under the AIA's new first-inventor-to-file regime, and thus is still in its infancy.

The AIA proceeding currently garnering the most attention from the pharmaceutical industry is inter partes review ("IPR"). The AIA created IPR to replace inter partes reexamination—therefore, IPR resembles the earlier reexamination procedure in many respects.[88] Like inter partes reexamination, IPR challenges are available to anyone other than the patent owner,[89] and the validity of the patent can only be challenged for either obviousness or lack of novelty.[90] An IPR

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[82] *Patent Quality Improvement: Post-Grant Opposition: Hearing Before the Subcomm. on* Courts, The Internet & Intellectual Prop. of the H. Comm. on the Judiciary, 108th Cong. 1 (2004) (statement of Rep. Lamar Smith, Chairman, Subcomm. on Courts, the Internet & Intellectual Prop.).

[83] Sen. Patrick Leahy, *supra* note 74; *see also* 57 Cong. Rec. S5428 (daily ed. Sept. 8, 2011) (statement of Sen. Patrick Leahy) (asserting that the AIA post-issuance review proceedings provide more protections to patent holders against frivolous requests and harassment).

[84] *See, e.g.*, 157 Cong. Rec. H4485-86 (daily ed. June 23, 2011) (statement of Rep. Lamar Smith) (explaining Congress's thoughts regarding the predatory behavior of patent trolls).

[85] H.R. Rep. No. 112-98, at 46 (2011).

[86] Mark Consilvio & Jonathan Stroud, *Unravelling the USPTO's Tangled Web: An Empirical Analysis of the Complex World of Post-Issuance Patent Proceedings*, 21 J. OF INTELL. PROP. L. 1, 12 (2014).

[87] 35 U.S.C. § 321 (2012).

[88] *Id.* §§ 311-319.

[89] *Id.* § 311(a).

[90] *Id.* § 311(b).

can be requested at any point during a patent's lifetime, beginning nine months after the patent's issuance.[91] However, an IPR may not be sought if the petitioner has previously filed a civil action challenging the validity of the same claim,[92] or has been sued for infringing the patent in question more than a year prior.[93]

However, IPR differs from the earlier inter partes reexamination in two important respects. First, unlike the paper administrative proceeding of inter partes reexamination, IPR is an adjudicative proceeding before the newly-created Patent Trial and Appeal Board (PTAB). The PTO will grant an IPR request (i.e. make an "institution" decision) and order a full trial before the PTAB if there is a "reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."[94] A PTAB trial resembles a traditional trial, but with more limited discovery, depositions, and cross-examination.[95]

Second, IPR offers users a significantly speedier resolution than did inter partes reexamination. An inter partes reexamination often took years to reach a decision. In contrast, the PTAB must, by statute, make a final decision on an IPR claim within twelve to eighteen months.[96]

IPR is much more popular than the previous reexamination procedures. Between 2000 and its abolition in 2012, there were a total of 1,919 inter partes reexamination requests filed, or on average, 148 per year.[97] Between 2000 and 2014, there were a total of 7,709 ex parte reexamination requests filed, or on average, 514 per year.[98] Additionally, in the first nine months of fiscal 2016, 1,126 IPR petitions have already been filed.[99] By contrast, fiscal years 2014 and 2015 saw the filing of 1,310 and 1,737 IPR petitions, respectively.[100]

Moreover, IPR is significantly more friendly to patent challengers than the previous reexamination procedures. Of the completed trials that have reached a final written decision, the PTAB has invalidated at least some of the patent claims in a

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[91] *Id.* § 311(c)(1). An IPR request cannot be filed until the post-grant review window has expired. *Id.* § 311(c)(2).

[92] 35 U.S.C. § 315(a)(1) (2012).

[93] *Id.* § 315(b).

[94] *Id.* § 314(a).

[95] *Id.* § 326(a)(5); 37 C.F.R. § 42.51-42.53 (2012).

[96] 35 U.S.C. § 316(a)(11) (2012).

[97] U.S. PAT. & TRADEMARK OFF., *supra* note 77, at 2.

[98] *Id.* at 1.

[99] U.S. PAT. & TRADEMARK OFF., *supra* note 3, at 3.

[100] *Id.*

patent in 85% of cases and *all* of the patent claims in a patent in 70% of cases.[101] By contrast, from 1999 to its abolition in 2012, only 31% of inter partes reexaminations resulted in the cancellation of all claims of the challenged patents.[102] Similarly, from its advent in 1981 through 2014, only 12% of ex parte reexaminations have ended with the cancellation of all of the challenged patents' claims.[103]

IV
IPR'S PRO-CHALLENGER BIAS

Congress designed the new IPR proceeding to improve patent quality by providing a more efficient pathway to challenge patents of dubious quality. The popularity of IPR compared to the pre-AIA reexamination procedures suggests that many challengers perceive significant advantages in the new proceedings. For many types of patents, an increase in post-issuance proceedings should produce clear social benefits: the more efficient resolution of patent disputes will allow more resources to be allocated to productive purposes. However, for pharmaceutical patents, IPR proceedings may instead create *significant* social costs. Unlike other industries, specific qualities of both the pharmaceutical industry and pharmaceutical patent litigation combine to create very different effects for the new IPR proceeding.

With the Hatch-Waxman Act and the BPCIA, Congress provided a litigation pathway for challenging pharmaceutical patents that balances the interests of brand patent holders with generic patent challengers. By all accounts, Hatch-Waxman has successfully achieved its goals of promoting brand innovation while facilitating generic entry. Generic drugs now account for 89% of drugs dispensed,[104] yet brand companies still invest significantly in R&D, accounting for over 90% of the spending on the clinical trials necessary to bring new drugs to market.[105] Although the BPCIA is still in its infancy, it was also explicitly designed to protect biologics' patent terms while incentivizing biosimilar entry in the market.

Yet with IPR, Congress created an entirely new pathway for challenging pharmaceutical patents. As this section discusses, critical differences between district court litigation and IPR proceedings jeopardize the delicate balance Hatch-Waxman and the BPCIA sought to achieve between patent holders and patent

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[101] *Id.* at 10. Specifically, out of the 1046 completed trials (as of June 30, 2016, 896 (85.66%) have invalidated at least one claim, and 736 (70.36%) have resulted in all claims being invalidated. *Id.*

[102] U.S. PAT. & TRADEMARK OFF., *supra* note 77, at 1.

[103] *Id.* at 2.

[104] IMS INSTITUTE FOR HEALTHCARE INFORMATICS, *supra* note 10, at 46.

[105] PHRMA, *supra* note 11, at 35.

challengers. As IPR has grown in popularity, it has become evident that these proceedings favor patent challengers. This change threatens to disrupt the nature of competition in the pharmaceutical industry, brand companies' incentives to innovate, and consumers' access to life-improving and life-saving drugs.

First, in IPR proceedings, the PTAB applies a lower standard of proof for invalidity than do district courts in either Hatch-Waxman or BPCIA proceedings. In district court, patents are presumed valid and challengers must prove each patent claim invalid by "clear and convincing evidence."[106] In contrast, no such presumption of validity applies in IPR proceedings, and challengers must only prove patent claims invalid by the "preponderance of the evidence."[107] This significantly reduced burden of proof gives patent challengers in PTAB cases an important advantage over district court litigation.

In addition to the lower burden, it is also easier to meet the standard of proof in the PTAB trial. One of the most contested parts of patent litigation is claim construction. Claim construction is the translation of the technical patent claims that define the scope of the patentee's legal rights into understandable language.[108] District courts construe claims according to their "ordinary and customary meaning" to a person of ordinary skill in the art.[109] By contrast, the PTAB uses the more lenient "broadest reasonable interpretation" standard in IPR proceedings.[110] In many cases, these two standards will yield the same construction and conclusions on invalidity. In some cases the PTAB will interpret patent claims as "claiming too much" (using their broader standard), resulting in the invalidation of more patents.[111] Indeed, the Supreme Court recently recognized in *Cuozzo* that these different standards "may produce inconsistent results and cause added confusion"[112] and that "use of the broadest reasonable construction standard increases the possibility that the examiner

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[106] Microsoft Corp. v. i4i Ltd., 131 S. Ct. 2238, 2242 (2011) (holding that a clear and convincing showing of invalidity is required to invalidate patents).

[107] 35 U.S.C. § 316(e) (2012) (establishing a "preponderance of the evidence" standard in IPR proceedings).

[108] *See generally* Dennis Crouch, *Claim Construction: A Structured Framework*, PATENTLYO (Sept. 29, 2009), http://patentlyo.com/patent/2009/09/claim-construction-a-structured-framework-1.html.

[109] *See, e.g.*, *Phillips*, 415 F.3d at 1312-13.

[110] 37 C.F.R. § 42.100(b) (2012).

[111] *See, e.g.*, PPC Broadband, Inc. v. Corning Optical Communications RF, LLC**,** 815 F.3d 734 (2016) ("This case hinges on the claim construction standard applied—a scenario likely to arise with frequency. And in this case, the claim construction standard is outcome determinative.").

[112] *Cuozzo*, 136 S. Ct. 2131, at 2146.

will find the claim too broad (and deny it)."[113] Yet the Court concluded that, because the AIA did not specify which standard applies in PTAB trials, the decision of claim construction standard was left to the PTO.[114]

The use of the broadest reasonable construction is not new in the patent office. The PTO uses this standard during its initial examination of patent applications and during ex parte reexaminations.[115] In these proceedings, the justification for broadly interpreting claims is that patent owners will have an opportunity to amend their patents, so claims can be scrutinized using the broadest lens without necessarily resulting in patent invalidation.[116] However, patent owners are rarely allowed to amend claims in IPR proceedings even though the PTAB uses the broadest reasonable interpretation. Of the 118 completed trials in which the PTAB decided a motion to amend (which were requests to substitute patent claims) the board allowed the patent owner to amend claims in only six trials, or 5% of the total.[117] Thus, the PTAB's use of the broadest reasonable construction standard in IPR proceedings will necessarily result in more patent invalidations than in either district court litigation or in ex parte reexaminations.

PTAB decisions in IPR proceedings are also given more deference than district court decisions. A district court decision upholding the validity of a patent does not prevent a later PTAB challenge by the *same* patent challenger within a year, essentially giving patent challengers "two bites at the apple."[118] As long as an IPR petitioner meets the requirements—it has not been sued for infringing the patent in

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[113] *Id*. at 2145.

[114] *Id.* at 2136.

[115] *See, e.g.*, *Phillips*, 415 F.3d at 1316 ("The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction. . . ."); In re Yamamoto, 740 F.2d 1569, 1571 (Fed. Cir. 1984) (stating that claims subject to reexamination will "be given their broadest reasonable interpretation consistent with the specification, and limitations appearing in the specification").

[116] MPEP § 2111 ("Because applicant has the opportunity to amend the claims during prosecution, giving a claim its broadest reasonable interpretation will reduce the possibility that the claim, once issued, will be interpreted more broadly than is justified.").

[117] U.S. PAT. & TRADEMARK OFF., PATENT TRIAL AND APPEAL BOARD MOTION TO AMEND STUDY: 4/30/2016, at 4 (2016), http://www.uspto.gov/sites/default/files/documents/2016-04-30%20PTAB%20MTA%20study.pdf. But see the Federal Circuit order in *In re: Aqua Products, Inc.*, No. 2015-1177 (Aug. 12, 2016), in which the full court granted en banc review of the petitioner's argument that the PTAB has "unduly restricted" the ability to amend patent claims.

[118] The PTAB justifies this second bite by maintaining that the petitioner is not a party to district court proceedings and that the two venues possess different burdens of proof. *See, e.g.*, Amkor Tech., Inc. v. Tessera, Inc., IPR2013-00242, Paper 37 at 12 (P.T.A.B. Oct. 11, 2013).

question more than a year prior,[119] and has not previously filed a civil action challenging the validity of the same claim[120]—a patent challenger that was unsuccessful in invalidating a patent in district court may pursue a subsequent IPR proceeding challenging the same patent.[121] And the PTAB's subsequent decision to invalidate a patent can often "undo" a prior district court decision. In fact, a patent challenger who prevails in a subsequent IPR proceeding can avoid a prior district court judgment finding infringement and imposing damages or issuing an injunction.[122] Thus, pharmaceutical patent holders face persistent uncertainty about the validity of their patents.[123] Even if a patent is found valid in district court, and the validity is affirmed on appeal, the patent could later be found invalid in an IPR proceeding because the PTAB applies lower standards of proof and broader claim construction standards. The Federal Circuit could then affirm the PTAB's decision, because with the different standards, the PTAB's finding of invalidity is not necessarily in conflict with the district court's finding of validity.

Similarly, although both district court judgments and PTAB decisions are appealable to the Federal Circuit,[124] the court applies a more deferential standard of review to PTAB decisions. Whereas a district court's factual findings in a bench trial

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[119] 335 U.S.C. § 315(b) (2012).

[120] 35 U.S.C. § 315(a)(1) (2012). Importantly, a counterclaim challenging the validity of a patent claim in an infringement action is not considered a civil action. 35 U.S.C. § 315(a)(1), (3) (2012).

[121] 35 U.S.C. §§ 315, 325 (2012).

[122] *See generally* Jay Chiu et. al, *Pharmaceuticals at the Patent Trial and Appeal Board*, 30-32 (2015), http://www.goodwinlaw.com/news/2015/07/07_29_15-goodwin-procter-publishes-guidebook-on-litigating-pharmaceutical-cases?device=print; EPlus, Inc. v. Lawson Software, 789 F.3d 1349 (Fed. Cir. 2015) (vacating the injunction issued by the district court after a subsequent PTAB decision invalidated the patent); Fresenius USA, Inc. v. Baxter Int'l, Inc., 721 F.3d 1330, 1335, 1336 (Fed. Cir. 2013) (absolving the patent challenger of the damage award imposed by the district court after the USPTO subsequently cancelled the patent on reexamination).

[123] Some IPRs and district court litigation will naturally happen in tandem because IPRs will only consider invalidity determinations, while ANDA litigation also deals with infringement determinations. Generic companies may prefer to pursue a non-infringement determination in district court because, in contrast to a finding of invalidity, a finding of non-infringement keeps the patent in place so that competing generics will also have to show that they don't infringe or that the patent is invalid or unenforceable. Moreover, non-infringement determinations will often be cheaper to litigate. In a non-infringement determination, the generic company has all of the information about its product, so the costs of evaluating non-infringement should be lower. In contrast, an invalidity determination requires a prior art search and analysis as to whether the claimed invention is novel, non-obvious and useful.

[124] 35 U.S.C. § 141 (2012).

are reviewed for "clear error,"[125] the PTAB's factual findings are reviewed using the more deferential "substantial evidence" standard.[126] The closer judicial review of district court factual findings means that these decisions are more likely to be overturned on appeal than are PTAB decisions. The more deferential review granted to the PTAB's factual findings is especially troublesome given the more limited fact-finding in IPR proceedings. In contrast to the expansive discovery and witness testimony that is common in district court litigation, discovery is significantly restricted and live testimony is rarely allowed in IPR proceedings.[127] Thus, the Federal Circuit applies a more deferential review of factual findings that are based on less evidence. This approach is not only nonsensical, it will inevitably lead to more errors.

Another critical difference between district court litigation and IPR proceedings lies in the standing requirement. To challenge a patent in district court, a petitioner must have sufficient Article III standing, which the courts have generally interpreted to require that the petitioner has engaged in infringing activity and faces the threat of suit.[128] In contrast, IPR proceedings do not have a standing requirement, allowing any member of the public other than the patent owner to initiate an IPR challenge.[129] As a result, approximately 30% of IPR challengers have not been defendants in district court litigation, and thus would likely not have had Article III standing.[130]

Legal commentators, including advocates of administrative proceedings, have recognized that the lack of a standing requirement in IPR proceedings could lead to harassment suits brought by competitors intending only to impose costs on the other

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[125] FED. R. CIV. P. 52(a)(6); United States v. Cazares, 121 F.3d 1241, 1245 (9th Cir. 1997). Findings in a jury trial in district court are reviewed using the "substantial evidence" standard. However, review of claim construction will always be different between appeals from district court proceedings and PTAB trials because claim construction at the district court is always decided by the judge, and thus, reviewed for clear error.

[126] 5 U.S.C. § 706(e) (2012); *Merck*, 820 F.3d at 433.

[127] *See* 37 C.F.R. §§ 42.51-42.53 (2015).

[128] *See, e.g.*, MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007) (quoting Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941)).

[129] *See* 35 U.S.C. § 311(a) (2012). Yet, a challenger who loses at the PTAB may have to meet Article III standing requirements in order to appeal. *Cf.* Consumer Watchdog v. Wis. Alumni Research Found., 753 F.3d 1258, 1261 (Fed. Cir. 2014).

[130] *See* Saurabh Vishnubhakat, Arti K. Rai, & Jay P. Kesan, *Strategic Decision Making in Dual PTAB and District Court Proceedings*, 31 BERKELEY TECH. L.J. 45, 76 (2016).

party.[131] Indeed, the lack of a standing requirement has given rise to "reverse patent trolling," in which entities that are not litigation targets, or even participants in the same industry, offensively use IPR or the threat of IPR to profit. Under this opportunistic practice, reverse trolls threaten to file an IPR petition challenging the validity of a patent unless the patent holder agrees to specific pre-filing settlement demands. These demands are arguably extortion,[132] but with the high rate of decisions to institute IPRs and the high rate of patent invalidations in IPR proceedings, companies take a big risk if they do not agree to such demands.[133]

Moreover, pharmaceutical patents face the threat of another, distinct form of abuse under IPR—the novel hedge fund practice of short selling a brand drug company's stock, then filing an IPR challenge in hopes of crashing the stock and profiting from the short sale.[134] Pharmaceutical patents are especially vulnerable to this abuse because the stock value of a small or mid-size pharmaceutical company typically depends critically on the success of an individual drug, which in turn typically depends on an individual patent. Thus, while hypothetically invalidating a patent owned by Apple or Samsung may do little to affect the companies' stock price because of the variety of product offerings and multitude of patents underlying their technology, invalidating a pharmaceutical patent could cause a pharmaceutical company's stock to plummet. Indeed, the data on IPR petitioners suggest that pharmaceutical patents are especially vulnerable to this sort of abuse; whereas in most industries, over 70% of IPR challengers were defendants in district court litigation (granting them Article III standing), for the drug industry, this figure is less than 50%.[135] And while critics have argued that the hedge fund strategy amounts to

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[131] Jonathan Masur, *Patent Inflation*, 121 YALE L.J. 470, 522 (2011) ("[IPR] could potentially be abused by parties interested only in delaying and harassing competitors.").

[132] *See, e.g.*, Joseph Herndon, *IPRs Threatened/Filed as Money-Making Strategy*, PATENT DOCS (Aug. 16, 2016), http://www.patentdocs.org/2016/08/iprs-threatenedfiled-as-money-making-strategy.html; First Amended Complaint at 4, Chinook Licensing DE, LLC, v. RozMed LLC, C.A., No. 14-598-LPS (D. Del. June 13, 2014), ECF No. 9; Allergan Inc. v. Ferrum Ferro Capital LLC, No. SACV 15-00992 JAK (PLAx) (C.D. Cal. Jan. 20, 2016).

[133] *See* Joseph Gulfo, *Hedge Funds, 'Reverse Trolls' Crushing Biopharma Innovation*, CNBC (July 22, 2015), http://www.cnbc.com/2015/07/22/biopharma-hammered-by-hedge-funds-reverse-trolls-commentary.html.

[134] *See* Joseph Walker and Rob Copeland, *New Hedge Fund Strategy: Dispute the Patent, Short the Stock*, WALL STREET JOURNAL (Apr. 7, 2015), http://www.wsj.com/articles/hedge-fund-manager-kyle-bass-challenges-jazz-pharmaceuticals-patent-1428417408.

[135] Vishnubhakat, Rai & Kesan, *supra* note 130, at 85-86.

illegal market manipulation,[136] the PTAB has thus far allowed the practice, concluding that "profit is at the heart of nearly every patent and nearly every inter partes review,"[137] and "Congress did not limit inter partes reviews to parties having a specific competitive interest in the technology covered by the patents."[138]

The differences between district court litigation and IPR proceedings are creating a significant deviation in patent invalidation rates under the each pathway. From 1996 to 2015, patents were invalidated in 34% to 39% of district court cases.[139] Additionally, of the 1,046 PTAB trials in IPR proceedings that were completed by June, 2016, a shocking 70% resulted in the invalidation of all claims of the challenged patents.[140] This higher invalidation rate in IPR proceedings is especially meaningful because, while a challenged patent can only be invalidated in an IPR for lack of novelty or for obviousness, a challenged patent in district court can also be invalidated on other grounds.[141]

To date, IPR petitions filed on pharmaceutical patents have made up only a small percentage of the total petitions. Of the 4,253 IPR petitions filed as of March 2016, only 228, or 5.36% were filed on patented pharmaceuticals.[142] Yet the number

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[136] Kevin Penton, *Biogen Wants Kyle Bass to Give up Financial Docs at PTAB*, LAW360 (July 9, 2015), http://www.law360.com/articles/677449/biogen-wants-kyle-bass-to-give-up-financial-docs-at-ptab; *see also* 162 CONG. REC. H4361 (daily ed. July 6, 2016) (statement of Rep. Duffy) (expressing concern about a "potential[ly]" "deceptive and manipulative practice by some hedge funds to challenge the legitimacy of a drug patent while simultaneously shorting the drug manufacturer's stock. These particular hedge funds game the system" by "publiciz[ing] numerous patent challenges," "provok[ing] fear in the marketplace" and "driv[ing] down [the stock] prices" of these smaller companies.).

[137] *Celgene*, Nos. IPR2015-01092, IPR2015-01096, IPR2015-01102, IPR2015-01103 and IPR2015-01169, at 3.

[138] *Id.* at 4.

[139] PRICEWATERHOUSECOOPERS, *supra* note 2, at 9 fig.11. Earlier studies found invalidation rates in district courts were around 46%. *See* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q. J. 185, 205-06 (1998); Donald R. Dunner, *Introduction*, 13 AIPLA Q. J. 185, 186-87 (1985); Mark A. Lemley, *An Empirical Study of the Twenty-Year Patent Term*, 22 AIPLA Q. J. 369, 420 (1994) (finding that 56% of litigated patents to be valid between 1989 and 1994).

[140] U.S. PAT. & TRADEMARK OFF., *supra* note 3, at 10.

[141] It is possible that the patent invalidation rate in IPR may eventually decrease assuming that, shortly after the creation of IPR, there was an abundance of "low-hanging fruit" (i.e. easily invalidated patents which were previously difficult to challenge: (i) because of the Article III standing requirement; and (ii) because IPR enabled more patent challenges than are possible in district court).

[142] Kevin E. Noonan, *PTAB Statistics from Spring BIO IPCC Meeting*, PATENT DOCS (Apr. 17, 2016), http://www.patentdocs.org/2016/04/ptab-statistics-from-spring-bio-ipcc-meeting.html.

of IPR challenges to pharmaceutical patents continues to increase; twice as many IPR petitions were filed on pharmaceutical patents in 2015 compared to 2014, and the number is on pace to increase again in 2016.[143]

Although only a handful of these pharmaceutical IPR petitions have reached a written decision in a PTAB trial, it appears that, similar to other industries, brand patent holders are faring worse in IPR proceedings. The PTAB has invalidated approximately 50% of the total claims considered in written decisions.[144] However, of the 220 Hatch-Waxman cases litigated to trial or summary judgment from 2000 to 2012, only 21% resulted in invalidation of the patents.[145]

V
CORRECTING THE IMBALANCE

The growing popularity of IPR threatens to dislodge the delicate balance that Hatch-Waxman and the BPCIA sought to strike between brand patent holders and generic patent challengers. To achieve this balance, Hatch-Waxman's litigation pathway includes several protections for patent holders. In contrast, IPR proceedings clearly tilt the balance in the patent challenger's favor. Although IPR challenges to pharmaceutical patents do not yet occur in large numbers, their popularity is increasing swiftly. Moreover, even the risk of facing a pro-challenger IPR is enough to create significant uncertainty for brand drug companies. IPR makes intellectual property rights less certain: patents are more likely to be invalidated than they are in district court and even a favorable district court ruling doesn't guarantee that a patent won't be invalidated by a subsequent IPR.

Uncertain patent rights will, in turn, lead to less innovation in the pharmaceutical industry. Brand drug companies are largely responsible for pharmaceutical innovation; since 2000, they have spent over half a trillion dollars on R&D, and they currently account for over 90% of the spending on the clinical trials necessary to bring new drugs to market.[146] But if brand companies can't rely

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[143] U.S. PAT. & TRADEMARK OFF., *supra* note 3, at 5 (indicating that there were ninety-two IPR petitions on pharmaceutical patents in 2014, 167 in 2015 and 159 as of June 30, 2016).

[144] *Id.* at 15.

[145] Jacob S. Sherkow, *Litigating Patented Medicines: Courts and the PTO*, at 5 (Stanford Law Working Paper, 2015), http://law.stanford.edu/wp-content/uploads/sites/default/files/event/862753/media/slspublic/Litigating%20Patented%20Medicines20-%20Courts%20and%20the%20PTO.pdf.

[146] PHRMA, 2015 PROFILE BIOPHARMACEUTICAL RESEARCH INDUSTRY 1, 26, 35-36 (2015), http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf. *See generally* Kaitin,

on their patents, they will have less incentive to engage in costly R&D. Companies will not spend the billions of dollars it typically costs to bring a new drug to market when they can't be certain if the patents for that drug can withstand IPR proceedings that are clearly stacked against them.[147] Indeed, a substantial body of literature shows that strong, predictable patent rights are critical for innovation.[148] If IPR increases the uncertainty of pharmaceutical patent rights, innovation will suffer, harming consumers' health outcomes.[149]

Although proponents of IPR claim that Hatch-Waxman "has been so thoroughly gamed" that it no longer promotes generic entry in the market,[150] the evidence does not support this assertion. Generic drugs now account for 89% of drugs dispensed,[151] and within twelve months of generic entry, these drugs regularly capture over 80% of brand drugs' market share.[152] Moreover, generic utilization continues to grow; these drugs will soon account for over 90% of drugs dispensed in this country. While strategies adopted by certain pharmaceutical companies have been an attempt to avoid generics' continued erosion of brand market share, the

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Bryant & Lasagna, *supra* note 23, at 414 (showing that 92% of new drugs are discovered by private branded companies).

[147] *See* JOSEPH A. DIMASI, DIR. OF ECON. ANALYSIS, TUFTS CTR. FOR THE STUDY OF DRUG DEV., BRIEFING: COST OF DEVELOPING A NEW DRUG (Nov. 18, 2014), http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf.

[148] *See, e.g.*, In re Bilski, 545 F.3d 943, 977 (Fed. Cir. 2008), *cert. granted sub nom.* Bilski v. Doll, 129 S. Ct. 2735 (2009) (Newman, J., dissenting) ("Uncertainty is the enemy of innovation. These new uncertainties . . . diminish the incentives available to new enterprise . . . ."); Jason Scott Johnston, *Uncertainty, Chaos, and the Torts Process: An Economic Analysis of Legal Form*, 76 CORNELL L. REV. 341, 344 (1991) ("[U]ncertainty has been shown to have potentially serious economic consequences in discouraging certain socially desirable, but risky, activities."). *See generally* Craig Allen Nard, *Certainty, Fence Building, and the Useful Arts,* 74 IND. L.J. 759, 759 (1999).

[149] Frank R. Lichtenberg, Columbia University & National Bureau of Economic Research, Conference Presentation on The Economic Value of Medical Research, Pharmaceutical Innovation, Mortality Reduction, and Economic Growth (Dec. 2-3, 1999), http://m.laskerfoundation.org/media/pdf/pharmaceuticalimrec.pdf. (noting empirical estimates of the benefits of pharmaceutical innovation indicate that each new drug brought to market saves 11,200 life-years *each year*).

[150] Gene Quinn, *Senators Mistaken, IPRs Do Not Frustrate Hatch-Waxman*, IP WATCHDOG (June 4, 2015), http://www.ipwatchdog.com/2015/06/04/senators-mistaken-iprs-do-not-frustrate-hatch-waxman/id=58397/.

[151] IMS INSTITUTE FOR HEALTHCARE INFORMATICS, *supra* note 10, at 46.

[152] Grabowski, Long & Mortimer, *supra* note 16, at 207.

courts have typically addressed any practices found to be anticompetitive.[153] Certainly closing any occasional perceived loophole is smarter than providing an end run around Hatch-Waxman and creating an entirely new to pathway to challenge patents.

Instead, Congress should align certain provisions in IPR to mirror those in Hatch-Waxman. First, Congress should ensure that IPR patent claims are interpreted using the same claim construction standard as courts use in Hatch-Waxman litigation. Currently, district courts construe claims according to their "ordinary and customary meaning" to a person of ordinary skill in the art,[154] but the PTAB uses the more lenient "broadest reasonable interpretation" standard in IPR proceedings.[155] Changing the IPR claim construction standard to match that of the courts will ensure that the PTAB is not invalidating too many patents, particularly when patent owners cannot easily amend their claims. Alternatively, if the claim construction standards in IPR and Hatch-Waxman litigation are not aligned, the right to amend in IPR proceedings should be expanded. Then, the justification for using the "broadest reasonable interpretation" in IPR would correspond to the justification for using this standard in initial patent examinations and ex parte reexaminations: because patent owners will have an opportunity to amend their patents, claims can be scrutinized using the broadest lens without necessarily resulting in patent invalidation.

Indeed, the Supreme Court recently recognized in *Cuozzo* that these different standards "may produce inconsistent results and cause added confusion,"[156] and that "use of the broadest reasonable construction standard increases the possibility that the examiner will find the claim too broad (and deny it)."[157] However, the court concluded that only Congress was in a position to mandate a different statute:

> We interpret Congress' grant of rulemaking authority in light of our decision in Chevron . . . [w]here a statute is clear, the agency must follow the statute . . . But where a statute leaves a "gap" or is

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[153] These strategies include reverse payment settlements in cash, certain product hopping situations (in which the manufacturers fabricate safety concerns or falsely disparage the original drug to drive consumers to the new substitute), and abuse of the REMS program. *See e.g.*, Joanna Shepherd, *The Prescription for Rising Drug Prices: Competition or Price Controls*?, HEALTH MATRIX (forthcoming 2017), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2743242.

[154] *See e.g.*, *Phillips*, 415 F.3d at 1312-13.

[155] 37 C.F.R. § 42.100(b).

[156] *Cuozzo*, 136 S. Ct. at 2146 (majority opinion).

[157] *Id.* at 2145 (majority opinion).

> "ambigu[ous]," we typically interpret it as granting the agency leeway to enact rules that are reasonable in light of the text, nature, and purpose of the statute . . . The statute contains such a gap: No statutory provision unambiguously directs the agency to use one standard or the other.[158]

Second, Congress should provide that standards of review in the Federal Circuit are the same for PTAB decisions and district court decisions. Currently a district court's factual findings are reviewed for "clear error,"[159] but the PTAB's factual findings are reviewed using the more deferential "substantial evidence" standard.[160] The inconsistency is especially troublesome given that PTAB factual findings are based on less evidence than are court factual findings. Aligning the standards of review will ensure that, at least at the appellate level, court decisions and PTAB decisions will be reviewed with equal deference.

Indeed, courts have recognized the problems with the inconsistent standards. In April, 2016, the Federal Circuit denied an en banc review on whether the clear error standard should be applied in appeals from IPR proceedings.[161] The Court concluded that the "application of the substantial evidence standard of review is seemingly inconsistent with the purpose and content of the AIA,"[162] yet the Court was not the correct venue to change the standard: "Because Congress failed to expressly change the standard of review employed by this court in reviewing Board decisions when it created IPR proceedings via the AIA, we are not free to do so now."[163] Instead, the Court called on Congress to align the standards of review: "a substantial evidence standard of review makes little sense in the context of an appeal from an IPR proceeding. But the question is one for Congress."[164]

Third, Congress could eliminate certain abuses of IPR by adding a standing requirement that mirrors Article III standing. Currently, any member of the public other than the patent owner can initiate an IPR challenge.[165] The lack of a standing requirement has allowed reverse patent trolls and hedge funds to exploit IPR proceedings for profit. And although the pharmaceutical industry is fighting the abuses of reverse trolls,[166] and IPR challenges by hedge funds may ultimately prove

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[158] *Id.* at 2142 (majority opinion).
[159] FED. R. CIV. P. 52(a)(6); *Cazares*, 121 F.3d at 1245.
[160] 5 U.S.C. § 706(e) (2012); *Merck*, 820 F.3d at 433.
[161] *Merck*, 820 F.3d at 433.
[162] *Id.*
[163] *Id.*
[164] *Id.*
[165] 35 U.S.C. § 311(a) (2012).
[166] *See* Herndon, *supra* note 132.

to be an ineffective strategy,[167] even the risk of such predatory challenges create uncertainty for patent owners.

Congress currently has bills pending before it that would limit standing to exclude parties wielding the IPR for either extortionary purposes or for non-patent related consequences, such as affecting a company's stock value. [168] Adding such a standing requirement would prevent abuse of the IPR proceedings by parties that do not have a direct interest in the validity of a patent.

Alternatively, Congress could conclude that amending the AIA to align all IPR proceedings with Hatch-Waxman litigation is overkill because the current inconsistencies are only relevant and meaningful to pharmaceutical patents. In this case, Congress could instead exempt biopharmaceutical patents from the AIA, excusing patents already subject to Hatch-Waxman or the BPCIA from the IPR process entirely.[169] There is certainly a precedent for such reform—Congress has treated pharmaceutical patents differently from other types of patents since at least 1984. A carve-out would preserve the efficiency benefits of IPR for all non-pharmaceutical patents while restoring the balance that was established by Hatch-Waxman over three decades ago and is critical to pharmaceutical innovation.

CONCLUSION

For patents in most industries, IPR offers a new, efficient alternative to challenge patents of dubious quality. However, for pharmaceutical patents, IPR is a means to avoid the litigation pathway created under Hatch-Waxman over thirty years ago. Critical differences between district court litigation in Hatch-Waxman proceedings and IPR jeopardize the delicate balance Hatch-Waxman sought to achieve between patent holders and patent challengers. As IPR has grown in popularity, it has become evident that these proceedings favor patent challengers; compared to district court challenges, patents are found invalid in almost twice as many IPR challenges.

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[167] *See* J. Gregory Sidak & Jeremy O. Skogs, *Attack of the Shorting Bass: Does the Inter Partes Review Process Enable Petitioners to Earn Abnormal Returns*, 63 UCLA L. REV. DISC. 120, 125-26 (2015).

[168] *See* Support Technology and Research for Our Nation's Growth (STRONG) Patents Act, S. 632 (2015); Innovation Act, H.R. 9, 114th Cong. (2015).

[169] *See* Claire Laporte, *One Patent Law, Two Economic Sectors: Is the One-Size-Fits-All Patent Law Still Workable?*, Health Aff. (Mar. 17, 2016), http://healthaffairs.org/blog/2016/03/17/one-patent-law-two-economic-sectors-is-the-one-size-fits-all-patent-law-still-workable/.

In recent decisions, courts have recognized the anti-patentee bias of IPR, yet punted to Congress the job of changing the provisions. It is critical that Congress reduce the disparities between IPR proceedings and Hatch-Waxman litigation. The high patent invalidation rate in IPR proceedings creates significant uncertainty in intellectual property rights. Uncertain patent rights will, in turn, disrupt the nature of competition in the pharmaceutical industry, drug innovation, and consumers' access to life-improving drugs.

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CORRELATIVE OBLIGATION IN PATENT LAW: THE ROLE OF PUBLIC GOOD IN DEFINING THE LIMITS OF PATENT EXCLUSIVITY

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In light of the recent outrageous price-spiking of pharmaceuticals, this Article questions the underlying justifications for exclusive rights conferred by the grant of a patent. Traditionally, patents are defined as property rights granted to encourage desirable innovation. This definition is a misfit as treating patents as property rights does a poor job of defining the limits of the patent rights as well as the public benefit goals of the system. This misfit gradually caused an imbalance in the rights versus duties construct within patent law. After a thorough analysis of the historical and philosophical perspectives of patent exclusivity, this Article concludes that the extent of exclusivity that patent monopoly currently bestows is unsupported by the philosophy of patent exclusivity that asserts strong public benefits. Alternatively, this Article presents the law of contracts as embodying a framework within which patent law can fit better. By viewing the grant of a patent as a contract with the government in exchange for the patent holder providing a benefit to society, patent owners shall have duties to the society that correspond to their rights under the patent.

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INTRODUCTION

Of all the thieves, robbers, murderers and rapists, one man emerged the "most hated man in America" in the year 2015. That man was Martin Shkreli, the Chief Executive of Turing Pharmaceuticals, and his infamy was a direct reaction to raising the price of Daraprim, a generic drug originally developed in the 1950s, by 5000%.[1] Although the patent on the Turing drug had expired, the price of pharmaceuticals in patent monopoly contexts continues to represent a significant international debate. The price of pharmaceuticals is an important election issue in the United States. In January 2016, fifty Democratic members of the House, led by Representative Lloyd Doggett of Texas, urged government agencies to consider diluting or diminishing the exclusive rights over patents on pharmaceuticals.[2] While the pharmaceutical industry denounced reductions in patent exclusivity as arbitrary on the grounds that they would stifle innovation, non-governmental organizations and the public seemed broadly in favor.[3] At the center of this debate is the role of the exclusivity conferred by the grant of a patent. Contemporary issues involving patent law have struggled to define the limits of patent exclusivity in the context of addressing the ability of patents to deliver the purported objective

[1] Zakir Thomas, *Martin Shkreli: The Man of the (Pharma) Year 2015*, SPICYIP (Jan. 15, 2016), http://spicyip.com/2016/01/guest-post-martin-shkreli-the-man-of-the-pharma-year-2015.html.

[2] Kimberly Leonard, *Can the Government Already Control Drug Prices?*, U.S. NEWS (Jan. 11, 2016), http://www.usnews.com/news/articles/2016/01/11/congressional-democrats-urge-nih-to-act-on-drug-prices.

[3] *Id*.

of public benefit. The effect of patent trolls on innovation, access to essential medicines, and exclusive rights on basic research tools are a mere sample of issues that have raised doubts regarding the patent system's ability to serve its preordained promise of public benefit.[4] In all, the quest for a patent system that serves to encourage desirable innovation without imposing undue social cost is ongoing, and its end remains elusive.

Traditionally, scholarly discussions on the limits of patent exclusivity posit patents in functional terms. That is, patents are defined as property rights granted to encourage desirable innovation. The system was designed to capture the objective of enhancing public benefit by incentivizing creativity without imposing undue social cost. However, positing patent law within the property framework has been used to support a notion that the patent system is functioning to ultimately achieve its objectives.[5] Scholars and even courts rely on a property rhetoric to sustain the patent system.[6] Generally, the property based conception of patents has had the laudatory impact of working towards a system that results in more patents, which is decoded as more innovation, which, in turn, is discerned as an increase in public benefit.[7] Such a perception of patents has beneficially encapsulated patent law with the appealing sheen of producing public benefit.[8]

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[4] *See Electronic Frontier Foundation: Defending Your Rights in the Digital World*, ELEC. FRONTIER FOUND., https://www.eff.org/issues/resources-patent-troll-victims (last visited Sept. 2, 2016); *see also* James Bessen, *The Evidence Is In: Patent Trolls Do Hurt Innovation*, HARV. BUS. REV. (Nov. 2014), https://hbr.org/2014/07/the-evidence-is-in-patent-trolls-do-hurt-innovation. *See generally* Robert L. Stoll, *Patent Trolls: Friend or Foe*, WIPO MAGAZINE (Apr. 2014), http://www.wipo.int/wipo_magazine/en/2014/02/article_0007.html; U.S. CONST. art. 1, § 8, cl. 8.

[5] *See* William Fisher, *Theories of Intellectual Property*, *in* NEW ESSAYS IN THE LEGAL AND POLITICAL THEORY OF PROPERTY, 168, 169 (Stephen R. Munzer ed., 2001); Horne v. Dept. of Agric., 135 S. Ct. 2419, 2441-43 (2015) (holding that the Takings Clause imposes a "categorical duty" on the government to pay just compensation whether it takes personal or real property, thereby overruling the Ninth Circuit, which had previously held that personal property receives less protection under the Takings Clause than real property); *see also* Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause*, 87 B.U. L. REV. 689, 689 (2007).

[6] *Id.*

[7] *See, e.g.*, Harold Wegner, *China Leads Top Five Patent Filing Countries*, LAIPLA (Mar. 13, 2016), http://www.laipla.net/china-leads-top-five-patent-filing-countries/; *see also* Jason Rantanen, *US Patent Application Filings for FY 2015*, PATENTLYO (Oct. 15, 2016), http://patentlyo.com/patent/2015/10/patent-application-filings.html.

[8] *See* John C. Stedman, *Invention and Public Policy*, 12 LAW AND CONTEMP. PROBS. 649, 649-79 (1947); *see also* David Kestenbaum, *Evaluating The Benefits And Costs Of Patents*,

This paper asserts that patent law is a misfit within the traditional property regime. That is, the prevailing notions of patents as an extension of property rights lead one to construe patents in terms of rights rather than obligations. Property law posits rights in correlative terms and thus, defines rights from the perspective of the duty of third parties. Thus, acquisition of patent rights signals a societal duty to forbear from the patented invention. However, the property-based construct of patents does a poor job of defining the limits of the rights. As such, patent law lacks a clear outline or measure of the patent owner's duties corresponding to the rights.

For instance, property regimes, rarely, if ever, provide for absolute ownership. While Blackstone may have touted an Englishman's "sole and despotic dominion" over his land, ownership over real property is regularly subject to public interests.[9] Eminent domain and government regulations over private property serve as examples of how public interests limit private property. Thus, in real property law, the components of ownership and the ensuing exclusivity have clear limits and are tied to the larger goals of establishing societal orderliness. In contrast, contemporary patent law struggles with defining the outer limits of patent exclusivity.[10] Importantly, over time, it has resulted in a lack of correlation or proportionality between exclusive rights and the public benefit goals it seeks to achieve.[11] For example, a patent owner has limited duties in return for acquiring the exclusionary rights. The patent owner has no direct duty towards securing the end of public benefit, save for the disclosure. The patent mechanism does not clearly define whether, and if so, when, public interest considerations supersede the private rights of the patent owner. For example, a pharmaceutical patent owner does not have a duty to institute access-enabling mechanisms.[12] Even during a

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NATIONAL PUBLIC RADIO (July 17, 2014), http://www.npr.org/2014/07/17/332205119/evaluating-the-benefits-and-costs-of-patents (discussing the costs and benefits of patents).

[9] 2 WILLIAM BLACKSTONE, COMMENTARIES *2 ("[T]he right of property; or that sole and despotic dominion which one man claims and exercises over the external things of the world, in total exclusion of the right of any other individual in the universe.").

[10] *See, e.g.*, JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 30-70 (2008) (asserting and outlining the ways in which patent laws do not work well with property rights).

[11] *See* ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY 150 (2011) [hereinafter, JUSTIFYING IP] (discussing the role of proportionality).

[12] *See* 35 U.S.C. § 271; Thomas F. Maffei, *The Patent Misuse Doctrine: A Balance of Patent Rights and the Public Interest*, 1 J. PAT. & TRADEMARK OFF. SOC'Y 178 (1970); *see also* Stedman, *supra* note 8, at 649-79; Jeanne C. Fromer, *Should The Law Care Why Intellectual Property Rights Have Been Asserted?*, 32 HOUS. L. REV. 549 (2015).

public health crisis, a patent owner is not legally obligated to price differentially or license the patent, voluntarily or compulsorily.[13] While patent owners have a duty to honor a state's power of eminent domain, the practice of compulsory licensing has been controversial.[14] Thus, under the current structure, the obligation of patent owners in the context of the larger goals of the system is unclear. A lack of clear limits, this paper highlights, has caused an imbalance in the rights versus duties construct within patent law. It has also blurred the lines that define the public benefit goals of the system.

This shift in rhetoric towards a rights-centric approach has resulted in a more Blackstonian view of patent protection, causing patent law to move away from the public benefit goals of the system. Consequently, instrumental elements of the patent system have coalesced to predominantly protect the inventor. In turn, public benefit aspects of the system have been relegated to the status of a by-product. Patent law has long suffered from a lack of a realistic scale to measure its output, which has led to technical measures such as the number of patents to become predicates of its outcome. Slowly, patent disclosures increasingly became perceived as the sole exchange for gaining exclusivity. Disclosure has come to be treated as the singular constituent element that delivers the objectives of the system.[15] The resulting tendency is to treat quantitative measures – the number of patents issued – as a proxy for desirable innovation that is presumed to benefit the public. Consequently, more private property has come to denote more public benefit. That is perhaps why more patents are generally considered desirable. We are at a point where scholars, and even courts, express their discontent over the quality of innovation and disclosures.[16]

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[13] *See generally* U.S. CONST. amend. V ("[N]or shall private property be taken for public use, without just compensation."). Eminent domain has always been an exception to the acquisition of private property, though the extension of the same principles in patent law has been much more controversial.

[14] Mark W. Lauroesch, *General Compulsory Patent Licensing in the United States: Good in Theory, But Not Necessarily in Practice,* 6 SANTA CLARA HIGH TECH. L.J. 41 (1990); *see* Cole M. Fauver, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come,* 8 NW. J. INT'L L. & BUS. 666 (1988).

[15] *See* PETER DRAHOS, A PHILOSOPHY OF INTELLECTUAL PROPERTY 213 (1996) (explaining that the term instrumentalism is connected with the doctrine of pragmatism which in law, refers to the idea of law serving as a tool, although Drahos would define the non-duty based instrumentalism as outlined in this paper as a form of proprietarianism).

[16] *See* In re Bilski, 545 F.3d 943, 1004 (Fed. Cir. 2008) (Mayer, J. dissenting) (referring to the low-threshold for patent eligibility to note that it has resulted in patents ranging from the

This paper's main assertion is that the extent of exclusivity that patent monopoly currently bestows seems unsupported by the doctrinal construct of the philosophy behind exclusivity.[17] Thus, at the outset, the discourse in this paper outlines the historical as well as the philosophical perspectives of patent exclusivity. A nuanced observation of the history of patent exclusivity reveals that the basic doctrinal and normative structure of patent law provides limited exclusivity focused on achieving the one goal of public benefit. Consequently, the goal of securing public benefit defines the limits of exclusivity, and by default, the patent system. That is, public benefit serves as the scale to measure the merits of the patent system.[18] Such a measure directly addresses the obligation of the patent system and provides an outcome not only addressing the rights in patents, but more importantly, their limits.

Next, the paper traces the prevailing rights over patents. The discussion outlines how scholars and courts historically associated patent rights as a means to achieve two functional ends,[19] namely: (i) encouraging or incentivizing innovation to achieve larger public benefit goals; and (ii) disseminating information through disclosure.[20] Over time, each of these outcomes has come to represent interrelated functions, regardless of whether they do or not in fact. Disclosure has come to be

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somewhat ridiculous to the truly absurd); Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 641, 667-69 (2011) (asserting that unlike how it is in its current form, the patent document should be readable to fully perform its teaching function); *see also* Charles Duhigg & Steve Lohr, *The Patent Used as a Sword*, N.Y. TIMES, Oct. 8, 2012, at A14; Benjamin N. Roin, Note, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007 (2005). *See generally* ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT (2002).

[17] *See* David B. Schorr, *How Blackstone Became a Blackstonian*, 10 THEORETICAL INQUIRIES IN LAW 103, 104-06 (arguing that Blackstone himself "did not believe that this absolutist and individualist conception" of property squared with the prevailing British notions of property).

[18] *See generally* GEORGE C. CHRISTIE & PATRICK H. MARTIN, JURISPRUDENCE, TEXT AND READINGS ON THE PHILOSOPHY OF LAW (3d ed. 2007).

[19] *See* Roin, *supra* note 16; see also Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123 (2006); Eldred v. Ashcroft, 537 U.S. 186, 227 (2003) (Stevens, J., dissenting); Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998) (stating that the patent system should be thought of as "a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time"); Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 429 (1984).

[20] *See* Roberto Mazzoleni & Richard R. Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 RES. POL'Y 273, 274-300 (1998). *See generally* U.S. PATENT & TRADEMARKS OFFICE, THE STORY OF THE AMERICAN PATENT SYSTEM: 1790-1952 (1953).

interrelated with inventive presence to the extent that more disclosure has come to mean more inventive activities. Slowly, under the contemporary view, securing patent rights is implicitly considered as satisfying the twin objectives of encouraging innovation and disseminating information. Such a construct, this paper asserts, dampens the presence of a duty of the patent owner to society. Instead, it has posited patent grants largely within a rights paradigm, diluting the duty requirement of the patent holder. Slowly, the grant of a patent is presumed to fulfill the corresponding duty to discharge the innovation and dissemination objectives of the patent system. The realigned rights and duties relationship in its prevailing form has led to a distorted understanding of patent law divorced from its social responsibilities. Thus, the absoluteness of the currently prevailing form of rights over patents, generally attributed as a by-product of association with property law, is perhaps misguided.[21]

Last, the paper asserts that the patent owner has a corresponding duty which arises from the overlay of the law of contracts on underlying patent law theories. The characteristic feature of contract law, on which intellectual property is heavily based, imposes corresponding obligations or responsibilities over the rights holder. The paper draws support from historic and philosophical sources of intellectual property law to assert that the overlay of the law of contracts on patents cannot be ignored. Instead, the overlay of the law of contracts is desirable because it can better tailor patent law to encourage innovation without undue social costs. The grant of monopoly rights is a contract with the government in exchange for the patent holder providing a benefit to society. The intrinsic nature of contract law imposes corresponding obligations on the rights holder. The contract necessarily balances granted rights with imposed corresponding obligations of the patent owner. That is, the patent owner would be subject to an obligation in proportion to the rights granted.[22] Such a design would result in public benefit goals inherently limiting the ambit of patent exclusivity.

The historic role of the exclusivity doctrine, from which Part I of this paper proceeds, is the obvious starting point to appreciate the role and architecture of the exclusivity doctrine in the context of the public benefit expectations. Part II

[21] *See also* Shubha Ghosh, Duty, Consequences, & Intellectual Property, 10 U. ST. THOMAS L.J. 801 (2013) (noting that the heavy reliance on utilitarianism has resulted in an approach that measures success based on an aggregated rather than an individualist outcome). Ghosh points out that a measure of success under the utilitarian theory would consider technical success first, and consequences second. *Id.* at 8.

[22] *See generally* MERGES, *supra* note 11, at 150-51.

highlights how instrumental elements of the contemporary patent regime have suffered from an acute disconnect with the targeted objectives of the system, resulting in a rights-centric patent system. Next, Part III defines the ambit of the correlative duty to delineate the rights and obligations in the background of the current system. In doing so, Part III examines the kernel of the rights in patents as well as the source of the duty not to infringe and concludes that patent law needs to be reoriented from the perspective of the grant in order to achieve the public benefit objectives.

I
OF EXCLUSIVITY & PUBLIC BENEFIT

This part explores the doctrinal core of patent exclusivity and presents a historical understanding of the doctrine in terms of its objectives. The historical orientation of patents is examined in the context of its nexus with the public benefit obligation. In doing so, the narrative postulates that patent exclusivity can be most effective when viewed from its ordained public function. Hence, patent exclusivity is meant to be limited by larger public benefit considerations. Disclosures, while serving an important role, cannot represent the sole exchange for gaining exclusive rights.

A. A Historical Overview of the Doctrine of Exclusivity

The core of patent law's doctrinal and normative structure can best be elucidated from the writings of Thomas Jefferson.[23] In denying a connection between patent law's proprietary underpinnings and natural rights, Jefferson asserts that the exclusive right to the invention is a direct return for the benefit that the society will derive.[24] Jefferson describes the concept of stable ownership as a mere gift of social law as opposed to a natural right.[25] Jefferson indicates that the exclusive right of the patent owner is not a natural right, but instead is an encouragement "to pursue ideas which may produce utility but this may or may not be done, according to the will and convenience of the society, without claim or

[23] *But see* Adam Mossoff, *Who Cares What Thomas Jefferson Thought about Patents? Reevaluating the Patent Privilege in Historical Context*, 72 CORNELL L. REV. 953 (2007).

[24] Letter from Thomas Jefferson to Isaac McPherson, No Patents on Ideas (Aug. 13, 1813), http://www.red-bean.com/kfogel/jefferson-macpherson-letter.html; Letter from Thomas Jefferson to James Madison (July 31, 1788), *in* 1 THE FOUNDERS' CONSTITUTION 476 (Philip B. Kurland & Ralph Lerner eds., 1987).

[25] *See* Adam D. Moore, *A Lockean Theory of Intellectual Property*, 21 HAMLINE L. REV. 65, 65 n.5 (1997) (noting that Thomas Jefferson explicitly disavowed any natural-law underpinning of intellectual property rights).

complaint from anybody."[26] Thus, benefit to society is the central theme in Jefferson's thinking. Jefferson emphasizes the line that segregates items for which society can suffer "the embarrassment of an exclusive right" from those for which it cannot.[27] For Jefferson, products that can benefit from exclusive rights ought to be clearly distinguished from those that do not deserve or require such protection, although he acknowledges the difficulties of the exercise.[28] Patent Commissioner Conway Coe would later rephrase the trade-off as one where "giving the inventor a limited amount of protection, [it] assures society of the benefits of his genius."[29] Thus the internal core of patent law connects societal benefit to the vested exclusive rights.[30]

The inherent dilemmas confronting the rights versus obligation question were captured by Thomas Jefferson in his letter to Isaac McPherson.[31] Jefferson, himself an inventor and a draftsman of the 1793 Patent Act,[32] outlined to McPherson in 1813 the social and economic rationale of the patent system.[33] He wrote, "[s]ociety may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from anybody."[34] The societal discretion outlined in Jefferson's conception of patents creates the impression of a contract, which posits society's benefit as the consideration for patent exclusivity.

In his classical treatise on patent law, and like many other scholars after him, George Curtis defines patents from a contractual standpoint as a "grant by the government, to the author of a new and useful invention, of the exclusive right, for

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[26] Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), http://www.let.rug.nl/usa/presidents/thomas-jefferson/letters-of-thomas-jefferson/jefl220.php [hereinafter *Letter to McPherson*].

[27] *Id.*

[28] *Id.* ("Considering the exclusive right to invention as given not of natural right, but for the benefit of society, I know well the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not.").

[29] *See* THE STORY OF THE AMERICAN PATENT SYSTEM: 1790-1952, *supra* note 20.

[30] *Id.*

[31] *Letter* to *McPherson*, *supra* note 26.

[32] *See* P.J. Federico, *Operation of the Patent Act of 1790*, 18 J. PAT. OFF. SOC. 237, 238 (1936); *see also* Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 7 (1996).

[33] *See Graham*, 383 U.S. at 7-9.

[34] *Id.* at 37 n.2; *see also* THOMAS JEFFERSON, VI WRITINGS OF THOMAS JEFFERSON, 180-81 (Washington ed. 2013).

the term of invention, of practicing that invention."[35] The consideration for the grant, Curtis reflects, "is the benefit to the society resulting from the invention."[36] When viewed through a contract law lens, a patent subjects an inventor to an obligation to provide benefits to the public in exchange for the public's refrainment from the patented invention.

The primacy of the social benefit component of patents has survived to date and forms an integral part of U.S. patent law. For instance, at a speech delivered during the Centennial Celebration of the American Patent System in 1891, W.C. Dodge reiterated that our patent system is based on the idea of primarily benefitting the public and not the inventor.[37] The U.S. Supreme Court endorses the view that exclusivity is a sufferance self-imposed by society (designed as an award by the government to the inventor) to generate a larger public good. In *Graham*, the Supreme Court echoed Jefferson's words in holding that "the patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge."[38] Similarly, Margaret Chon argued in 1993 that James Madison, whose thinking had significant impact on U.S. patent law, subscribed to the view that "the public good fully coincides with the claims of individuals."[39] Chon discusses how Madison repeatedly claimed that there is no contradiction between simultaneously maximizing self-interest and the public good.[40] Thus, the social benefit component of patents seems to have survived contemporary times. In sum, the societal tolerance of the monopoly is to encourage creation of more innovations that benefit society, whereas disclosures merely help make the knowledge public. Society will,

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[35] GEORGE TICKNOR CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS IN THE UNITED STATES OF AMERICA 1 (2d ed. 1854).

[36] *Id.*

[37] James L. Ewin, *The Minor Innovations of the Century*, *in* UNITED STATES BICENTENNIAL COMMEMORATIVE EDITION OF PROCEEDINGS AND ADDRESSES 478 (1892).

[38] *Graham*, 383 U.S. at 9 ("The grant of an exclusive right to an invention was the creation of society – at odds with the inherent free nature of disclosed ideas – and was not to be freely given. Only inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly.").

[39] *See* Margaret Chon, *Postmodern "Progress": Reconsidering the Copyright and Patent Power*, 43 DEPAUL L. REV. 97, 137-38 (1993); *see also* THE FEDERALIST NO. 43 (James Madison).

[40] *Id.* at 138.

for its own benefit, bear the correlative duty of tolerating the exclusive right for the term of the patent.[41]

B. A Philosophical Perspective of the Exclusivity Doctrine

Against this historical background of the doctrinal core of patent exclusivity, the philosophy of patent exclusivity, outlined below, further asserts the strong public benefit underpinnings in this area of the law. The predominant focus was seemingly on the end objective of the system. This part highlights that whether from a natural rights, private, or public law perspective, patents were viewed as fulfilling a social benefit objective. Thus, the narrative postulates that the role of exclusivity was limited and confined by the larger needs of the society. In doing so, this section asserts that exclusivity can be most effective when viewed from such an ordained public function.

The role of public benefit in the context of the awarded exclusive rights has traditionally resonated as part of the discussions on patents. Captured originally by Jefferson, the importance of the public benefit end has been reiterated by other distinguished experts.[42] For instance, the Honorable William E. Simonds, Commissioner of Patents, reasoned that the extent of *natural right* exclusivity in intellectual property creations should be subject to limitations such as the principle of necessity.[43] "Each original inventor of an improvement in the useful arts," he outlined, "has . . . the same kind of a title to the exclusive enjoyment thereof . . . ."[44] Commissioner Simonds further added, "[w]hile the exclusive natural right to an invention is a correct thing in theory, its exercise is suppressed through necessity."[45] Although Simonds considered patents as natural rights (unlike Jefferson, who posited patent rights as social rights), he nonetheless found that necessity could circumscribe the extent of the rights. Thus, interference into patent

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[41] *See* Dotan Oliar, *Making Sense of the Intellectual Property Clause: Promotion of Progress as a Limitation on Congress's Intellectual Property Clause*, 94 GEO. L.J. 1771, 1816 (2006) ("[The] three considerations — the fact that the Framers would not adopt the intellectual property proposals in the plenary form in which they were made, the political makeup of the Convention, and the origin of the words in the Progress Clause as qualifiers of other powers — all contribute to one consistent story according to which the Progress Clause was intended to limit Congress's intellectual property power.").

[42] JEFFERSON, *supra* note 34.

[43] *See* William E. Simonds, *Natural Right of Property in Intellectual Production*, 1 YALE L.J. 16, 24 (1891).

[44] *Id.* at 24.

[45] *Id.* at 25.

exclusivity to ensure societal benefit is viewed as a legitimate exercise serving the objective of the system. Elsewhere Simonds outlined that "[i]n all forms of society all kinds of property are held under such conditions and limitations as society deems reasonable. Under the right of eminent domain governments take private property for public use on suitable remuneration when public necessity and convenience demanded,"[46] and that "[i]t is therefore entirely reasonable that society should set a limit to the enjoyment of the natural right of property in intellectual productions."[47]

Three important points stand out from Simonds' work that are exemplary of early thinking regarding the limits of rights of the inventor.[48] First, early thinking on patent law was pervaded by concerns of its outcome – that is, the system's ability to achieve its preordained objectives – rather than the rights that it created. Even a natural rights theorist such as Simonds considered circumscribing patent exclusivity to achieve the system's objectives. Second, early developments of patent law seemed to repeatedly warrant interference into patent exclusivity if the patent system was not primarily functioning to ensure flow of benefits to society. Thus, it leaves a perception that early thinking revolved around the concept of society tolerating the grant of some rights on the inventor, as opposed to an inventor earning these rights. Third, the obvious view from the societal lens dictates adequate limitations if the end – the public benefit objective of the system – is not well served.

These three points taken together demonstrate that the correlative duty is not a per se reward for the inventor's genius, but a toleration by society, driven and dictated by the larger public benefit. An inventor can gain recognition and rights as a consequence of the invention, but the exclusivity aspect of the right is simply an intended by-product of the correlative duty that the society willingly tolerates. From the perspective of the law of contracts, correlative duty can be viewed as a consideration for the larger public benefit. Simonds' background as the Commissioner of Patents perhaps defined his conception of patents as a natural right. Yet both Simonds and Jefferson seem to suggest that the operation of patent law and the exercise of exclusivity is circumscribed by the needs of society.

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[46] *Id.* at 23.

[47] *Id.* at 24.

[48] *See* MERGES, *supra* note 11, at 148 (expounding fully Locke's theory of property and applying it to intellectual property rights).

Interestingly, Professor Balganesh makes a similar assertion in the background of H.L.A. Hart's philosophy with respect to copyright law.[49] Professor Balganesh suggests that "while the [rights and duties] always go together, the systematic neglect of copyright's 'duties' in copyright jurisprudence and scholarship has over time skewed our understanding of copyright's basic structure as an area of law endowed with an obligatory dimension. . . ."[50] Patent law suffers from the same malaise. The rights package of patents necessarily embodies obligations imposed on patent holders, a corresponding obligation to bring forth public benefit. The framework of the obligations are perhaps reminiscent of the bipolar feature of private law highlighted by Professor Balganesh, who noted that the rights package vested on the inventor necessarily imposes a correlative duty on the society to not infringe, and a corresponding obligation on the inventor to generate public benefit.[51] When exclusive rights are considered from the perspective of the self-imposed correlative duty of society to refrain from the property in exchange for public benefit, patent law can be accommodated into the edifice of private law. In turn, the inventor's corresponding duty to society arises from the overlay of the law of contracts over theories of intellectual property law.[52]

While patent law is not a perfect fit within the property regime, broad encapsulation of the limits of patent rights treads closely with the Lockean theory of property. Locke elaborates, "Nothing was made by God for Man to spoil or destroy."[53] Locke conceives of property rights as entitlements to a person for exercising labor:

> The same law of Nature that does by this means give us property, does also bound that property too. . . . As much as anyone can make use of to any advantage of life before it spoils, so much he may by his labor fix his property in. Whatever is beyond this is more than his share, and belongs to others. . . .[54]

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[49] Shyamkrishna Balganesh, *The Obligatory Structure of Copyright Law: Unbundling the Wrong of Copying*, 125 HARV. L. REV 1664, 1665-66 (2012).

[50] *Id*. at 1666.

[51] *See id*. at 1667-68.

[52] *See id.*; Raymond T. Nimmer, *Breaking Barriers: The Relation Between Contract and Intellectual Property Law*, 13 BERKELEY TECH. L.J. 827, 844 (1998) (writing with reference to copyright law although the same principles can be applied to patent law).

[53] JOHN LOCKE, TWO TREATISES OF GOVERNMENT 136 (Thomas I. ed., 1947) (1690).

[54] *Id.*

Thus, under the Lockean conception of property, the appropriation of property rights is only through the creator's own sweat of the brow, and the right is subject to the sufficiency and spoliation obligations. The sufficiency restriction requires that one must leave "enough and as good" for others, which Locke asserts is an integral part of a just property regime. The spoliation principle states that the creator may only appropriate as much as the creator is able to use, and may not claim ownership of so many natural resources that some of them spoil before he is able to use them.[55]

Locke's theory of sufficiency and spoliation goes further than Simonds' necessity theory and provides a clearer limitation to the natural rights over property. In the patent context, while Locke's theory fully recognizes the rights of the inventor, it also subjects the rights to the sufficiency and spoilage limitations. Locke's implication is that the space for disputes over property exists because resources can become limited even though they may presently exist in abundance. That is, an inventor's appropriation should be limited by need and not greed. Also, property holders must leave "enough and as good" for others. Locke repeatedly suggests that there is something morally wrong with distributions in which some people's property leaves others with very little.[56] Ironically, largess of possession has come to present a problem in the contemporary patent system. That is, the grant of patent rights cannot work to the detriment of social benefit. If it does, the sufficiency proviso will empower society to use the property for public benefit. Commenting on this, John Simmons would later say, "[t]he clear implication is that in later ages, when scarcity is a problem, there is room for doubt about . . . largeness of possession."[57]

Writing about the Lockean provisos in the context of copyright law, Wendy Gordon asserts, "[i]f a new creation renders the public domain less valuable, the proviso gives people a privilege to use the new creation to the extent necessary to make themselves as well off as they previously were."[58] Among other things, Gordon asserts that this means that major cultural developments must be open for

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[55] George H. Smith, *John Locke: Some Qualifications in Locke's Theory of Property*, LIBERTARIANISM.ORG (Nov. 2015), *available at* http://www.libertarianism.org/columns/john-locke-some-qualifications-lockes-theory-property.

[56] Daniel M. Layman, *Sufficiency and Freedom in Locke's Theory of Property*, EUR. J. POL. THEORY (2015), *available at* http://ept.sagepub.com/content/early/2015/06/01/1474885115587118.full.pdf.

[57] JOHN A. SIMMONS, THE LOCKEAN THEORY OF RIGHTS 291 (1992).

[58] Wendy J. Gordon, *A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property*, 102 YALE L.J. 1533, 1572 (1993).

all to use in order to preserve the integrity of the public domain.[59] In the patent context, life-saving drugs created using biodiversity products or drugs created using public funds are examples of classes of things that society should have access to use to the extent necessary. Gordon also concludes that the spoliation proviso in the copyright context prevents ownership over abstract ideas because it "preserves . . . public domain."[60] A similar limitation is needed in the patent context. Public health is a great example to serve as a bar for limiting exclusivity following the grant of the patent. Such limitations will also define the contours of the corresponding obligation of the patent owner in return for the rights gained. Lack of an adequate public interest exception and flexibility to enable access in the patent context can lead to disastrous outcomes. This is particularly the case, for example, in the event of a public health crisis, which can potentially be more disastrous in economic value than a copyright regime without a free speech exception. Such a reading underscores the importance of the public interest limitations of patent rights.[61]

In the context of Lockean exceptions, it is worth pointing out that Curtis believes that public benefits from patents flowed through two channels: first, the practice of the invention during the patent term; second, the opportunity to practice the patent after its expiration.[62] The Curtis treatise is perhaps the first to contextualize the importance of practicing the invention during the term. In doing so, Curtis seemingly connects exclusivity with the spoliation proviso in that it imposes a burden on the patentee to practice the invention during the patent term to prevent spoliation. Curtis' work is significant in highlighting a nexus between exclusivity vested on the inventor and the requirement that the inventor practice the invention during the term. The question of whether practice of the invention by the inventor during the term is relevant to securing the broader public benefit goals

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[59] *Id. But see* JEREMY WALDRON, GOD, LOCKE AND EQUALITY: CHRISTIAN FOUNDATIONS IN LOCKE'S POLITICAL THOUGHT 158-63 (2002) (asserting that sufficiency is not a limitation especially where resources are scarce).

[60] *Id.*

[61] *But see* Jeremy Waldron, *From Authors to Copiers: Individual Rights and Social Values in Intellectual Property*, 68 CHI.-KENT L. REV. 841, 847 (1993) ("Being constrained by rules of intellectual property is a different matter from being constrained by material property rules. The homeless person may freeze or starve because he finds himself excluded from every sheltered place and prohibited from taking literally any piece of food."). Waldron's assertions completely ignore the impact of being constrained by intellectual property from accessing essential medication.

[62] CURTIS, *supra* note 35.

of the system has become an important issue.[63] Curtis' conception of exclusivity as creating at least an opportunity for the public to practice the invention is much broader than a mere disclosure to the public. At the very minimum, it prevents the patentee from hoarding the patent by not putting it into use during the patent term. This conception of exclusivity prevents inventors from circumventing the patent system by deliberately not practicing the invention and, in effect, hiding the invention from the public during the term of the patent.

The above discussion on exclusivity is important to understand the foundations of the exclusivity doctrine. The repeated resonance of the public benefit objective is a common theme that informs both the historical and philosophical foundations of the exclusivity doctrine. It is imperative for the contemporary patent regimes to be engaged with the foundational objectives for the system. With that background, the discussion below outlines the role of patent disclosure to determine its role vis-à-vis patent exclusivity as well as the objectives of the system.

II
THE EMERGENCE OF A RIGHTS-CENTERED PATENT REGIME

This part traces how, over time, the U.S. patent regime has become more rights-centric by focusing on the assumption that more disclosures entail more innovation. Such an encapsulation of the patent regime relegated the public benefit objective to a secondary position as a by-product instead of a mandatory obligation. The discussion below begins with how disclosures came to occupy a central position. It then highlights the various roles that courts have embraced for patent disclosures, which in turn has taken the focus away from the question of whether the system is serving its historical objective of benefitting society.

A. Early Signs of Disconnect

This section examines the engagement of the exclusivity doctrine with the disclosure aspect of patent registration. In doing so, it traces the effect of such engagement as resulting in a disconnect of the exclusivity doctrine from its intended goals and public benefit expectations.

Historically, it would be incorrect to categorize the U.S. patent system as tending towards the rights side of the balance. In *Kendell v. Windsor*,[64] the Supreme Court noted that "[t]he limited and temporary monopoly granted to

[63] *Id.*

[64] Kendall v. Winsor, 62 U.S. 322, 328 (1858).

inventors was never designed for their exclusive profit or advantage . . . the benefit to the public or community at large was another and doubtless the primary object in granting and securing that monopoly."[65] Rather, "the true policy and ends of the patent laws enacted under this Government are disclosed in that article of the Constitution . . . 'to promote the progress of science and the useful arts,' contemplating and necessarily implying their extension, and increasing adaptation to the uses of society."[66] Courts were cautious not to create unwarranted private property. The skepticism against granting a patent was so high that there was a time when Justice Jackson himself lamented that "the only patent that is valid is one which this court has not been able to get its hands on."[67]

Yet the seeds of a rights-centric regime were laid much earlier. The constitutional powers of Congress notwithstanding, courts – especially the U.S. Supreme Court – have played an important role in shaping the doctrine.[68] Two cases in the early 1800s arguably set the tone for correlating public acquisition at the end of the patent term as fulfilling the components of the exclusivity obligation. In *Evans v. Eaton*,[69] the Supreme Court held that "patent law confers a benefit on the discoverer of any artful invention, which consists in a monopoly of his invention for a limited time."[70] Further, "[t]he consideration which it requires him to pay for this benefit, is to put the public in possession of his invention; so as to enable all to use it, *after his* monopoly shall expire."[71] The Court's use of the term "consideration" alluded to the patent holder putting the public in possession of the invention in exchange for securing the rights. But the Court defined the consideration in exchange for exclusivity as the public benefitting and progressing from the invention *after* the monopoly expires, focusing on disclosure and ignoring other important aspects such as the public benefit from practicing the invention

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[65] *Id*. The House Committee reporting on the 1909 Copyright Act echoed the same sentiment: "[T]he enactment of copyright legislation by Congress under the terms of the Constitution is not based upon any natural right that the author has in his writings, . . . but upon the ground that the welfare of the public will be served . . . ." H.R. REP. NO. 60-2222, at 7 (1909).

[66] *Kendall*, 62 U.S. at 328.

[67] Jungersen v. Ostby & Barton Co., 335 U.S. 560, 572 (1949).

[68] U.S. CONST. art. I, § 8, cl. 8. The concept of exclusivity is ingrained in the Constitution "to promote the Progress of Science and useful Arts, by securing for limited Times to authors and inventors the exclusive right to their respective Writings and Discoveries." *Id.*

[69] Evans v. Eaton, 20 U.S. 356 (1818).

[70] *Id.* at 413; *see also* MERRILL D. PETERSON, THOMAS JEFFERSON AND THE NEW NATION: A BIOGRAPHY 937-38 (1975).

[71] *Evans*, 20 U.S. at 413-14; *see also* U.S. CONST. art. I, § 8, cl. 9.

during the patent term. Similarly, in the 1829 case *Pennock v. Dialogue*,[72] Justice Story opined that the crux of the patent system is to enable the public to ultimately acquire the innovation while recording "due regard" to the inventor in the form of exclusivity.[73] While it is clear that the Court conceptualized the objective of a patent in terms of public acquisition of the invention, these cases implied that the public benefit aspect of exclusivity can flow after the patent term.

Further, these cases also laid the foundation for a steady instrumental development of patents by positing a patent holder's exclusive rights on a broad platform of the progress of science and arts.[74] That is, they led to an organic appreciation wherein the relationship between patents and the progress requirement was measured by the quantity of patents, which in turn, fed into the public benefit. The result was a slow process that steadily divorced or distanced the inventor from any direct obligation to achieve the ultimate goal of public benefit. To date, the constituent elements of the "progress" requirements remain unresolved. Whether it is the disclosure, number of patents, technological advancement, public benefit, or a combination of one or more of these factors, remains unsettled.[75] Over time, however, courts have come to view patent protection as a necessity for encouraging innovation despite economic studies to the contrary, which, in turn, has resulted in a view that the extent of private property rolled out is a standard measure of progress.[76] But even assuming that the number of patents issued can

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[72] Pennock v. Dialogue, 27 U.S. 1 (1829).

[73] *Id*. at 12 ("The constitution of the United States has declared, that congress shall have power 'to promote the progress of science and useful arts, by securing *for limited times*, to authors and inventors, the exclusive right to their respective writings and discoveries.' It contemplates, therefore, that this exclusive right shall exist but for a limited period, and that the period shall be subject to the discretion of congress.").

[74] *Id.*; *see also* Diamond v. Chakrabarty, 447 U.S. 303, 315-16 (1980); Oliar, *supra* note 41, at 1816.

[75] Simone A. Rose, *The Supreme Court and Patents: Moving Toward a Postmodern Vision of "Progress"?*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1197, 1203 (2013).

[76] *See* Ass'n for Molecular Pathology v. USPTO, 653 F.3d 1329, 1371 (Fed. Cir. 2011) (arguing that patent protection for genomic material, including isolated genes is crucial for continued innovation and economic growth of biotechnology industry). Judge Newman wrote:

> The decisions in *Allappat* and *State Street Bank* confirmed the patent eligibility of many evolving areas of commerce, as inventors and investors explored new technological capabilities. The public and the economy have experienced extraordinary advances in information-based and computer-managed processes, supported by an enlarging patent base. The PTO reports that in Class 705, the examination classification associated with "business methods" and most likely to receive inventions that may not use machinery or transform physical matter, there

serve as a loose measure of technological advancement, the public benefit aspect of progress, or in other words, the application of the technology towards societal progress, remains unclear.[77] That is, the patent system has been clearly posited as being ordained by the Constitution to promote progress, but much is needed to decipher the elements of progress. It cannot be mechanically equated with either technological advancement or number of patents issued without a clear delineation of public benefit goals.

Under basic contract theories, on which patent law is partly premised, vesting rights sans appropriate obligations (which happens if the term "progress" is not viewed as a limitation) would skew the contract. Thus, the constituents of progress should be defined so that the mere act of invention is not associated as a contribution to progress, whether or not it does in fact. The currently prevailing and seemingly narrow view of progress is not universally accepted, and in fact fits uneasily with constitutional goals of countries that define economic and social advancement as an element of progress.[78] International trade agreements also recognize a broader definition of progress. For example, Article 7 of the Agreement on Trade-Related Aspects of Intellectual Property Rights notes that protecting and enforcing intellectual property rights "should contribute . . . to a balance of rights and obligations" of members in a manner conducive to social and economic welfare.[79] Thus, benefits to the society from access, sustainability of the ensuing development, public health, and food security – defined more generally as

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> were almost 10,000 patent applications filed in FY 2006 alone, and over 40,000 applications filed since FY 98 when *State Street Bank* was decided. An amicus in the present case reports that over 15,000 patents classified in Class 705 have issued. The industries identified with information- based and data-handling processes, as several amici curiae explain and illustrate, include fields as diverse as banking and finance, insurance, data processing, industrial engineering, and medicine.

In re Bilski, 545 F.3d at 992 (Newman, J., dissenting), *aff'd but criticized sub nom.* Bilski v. Kappos, 130 S. Ct. 3218 (2010).

[77] Rose, *supra* note 75, at 1201.

[78] The Indian Constitution emphasizes balancing social and economic rights. *See* INDIA CONST. pmbl. Article 21 of the Indian Constitution guarantees the right to life, which includes the right to good health. *See id*. art. 21.

[79] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 7, Apr. 15, 1994 [hereinafter TRIPS].

public benefit – are all factors that form important measurements of progress.[80] Such a construction of progress serves as a limitation to the exclusive rights conferred in expectation of progress.[81] Unfortunately, the Supreme Court has provided little guidance on the progress limitation of the intellectual property clause of the Constitution.[82]

Notably, in 1908, the Supreme Court was presented with an opportunity to define a limit to patent rights vis-à-vis the public benefit objectives.[83] The Supreme Court, in *Continental Paper Bag*, considered whether it could restrain the infringement of a patent "which has long and always and unreasonably been held in nonuse . . . instead of being made beneficial to the art to which it belongs."[84] The question presented was whether an inventor could choose not to exploit the patent during its term, or in other words, whether the owner of an unused patent is limited in law from alleging infringement.[85] In dealing with this question, the Court emphasized that exclusivity characterized the absoluteness of the inventor's property rights: "[E]xclusion vests a legal privilege on the inventor to withhold

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[80] *See* Rose, *supra* note 75, at 1198 ("A radicalized modern view of patent law allows us to challenge the incentive-centered narrative of promoting progress and consider this narrative's impact on future discoveries, humanism, morality and the environment.").

[81] *See* Oliar, *supra* note 41, at 1804-05 (cogently constructing how from a historical, interpretative and policy perspective, the term "progress" is meant to serve as a limitation of the Constitutional powers of the Congress in the IP clause); Jeanne C. Fromer, *The Intellectual Property Clause's External Limitations*, 61 DUKE L.J. 1329, 1339 (2012); Rose, *supra* note 75, at 1201 n.11 ("Both Oliar and Fromer evaluate the structural composition of the IP Clause and persuasively argue that the nonbinding precedent view is incorrect since it fails to give meaning to the first 'empowerment' portion of the clause and goes against the natural textual reading or an ends-means relationship between providing exclusive rights (the means) to promote the end result of promoting progress."). *But see* 1 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER, NIMMER ON COPYRIGHT § 1.03 (2004) (treating the "progress" portion of the IP clause as a preamble term introducing Congress's broad powers in implementing Patent and Copyright protection).

[82] *See* Malla Pollock, *What Is Congress Supposed to Promote? Defining "Progress" in Article I, Section 8, Clause 8 of the United States Constitution, or Introducing the Progress Clause*, 80 NEB. L. REV. 754, 767 (2001); Rose, *supra* note 75, at 1203 (clarifying that progress in the paper references a general sense and not progress in the copyright sense).

[83] *See* United States v. Am. Bell Tel. Co., 167 U.S. 224, 250 (1897) ("The inventor is one who has discovered something of value. It is his absolute property. He may withhold the knowledge of it from the public, and he may insist upon all the advantages and benefits which the statute promises to him who discloses to the public his invention.").

[84] Cont'l Paper Bag Co. v. E. Paper Bag Co. (*Continental Paper Bag*), 210 U.S. 405, 422 (1908).

[85] *Id.*

knowledge from the public while insisting on deriving the advantages and benefits the statute promises."[86] Unused patents deprive the public of the patent's benefits during the term and thus prejudicially impact the public interest.[87] The Court refused to acknowledge the effects of nonuse on competition or on public rights.[88] Instead, the Court noted, "[i]t is the privilege of any owner of property to use or not use it, without question of motive."[89] As a result, the Court filtered out "working the invention during the term" from the public benefit aspect, thereby leaving "disclosure" as the sole residue that constitutes the public benefit output. In doing so, *Continental Paper Bag* marked a watershed moment, showcasing a shift towards treatment of patents as absolute property instead of a governmental grant which entails responsibilities towards the public.

After *Continental Paper Bag*, judicial opinions supporting limitations on exclusivity have remained as minority opinions.[90] Indeed, the Supreme Court expressly reconsidered *Continental Paper Bag* in *eBay v. MercExchange*,[91] but unfortunately refused to reject or adopt a different approach, such as requiring the use or practice of the patented material during the term.[92] The decision found that

[86] *Id.* at 424; *see also Am. Bell Tel. Co.*, 167 U.S. at 249.

[87] *See id.*

[88] *Continental Paper Bag*, 210 U.S. at 425 (internal quotation marks omitted) (responding to the petitioner's assertion regarding the effect on competitors, the Court added that "whenever this court has had occasion to speak, it has decided that an inventor receives from a patent the right to exclude others from its use for the time prescribed in the statute. And, for his exclusive enjoyment of it during that time, the public faith is pledged").

[89] *Id*. at 429.

[90] Restricting exclusivity has remained the minority position in the United States. For example, the dissent of District Judge Aldrich in the First Circuit, from where *Continental Paper Bag* was appealed, favored restricting patent rights on the grounds that nonuse of patents for private benefits discouraged inventive activity. *See* Cont'l Paper Bag Co. v. E. Paper Bag Co., 150 F. 741 (1st Cir. 1906). Judge Aldrich stated that patents were meant to encourage invention by protecting the right to make, use and vend the product in public interest. Hence, he opined that the court should discourage activities hindering that objective by preventing the patent owner from alleging infringement. Judge Aldrich felt that the patent owner's nonuse was for unconscionable private pecuniary gain. In not restricting the patent owner's right, Judge Aldrich felt that the court of equity helped the owner to accomplish nonuse for private gains and thus contravened the spirit of equity and public policy. *Id.* at 745, 757. Justice Douglas recaptured the substance of Judge Aldrich's opinion, albeit in his dissent, in Special Equip. Co. v. Coe, 324 U.S. 370 (1945). Justice Douglas argued that courts should interfere where patent owners misuse patents since patents are conditioned on public purposes per U.S. CONST. art. I § 8, cl. 8. *See* Special Equip., 324 U.S. at 384; *see also Cont'l Paper Bag Co.*, 150 F. at 744-45, 757.

[91] eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).

[92] *See id.* at 393.

infringement remedies should be subject to the traditional four-factor test based on equitable considerations to determine whether an injunction should issue in favor of a patent owner against an alleged infringer.[93] However, the Supreme Court did not go further to treat nonuse of the patent by the owner as a ground to deny injunctive relief or be a central part of the four-factor test.[94] Of particular interest is Justice Kennedy's concurrence, which specifically identifies that "[a]n industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees."[95] While Justice Kennedy strongly advocates against automatically affirming a patentee's absolute right to exclude through injunctions in cases of non-practicing patentees, the concurrence urges courts to grant damages of reasonable royalties.[96] The guidance from the Supreme Court has resulted in courts increasingly approving reasonable royalties and vacating permanent injunctions.[97] Yet *Continental Paper Bag* stands in contrast to the wisdom of the Curtis treatise.[98] The case serves as an early exemplar of how courts have failed to construe practice of inventions during the patent term as part of the inventor's obligation to contribute to the public benefit paradigm in return for exclusivity.[99] Unfortunately, courts have not ventured to determine whether a patentee's rights entail an obligation, in public interest, to practice the

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[93] *Id.*

[94] *Id.*

[95] *See eBay*, 547 U.S. at 395-97 (Kennedy, J., concurring).

[96] *Id.*

[97] *See, e.g.*, Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1380-81 (Fed. Cir. 2008) (approving a reasonable royalty award and vacating an injunction); *See* Neil Tyler, *Patent nonuse and technology suppression: The use of compulsory licensing to promote progress,* 162 U. Pa. L. Rev. 451, 467 (2013)*; See also* Jaideep Venkatesan, *Compulsory Licensing of Nonpracticing Patentees After* eBay v. MercExchange, 14 VA. J.L. & TECH. 26, 31 (2009) ("These courts have decided, though not always expressly, that a nonpracticing patentee is entitled only to the royalty it would have earned had the parties executed a license . . . .").

[98] CURTIS, *supra* note 35.

[99] See, for example, SCM Corp. v. Xerox Corp., 645 F.2d 1195 (2d Cir. 1981) where Xerox was sued for refusing to use or license its patents involving its paper copier technology. The court asserted that this was a lawful exercise of its patent rights. *See also* PETER MEINHARDT, INVENTIONS, PATENTS AND MONOPOLY 189 (1946) ("Probably 80 to 90 percent of all patented inventions are not worked in practice."). *See also* Kurt M. Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*, 15 HARV. J.L. & TECH. 389, 394 (2002) (discussing the anticompetitive effects of patent nonuse); *see also* SRIVIDHYA RAGAVAN, PATENT AND TRADE DISPARITIES IN DEVELOPING COUNTRIES, OXFORD UNIVERSITY PRESS (2012) (highlighting how internationally, jurisdictions like India did emphasize the practice through working requirements and how the TRIPS Agreement has forced such requirements to be amended on the grounds that it affects international trade).

patent during the term. Emphasis on practicing the patent during its term could have prevented some of the woes from *Continental Paper Bag*, as outlined below.

B. Woes of Continental Paper Bag

Continental Paper Bag set the tone for the manifestation of several woes from not obligating the practice of patents during the term. First, *Continental Paper Bag* has served as an important background to establish the absoluteness of the exclusive rights during the patent term and thus ignore public interest-based responsibilities of patentees to practice during the term of the patent.[100] Over time, patent owners have capitalized on patents by not practicing the invention during the term and reaping the benefits by asserting the patent strategically against (often unassuming) practicing entities.[101] Patent owners keep the patent from the public until it can be successfully asserted against a practicing entity. The perversity of the problem is best understood through the reality that a new business model has developed where patent owners benefit from hoarding instead of using the patent.[102] This behavior has led to 'trolling,' which is defined as the act of using the patent merely as an assertion tool (to assert against infringers) and not as a tool for furthering innovation.[103] That a considerable number of patent holders choose to find hoarding more rewarding than commercializing the patent during the monopoly term is telling of the woes that have affected the system from not associating practice of the invention during the term with the larger goals of the system.

Second, failing to associate the use of the patent with the resulting public interest goals has strengthened the association of disclosure with the ultimate goals of the system.[104] Slowly, the status of disclosure has been elevated as the main *quid*

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[100] *Continental Paper Bag*, 210 U.S. at 424.

[101] *See, e.g.*, F.T.C., TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 38-39 (2003), http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

[102] *See, e.g., MercExchange*, 547 U.S. at 396-97 (2006) (Kennedy, J., concurring) ("An industry has developed in which firms use patents not as a basis for production and selling goods but, instead, primarily for obtaining licensing fees.").

[103] *See* Saunders, *supra* note 99 (discussing the anticompetitive effects of patent nonuse).

[104] Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1028 (1989) ("The incentive to disclose argument, which has been more popular with the courts than with commentators, rests on the premise that in the absence of patent protection inventors would keep their inventions secret in order to prevent competitors from exploiting them."); *see also* Fritz Machlup, Subcomm. on Patents, Trademarks, and Copyrights of the S. Comm. on the Judiciary, 85th Cong., *An Economic Review of the Patent System*, 32-33 (1958) (discussing four theses that are offered for patent protection:

pro quo of the inventor's monopoly.[105] Although the constitutional goal of "promoting the progress of useful arts" was never formally relegated to a secondary position,[106] the return for securing the bundle of rights was gradually narrowed to the element of public disclosure.[107] Even the Supreme Court effectively treated public disclosure as the only consideration in exchange for granting patent rights. Indeed, in 1933, the Supreme Court elaborated, "in consideration of [an invention's] disclosure and the consequent benefit to the community, the patent [wa]s granted."[108] This proposition later found its way into *Bonito Boats*,[109] the 1989 decision which laid the groundwork for the Court of Appeals for the Federal Circuit (Federal Circuit) to embrace the exact proposition.[110] Thus, disclosure came to be the only element needed to fulfill the progress requirement.[111] As the disclosure doctrine slowly became identified with the consequential public benefit and the progress of useful arts requirement, it was a natural shift to justify patentees' rights as a return for the disclosure made.

(i) the "natural-law" thesis; (ii) the "reward-by-monopoly" thesis; (iii) the "monopoly-profit-incentive" thesis; and (iv) the "exchange-for-secrets" thesis, and further elaborating on the last thesis that it works on the premise that in the absence of patent protection inventors would keep their inventions secret in order to prevent competitors from exploiting them); WILLIAM D. NORDHAUS, INVENTION, GROWTH, AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE 89 (1969).

[105] *See, e.g.*, Cole M. Fauver, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*, 8 J. INTL. L. BUS. 666, 668-70 (1998). That is, the inventor reveals the invention in return for the government's promise of a specified statutory monopoly on the production of the idea. *Id*. at 681; *see also* The Clean Air Act, 42 U.S.C. § 7608 (2006); Jondora Music Publ'g Co. v. Melody Recordings, Inc., 351 F. Supp. 572, 577 (D.N.J. 1972).

[106] *See* Timothy Holbrook, *The Treaty Power and the Patent Clause: Are There Limits on the United States' Ability to Harmonize?*, 22 CARDOZO ARTS & ENT. L.J. 1, 2-3 (2004) (asserting that the language in Article 1, § 8, cl. 8 of the Constitution "to promote the Progress of the Useful Arts" is the mandate to promote patents, and that the reference to "science" relates to the Copyright Act).

[107] Ewin, *supra* note 37, at 481.

[108] U.S. v. Dubilier Condenser Corp., 289 U.S. 178, 186 *amended by* U.S. v. Dubilier Condenser Corp., 289 U.S. 706 (1933).

[109] Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150-51 (1989).

[110] *See* Roin, *supra* note 16, at 2011-12 ("The Federal Circuit, which hears the bulk of patent infringement suits, frequently uses the same rhetoric, describing disclosure as the 'linchpin' and '*quid pro quo*' of the patent system."); s*ee also* W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1550 (Fed. Cir. 1983); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 970 (Fed. Cir. 2002).

[111] *See* Roin, *supra* note 16.

C. The Rights-Centric Regime

The above narrative highlighted how the disclosure requirement gained a central position in defining the objectives of the patent system. The narrative below describes how the disclosure requirement has been used to further expand the scope of patent rights. The disclosure requirement has resulted in more patents without necessarily resulting in a corresponding increase in innovation.

First, materials not disclosed in a specific manner were treated as being unknown to the public, and thus susceptible to creating private rights. The teaching, suggestion, and motivation (TSM) test serves as an example of this proposition. The TSM test was first applied in the 1960s by the Court of Customs and Patent Appeals (the Federal Circuit's predecessor) to determine the burden of proof for nonobviousness during patent prosecution.[112] In *ACS Hospital Systems*,[113] the Federal Circuit first enunciated that teachings of prior art references could be combined to prove obviousness only if there was a specific teaching, suggestion, or motivation in the prior art to do so.[114] By 1985, the Federal Circuit elevated this rule into a standardized prescription from which examiners could not derogate.[115] Consequently, examiners were prohibited from rejecting patent applications for obviousness unless they had "elucidate[d] . . . factual teachings, suggestions or incentives from th[e] prior art that show[] . . . the propriety of [the patented] . . . combination."[116] In other words, under the TSM test, the examiner bears the initial *prima facie* burden to show clear teaching, suggestion, or motivation from the prior art such that it would have led a person of ordinary skill in the art to combine the references to arrive at the claimed invention. Thus, a claimed application will be

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[112] *See* Application of Rinehart, 531 F.2d 1048 (C.C.P.A. 1976); Application of Regel, 526 F.2d 1399 (C.C.P.A. 1975); Application of Avery, 518 F.2d 1228 (C.C.P.A. 1975); Application of Imperato, 486 F.2d 585 (C.C.P.A. 1973); Application of Andre, 52 C.C.P.A. 1019 (1965).

[113] ACS Hosp. Sys, Inc. v. Montefiore Hosp. (*ACS Hospital Systems*), 732 F.2d 1572, 1577 (Fed. Cir. 1984); *see also* ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 664 (4th ed. 2007) [hereinafter MERGES & DUFFY].

[114] *See ACS Hospital Systems*, 732 F.2d at 1577.

[115] MERGES & DUFFY, *infra* note 120; *see also* Ashland Oil v. Delta Resins & Refractories, 776 F.2d 281, 297 (Fed. Cir. 1985).

[116] *Id.*; *see also* In re Kemps, 97 F.3d 1427 (Fed. Cir. 1996) (holding that the Patent and Trademark Office's factual determinations on the issue of obviousness, regarding which references teach and whether a reference teaches toward or away from claimed invention, are binding on the Court of Appeals, which employed the clearly erroneous standard). *But see* In re Gartside, 203 F.3d 1305 (Fed. Cir. 2000) (reversing the above decision and noting that the PTO Board's decision will be subject to substantial evidence standard under the Administrative Procedure Act).

considered *prima facie* nonobvious unless there is a showing of specific teaching, suggestion or motivation from the prior art to make the combination.[117]

The TSM test in effect lowered the threshold of *prima facie* obviousness during prosecution by creating a standardized prescription to determine an objective element. The TSM test was touted as a means to minimize examiners' subjectivity and reduce rejections of patent applications based on hindsight bias.[118] But it eliminated a critical element – the application of common sense of an examiner – from the obviousness determination.[119] Thus, the TSM standard created a unique form of legal obviousness by disengaging the examiner's use of common sense.[120] The end result was application materials otherwise obvious to a person of ordinary skill in the art which were able to clear the legal nonobvious threshold.[121] This greatly facilitated stacking more private rights to the detriment of the public domain. *In Re Dembiczak* stands as an outstanding demonstration of the above point.[122] There, the Federal Circuit held that a Halloween-themed trash bag was a patentable invention because there was no prior art showing a "clear and particular" teaching to use all of the claim limitations, namely, the use of a plastic bag in pre-manufactured orange color and with specific Halloween facial indicia.[123] *In re Dembiczak* was by no means an aberration, but instead formed part of a steady stream of cases where the line between obvious and nonobvious was determined by what was typecast in the prior art, as opposed to what existed in the public domain.[124] While the TSM test may have taken credit for reducing rejections based on hindsight bias, it clearly led to an over-allowance of patent applications.

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[117] *See* Application of Rinehart, 531 F.2d at 1052 (standing for the proposition that the burden shifts onto the patentee to prove nonobviousness of the claimed invention by putting forward objective evidence).

[118] Obviousness is an objective test conducted from the vantage point of a person of skill in the art. *See* 35 U.S.C. §103 (2012).

[119] Feroz Ali Khader & Srividhya Ragavan, *Proof of Progress: The Role of Obviousness Standard in the Indian Patent Office*, *in* GLOBAL PERSPECTIVES ON PATENT LAW 571 (2014).

[120] Srividhya Ragavan & Feroz Khader, *The Selection Of Patents: Regulatory Reforms versus Market Reliance To Weed Out Suspect Patents*, 46(1) INT'L REV. INTELL. PROP. & COMPETITION L. 38, 44 (2015).

[121] *Id*. at 44-45.

[122] *See* In re Dembiczak, 175 F.3d 994 (Fed. Cir. 1999) *abrogated by* In re Gartside, 203 F.3d 1305 (Fed. Cir. 2000).

[123] *See id.* at 1000.

[124] *See* Khader & Ragavan, *supra* note 119, at 596; *see also* Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1348 (Fed. Cir. 2000); Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1371 (Fed. Cir. 2000).

As for disclosures, in excluding specifically undisclosed materials from the definition of prior art, even if the material was otherwise obvious, the TSM test resulted in further elevating the role and importance of disclosures. The test stood on the assumption that submitted prior arts should be embodiments of every possible teaching and combination applicable to an invention. Consequently, materials not explicitly taught, suggested, or motivated by the prior art were susceptible to a *prima facie* clearance as being nonobvious.[125] The result was more patents, some of which embodied minor innovations, leading to more private rights to the detriment of the public domain and the progress requirement.[126]

The rigid application of the TSM test resulted in a marked difficulty "to invalidate bad patents, and thereby stifling innovation."[127] The costs to society from the monopolies awarded by patents embodying a lower obviousness threshold became unjustified.[128] The result was a perverse trend in the United States, where about fifty-five percent of patents were not renewed at the eight-year period after their issuance.[129] The TSM test was largely diluted after the Supreme Court intervened in *KSR v. Teleflex* and reestablished a common sense based approach

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[125] *See* Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 171 (2006) (asserting that the TSM test treats the nonobviousness requirement akin to the novelty test). Holbrook suggests that it is akin to having one reference "incorporating by reference" all of the other prior arts. *Id.*

[126] *Id.*

[127] Stephen G. Kunin & Andrew K. Beverina, *KSR's Effect on Patent Law*, 106 MICH. L. REV. 50, 50-51 (2007).

[128] *See* Brief of Intellectual Property Law Professors as Amici Curiae in Support of Petitioner at 9-11, KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007) (No. 04-1350); Brief of Amici Curiae Cisco Systems Inc. et al. in Support of Reversal for Petitioner at 2-3, KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007) (No. 04-1350) (arguing that the suggestion test's low bar to patentability made patents of technologically trivial subject matter possible); Brief for the United States as Amicus Curiae Supporting Petitioner at 10, KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007) (No. 04-1350) ("[The suggestion test] exacts a heavy cost in the form of unwarranted extension of patent protection to obvious subject matter."); *see also* Randall J. Hirsch, *Well Duh: Obviousness, Gas Pedals, and the Teaching-Suggestion-Motivation Test*, 6 NW. J. TECH. & INTELL. PROP. 89, 90 (2007) (asserting that the general criticism of the TSM test was that it set the threshold too low for patentability, allowing for the issuance of obvious patents, which contravenes public policy).

[129] William H. Brown, *Trends in Patent Renewal at the United States Patent and Trademark Office*, 17 WORLD PAT. INFO. 225, 227 (1995) (noting that in 1994, statistics indicated that only about fifty-five percent of patents are renewed at the end of the eight-year period).

similar to the statutory test in 35 U.S.C. § 103 to determine nonobviousness.[130] However, the historical development of the TSM test exemplifies how disclosures were elevated to a point where common sense had a limited role.

Biotechnology patents represent an area where the disclosure requirement has been extensively used to define the rights and limits of patenting.[131] For instance, a gradual lowering of standards in biotechnology inventions in the 1990s,[132] such as in *In Re Deuel*,[133] largely lowered the threshold for biotechnology patent applications, resulting in an increase in biotechnology patent activity.[134]

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[130] *KSR Int'l Co.*, 550 U.S. at 415-22. After *KSR*, the USPTO issued new examination guidelines outlining several bases for rejection under 35 U.S.C. § 103, one of which was the TSM test; *see* MANUAL OF PATENT EXAMINING PROCEDURE, § 2143 (U.S.P.T.O. 2008); *see also* Tom Irving, Lauren L. Stevens & Scott M. K. Lee, *Nonobviousness in the U.S. Post*-KSR *for Innovative Drug Companies*, 34 U. DAYTON L. REV. 157, 159 (2009).

[131] *See* Amy Maxmen, *The Great Gene-Patent Debate: How the Myriad Genetics Gene-Patent Case Might Affect Personalized Medicine*, NATURE (July 20, 2012), http://www.nature.com/news/the-great-gene-patent-debate-1.11044; Julia Carbone et al., *DNA Patents and Diagnostics: Not a Pretty Picture*, 28 NATURE BIOTECHNOLOGY 784 (2010); *see also* Mayo Collaborative Servs. v. Prometheus Labs., Inc. (*Mayo*), 132 S. Ct. 1289, 1302 (2012) ("The laws of nature at issue here are narrow laws that may have limited applications, but the patent claims that embody them nonetheless implicate this concern . . . [a]nd they threaten to inhibit the development of more refined treatment recommendations . . ."). *See generally* Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1371-77 (Fed. Cir. 2009); Petition for a Writ of Certiorari at 17, Ass'n for Molecular Pathology v. Myriad Genetics, Inc. *(Myriad*), 133 S. Ct. 2107 (2013) (No. 11-72517); Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 127 (2006) (Breyer, J., dissenting) ("The problem arises from the fact that patents do not only encourage research by providing monetary incentives for invention. Sometimes their presence can discourage research by impeding the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented information, sometimes prohibitively so.").

[132] *See, e.g.*, Amgen v. Chugai, 927 F.2d 1200, 1203-04 (Fed. Cir. 1991). *Amgen* was a decision rendered under 35 U.S.C. § 102(g), and thus not a question of obviousness. The case enabled the patentability of an adequately conceived DNA sequence. The Federal Circuit held that DNA sequences adequately defined in a manner sufficiently disclosing its actual structure and method of preparation would be considered as having been reduced to practice, even though an inventor may be unaware of its actual structure and nowhere near disclosing the actual structure. *Id.* at 1211; *see also* U.S. Patent No. 4,703,008.

[133] In re Deuel, 51 F.3d 1552, 1560 (Fed. Cir. 1995) (holding that obvious to try is not obvious); *see also* RAGAVAN, *supra* note 99, at 211-12.

[134] Sara Dastgheib-Vinarov, *A Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill*, 4 MARQ. INTELL. PROP. L. REV. 143 (2000).

This resulted in a proliferation of intellectual property rights in biomedical research.[135] As one court noted,

> [B]etween 1990 and 1998, the total number of biotechnology patents granted to U.S. corporations has quadrupled. In contrast, between 1990 and 1998, the total number of patents issued increased by about sixty percent. This large disparity is cause for concern. It suggests that the biotechnology industry is using the relaxed nonobviousness standard to obtain genomic patents simply for corporate gain.[136]

The increase in patent activity was attributed to a regime that adequately lowered thresholds, resulting in patenting of basic biotechnology research materials. It placed the biotechnology industry in a "spiral of overlapping patent claims in the hands of different owners."[137] The result was that some basic research materials became inaccessible owing to the private property status which also increased the access cost effectively slowing down the pace of innovation in this area.[138] While these realities mandated that the free-for-all in biotechnology patent applications be capped, they also highlighted that the system greatly facilitated accumulating patent rights.[139] The Federal Circuit attempted to fix such a rights-centric patent regime by expanding the doctrine of written description, a traditional disclosure doctrine, to include enabling functions, thereby further contributing to the elevation of disclosure.[140] In *Eli Lilly*, the Federal Circuit held that a functional definition of a gene would be insufficient to meet the written description requirement because it merely indicates what the gene does, rather than what it

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[135] *See* Anita Varma & David Abraham, *DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market*, 9 HARV. J.L. & TECH. 53, 78 (1996) ("On the one hand, based on prior art knowledge, the biotechnologist knows that sequencing around twenty amino acids is sufficient to obtain the cDNA sequence that codes for a particular protein, absent unforeseen difficulties. On the other hand, under current law, the expected product of this scientifically obvious manipulation is legally unobvious and thus patentable.").

[136] Dastgheib-Vinarov, *supra* note 134, at 165.

[137] Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. MAG. 698 (1998).

[138] *Id*.

[139] *Cf.* Dastgheib-Vinarov, *supra* note 134, at 165.

[140] Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566-69 (Fed. Cir. 1997); Shraddha A. Upadhaya, *The Postmodern Written Description Requirement: An Analysis of the Application of the Heightened Written Description Requirement to Original Claims*, 4 MINN. INTELL. PROP. REV. 65, 109-10 (2002).

is.[141] The Federal Circuit further held that a "meaningful disclosure" was the exchange for patent exclusivity and where the disclosure was inadequate, the material was susceptible to being denied protection.[142] From *Eli Lilly* in 1997 through the *Ariad* decision in 2010,[143] the Federal Circuit largely relied on enabling disclosures in the written description of biotechnology specifications as a correctional mechanism.[144]

The above narrative highlights how disclosures have steadily grown to occupy a central role in defining the rights and limits of patenting, obviating the need for broader discussions on public benefit and the constituents of the progress requirement.

III
RECOGNIZING RESPONSIBILITIES: CORRELATIVE OBLIGATION OF PATENTS

This part examines whether the normative framework imposes any obligation on the inventor by examining the relationship between patent rights and the theoretical bases of the societal duty not to infringe. In doing so, the narrative focuses on fundamental values and returns that characterize the notions of patenting. First, this part traces the philosophical underpinnings of the patent rights framework. Second, it examines the philosophical justifications for these rights to understand the framework for establishing the obligations of the right holder. Lastly, this part focuses on how the duty practically operates and directs the law to create fundamental values and returns (privilege duty) that characterize the notions of patenting.[145]

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[141] *Eli Lilly*, 119 F.3d at 1568; *see also* Lisa A. Karczewski, Comment, *Biotechnological Gene Patent Applications: The Implications of the USPTO Written Description Requirement Guidelines on the Biotechnology Industry*, 31 MCGEORGE L. REV. 1043, 1078 (2000) (arguing that the court's holding that a generic description of the genus such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" distinguishes the claimed genus only by function and hence is an inadequate written description).

[142] *See Enzo Biochem*, 323 F.3d at 970; *see also* Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 922 (Fed. Cir. 2004) (quoting *Enzo Biochem*, 323 F.3d at 970).

[143] Ariad Pharmaceuticals et al. v. Eli Lilly and Company (*Ariad*), 598 F.3d 1336 (Fed. Cir. 2010).

[144] *Id.* at 1358 (finding the Ariad patent invalid on the grounds that the patent failed to adequately describe the invention and thus, to enable the specification).

[145] DRAHOS, *supra* note 15, at 220-23.

A. Rights Framework

Western discourse on intellectual property law conceptualizes patents as incentivizing the inventor and gathering the benefits of the exercise through public disclosure.[146] Exploring patents from the perspective of the relationship between the rights and obligations is essential to appreciate the existing structure of the rights-obligations balance. The desire to innovate, fuel creative genius, and promote the progress of useful arts are all explanations that support the rights paradigm of the patent system.[147] These explanations, however, do not fully define the societal obligation imposed on third parties to refrain from infringing patents. The narrative below examines the philosophical underpinnings that can perhaps justify the correlative obligation construct and its relationship with the vested rights of the patent holder.

Bentham categorizes rights into two distinct typologies based on their relationships with legal obligation.[148] Bentham's first category encompasses rights resulting from the absence of legal obligations.[149] Here, the law may actively permit or passively not prohibit certain actions, leaving the right holder with the liberty to decide whether or not to exercise the right.[150] Bentham's second category addresses rights existing as a by-product of obligations imposed by law on others.[151] Patent exclusivity falls into this second category because it exists as a by-product of a statutorily imposed societal obligation not to infringe the patent. The legal obligation under the second category embodies a principal law "requiring the act which is obligatory" and a subsidiary law "requiring or permitting punishment for breach" of that obligation.[152] The failure to conduct oneself in a specified manner as required under a principal law should result in pain (or its equivalent, loss of pleasure), which is legally imposed by a subsidiary law as a punitive measure for non-compliance with the principal law.[153] H.L.A Hart refers to this as inherently embodying both imperative and probabilistic elements.[154] It is imperative in that sanctions are mandated by the subsidiary law and probabilistic in

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[146] *See, e.g.*, MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 191 (Wolters Kluwer Law & Business, 6th ed. 2012).

[147] *See, e.g.*, U.S. CONST. art. I, § 8, cl. 8.

[148] H.L.A HART, ESSAYS ON BENTHAM 165 (1982) [hereinafter ESSAYS ON BENTHAM].

[149] *Id*.

[150] *Id.* at 166.

[151] *Id.* at 165.

[152] *Id.* at 134.

[153] *Id.* at 131-32.

[154] *Id*. at 132-34.

that there is a probability of incurring sanctions if obligations are not fulfilled. Bentham terms this second category of rights as "services," typified by a "correlative obligation," which are requirements of action or forbearance imposed on third parties.[155] That is, a right is an "enforced service" that results when the law creates a correlative obligation that imposes a duty of forbearance on society in favor of the right holder.[156] A patent right is an "enforced service" wherein infringement of patents (even if by independent creation) represents an imposed legal obligation.[157] The correlative obligation of the society is a service right that provides the inventor the ability to benefit from a duty of forbearance imposed on the rest of the society.[158] In other words, having a right correlative conferred by law onto the right holder relative to an obligation denotes that it leads to a benefit.[159]

The benefits to the right holder under these circumstances tend to be indirect.[160] The right holder may, but does not have to, benefit directly from the performance of the legal obligation by others. Compliance by third parties with the legal obligation to refrain from infringing patented materials makes it conducive for the patent owner to benefit indirectly. Forbearance from the patented material by third parties prevents a potential loss.[161] Hence, the benefits that patent exclusivity confers on the patent holder are indirect, negative in nature, and dependent upon the compliance of third parties with their legal obligations. Bentham defines them as contingently beneficial laws and notes that the duties under such laws are relative to the right holder, who wields complete control over the area covered by the duty. A right holder may, for instance, decide to prosecute one individual with a duty of forbearance while deciding to waive his rights with regard to a similar transgression by another individual. The concept of the relative duty of the right holder contrasts with the more absolute nature of such duties under criminal law, where certain actions are prohibited against all individuals by enforcement of law.[162] Thus, under a contingently beneficial law, the correlative duties of third parties are akin to "species of normative property belonging to the

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[155] *Id*. at 168-69.
[156] *Id.*
[157] *Id*. at 169.
[158] *Id*. at 168-69.
[159] *Id.* at 168.
[160] *Id*. at 176-77.
[161] Daniel Sperling, POSTHUMOUS INTERESTS: LEGAL & ETHICAL PERSPECTIVES, CAMBRIDGE UNIVERSITY PRESS, at 72 (2008).
[162] ESSAYS ON BENTHAM, *supra* note 148, at 185 n.88.

right holder."[163] They are property that derives from norms that belong to identified individuals, under which the right holder is empowered by the legal provisions to enjoy a special control.[164] Termed as the power of "contrectation," the right holder's power is a legal permission to an act which, if done by any other, would result in the contravention of the law.[165]

The benefits flowing to the right holder from contingently beneficial laws invariably remain dependent on a plethora of causes and effects. For example, the patent application process has carefully tailored disclosure requirements to facilitate future replication.[166] Statutory requirements such as written description and enablement serve to ensure that even if the inventor perishes, the invention remains available to the public.[167] Thus, an inventor whose patent application falls short of statutory requirements like disclosure may see the flow of benefits discontinued under certain conditions. Similarly, a refusal to disclose the invention will lead to a refusal of the bundle of rights that forms the patent package. Thus, arguably disclosure is just one example of the expectation the general public receives in return for the correlative obligation not to infringe.[168] In return for the sufferance of the imposed correlative obligation, Bentham notes that the public as "unassignable individuals" acquire broad returns such as that from the disclosure.[169]

B. Justifications for the Rights

Having discussed the nature of rights, this section examines the reason for conferring such rights and possible reasons for the societal tolerance of the correlative obligation. Thus, this section examines each of the justifications for the correlative obligation, including the law of contracts.

The first of these reasons is perhaps a sense of generosity which provides a simple enough explanation. Unfortunately, it is unlikely to be the reason for the legal obligations tailored to benefit the right holder. If mankind uniformly had such

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[163] *Id*. at 185.
[164] *Id.*
[165] *Id.* at 169.
[166] *See, e.g.*, 35 U.S.C. § 112.
[167] *Id.*
[168] Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 545, 594-95 (2012) (highlighting that the disclosure requirements can convey benefits conducive to the objectives of the patent system).
[169] *See* ESSAYS ON BENTHAM, *supra* note 148**,** at 175.

a strong sense of generosity, or any other public interest based reason to promote innovation without any expectation to itself, arguably there would be no need for rules.[170] David Hume, in *The Book of Morals*, asserts, "Men being naturally selfish, or endow[e]d only with a confin[e]d generosity, they are not easily induc[e]d to perform any action for the interest of strangers, except with a view to some reciprocal advantage, which they had no hope of obtaining but by such a performance."[171] Hume adds that "[it is] only from the selfishness and confin[e]d generosity of men, along with the scanty provision nature has made for his wants, that justice derives its origin."[172] Thus, the question of the benefit to society from treating patented property as privileged, thereby forbearing from the property during the term.

A different construct examining the basis of correlative duty is a sense of individual morality.[173] That is, does a sense of moral obligation to not take away from the inventor what he created provide adequate justification for the society's tolerance of the correlative obligation? The interaction between law and morality is a romanticized aspect of our legal system. Like justice, morality remains elusive, and hence, provides easy explanations to appreciate normative structures. Thus, one can justify that moral obligation formed the basis of the legal obligation that imposes the correlative duty on the society. Yet, a positivist like Hart would assert that there is no necessary connection between law and morality.[174] Even assuming there is a connection between law and morality, morals that vest the correlative obligation on the inventor should also obligate the patent holder to certain duties in return for legal rights.

A further expansion of the concept of morality – religious morality – also fails to fully account for the self-imposed correlative duty of the society.[175] Religious morality asserts that God ordained labor as a fundamental right of men.[176] This reasoning posits that the creation of monopoly is consistent with the right to labor except that the king or lawmaker with powers to effectuate a

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[170] DAVID HUME, A TREATISE OF HUMAN NATURE, BOOK III: OF MORALS 519 (L.A. Selby-Bigge ed., Oxford 1896).

[171] *Id.*

[172] *Id.* at 495.

[173] ESSAYS ON BENTHAM, *supra* note 148, at 87-88.

[174] H.L.A. HART, THE CONCEPT OF LAW 202 (Oxford Univ. Press 1961). *See generally* Richard M. Dworkin, *Social Rules and Legal Theory*, 81 YALE L.J. 855 (1972).

[175] HART *supra* note 174; *see also* ESSAYS ON BENTHAM, *supra* note 148.

[176] *See* DRAHOS, *supra* note 15, at 22.

monopoly also has a duty to ensure that it is duly limited.[177] This position is reflected in the *Statute of Monopolies*, which notes that monopolies were tolerated only when they resulted in public good.[178]

Yet another justification for the patent system is that it meant to vest a privilege so as to promote the growth of "human capital" – that is, to encourage the transfer of valuable trade and technologies.[179] It is well documented that in thirteenth-century England, the Crown's prerogative in granting a monopoly was to generate more trade or technology and diffuse them into the society.[180] Professor Drahos, in tracing the historical and philosophical underpinnings of intellectual property rights including patents, supports the view that patent rights were considered a strong form of interference with negative liberties, or the right of others to pursue certain trade.[181] This view supports the proposition that the inventor had an obligation to the society and is well supported by the law of contracts.

The law of contracts, by imposing a reciprocal corresponding obligation on the patent holder, can provide a better justification for the correlative obligation in the context of patent rights. As such, in a bilateral contract, one party's obligation is correlative and reciprocal to the obligation of the other. A patent, as a government grant, repositions society as third-party beneficiaries. Imposing a duty (corresponding obligation) in exchange for the society's correlative obligation would be a functional aspect of the grant. That is, the society has a correlative duty not to infringe the patent in return for which the patent owner has a corresponding duty to the society which includes, but is not limited to, the disclosure. Hence, the inventor, in exchange for the grant, may be charged with obligations benefitting the society. Under these circumstances, the third party, presumably the public in the context of a patent, while being the direct beneficiary lacks the legal right to enforce the contract should a breach detrimentally affect him. The right correlative to the obligation, under these circumstances, is held by the party having the control over the correlative obligation. In effect, the society will have the correlative

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[177] *Id.* at 22-23.

[178] RAGAVAN, *supra* note 99, at 7-8. *See also* Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part II),* 76 J. PAT. & TRADEMARK OFF. SOC'Y 849, 879 (1994) [hereinafter Walterscheid (Part II)].

[179] *See* DRAHOS, *supra* note 15, at 31.

[180] *Id.*; *see also* RAGAVAN, *supra* note 99, at 4-5; Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part I),* 76 J. PAT. & TRADEMARK OFF. SOC'Y 697, 705-08 (1994); Walterscheid (Part II), *supra* note 178.

[181] *See* DRAHOS, *supra* note 15, at 220-23.

obligation not to infringe the patent, the government will have control over the obligation, and in exchange, the patent holder will be subject to the corresponding obligation to secure public benefit objectives. This view justifies governmental interferences in the form of, say, a compulsory license, when there is a problem affecting the flow of benefit to the society.

The contract-oriented view finds support in writings of H.L.A Hart, who, in alluding to Bentham's conception of the law of contracts, differentiates the imposition of duty under the law of contract as being "'incomplete' in a more radical way than the law underlying the institution of property."[182] Part of the reason for the incomplete status is that under the law of contracts, acts that fall within the determination of the duty paradigm are left undefined. Hart suggests that "this open area may be restricted in a greater or lesser degree by the law's insertion of compulsory clauses into contracts, or by its refusal to recognize the validity of certain types of agreement."[183] Thus, general law can provide for certain compulsory restrictions on rights under certain circumstances, or government as the grantor and the control holder can insert regulations of varying degrees, which is not new to modern intellectual property systems. Using contracts as a mechanism would bind the inventor to a corresponding obligation in return for the rights. Thus, the inventor would be subject to the exercise of the power of imperation – that is, the power to ensure that individuals act in conformity with a command.[184] Imperative theory has its basis on the power of legislative and administrative bodies to create rules and regulations that result in increased effectiveness or efficiencies. Extending the analogy to patents, imperative theory would conceive of patents as providing exclusive rights granted under a contract wherein the rights may be limited to achieve the public benefit goals of the system.

Under the patent regime, access to the invention for the public typically begins when the patent term is over. But the correlative duty of forbearance from the property, termed as "enforced service," begins immediately after the rights are acquired.[185] Considering this, treating disclosures as the unique goal in exchange for patent rights does not account for the imposed correlative obligation during the patent term. Further, if societal access to the invention through disclosures were the only goal, they can be effectively generated using other mechanisms, such as a one-time prize, which can also ensure faster societal access to the innovation.

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[182] ESSAYS ON BENTHAM, *supra* note 148, at 209.
[183] *Id.* at 209.
[184] *Id.* at 201.
[185] *Id*. at 168.

C. Patent Law from the Rights & Duties Framework

This section provides a framework for rights and duties in the context of patent exclusivity to appreciate the public benefit objectives of the patent system. The bundle of rights awarded with the grant of a patent can be condensed into offshoots of the negative exclusionary rights. That is, the patent holder's right is limited to excluding others from commercially exploiting the invention without a license. These negative rights contrast with the affirmative rights for a property owner to use and enjoy her property. The affirmative right to use one's property gives rise to the property owner's right to exclude others,[186] as exclusion is important to the owner's use and enjoyment of the property.[187] The patent regime's focus on negative rights is different from the real property regime, but is closer to the contractual grant. Unlike real property, patents are nonrivalrous, and thus one does not need an exclusive right as a functional necessity to practice the invention in the same way that a property owner needs an exclusive right to enjoy her property. That is, the inventor can continue to use and practice the invention even without the exclusive rights. Exclusivity does not vest any additional rights to use the patented invention. Hence, it becomes important to appreciate the role and characteristics of exclusivity in patents in order to appreciate the objectives for granting it.

Unlike in property law, where property rights are granted for facilitating possession of property, the rights of the patent owner are not awarded to facilitate possession of the invention. Patent rights are subject to traversing certain minimum thresholds of inventiveness, and are acquired after careful examination by the patent office. Possession can be inconsequential to patent law. Further, not all innovations and new ideas are granted patents. A novel invention can still fail to acquire the associated bundle of rights by being subject to a statutory bar,[188] lack of inventive genius, or other grounds for invalidity. Unlike in real property, where interference with ownership alone is sufficient to establish trespass, in patent law,

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[186] *Id.*; *see also* Wesley N. Hohfeld, *Some Fundamental Legal Conceptions as Applied in Judicial Reasoning*, 23 YALE L.J. 16, 32 (1913) (arguing that exclusion is considered important in property because it is "crucial to, and protects, a set of use privileges in relation to the res with which the owner is vested").

[187] Balganesh, *supra* note 49, at 1669 ("The duty of forbearance, which operates once a resource is owned, signals to individuals to avoid interfering with the resource without the owner's authorization.").

[188] Under the old 1952 act, novel subject matter *made someway public* more than one year before filing *could* have barred the inventor from getting a patent. *See* 35 U.S.C § 102(b) (2007) (amended 2011).

the determination of infringement requires proof of both ownership and validity. This sets patents apart from other forms of property.

Theoretically, every form of property (which includes the physical and the technological) would have a value (base worth) assuming there is free competition and no protection. Such base worth is the value of the property or the product covering the physical property and the technology, but without the privilege of exclusivity. The factum of exclusivity (or, relatedly, fencing of the property) can operate to impose an artificially higher market value on account of the artificial scarcity, but the minimum value or base worth should remain the same notwithstanding the presence of exclusivity. There is truly no reason to suspect that falling into the public domain would alter the property value, at least until there are substitutes in the market. In reality, unfenced land *per se* can be equally valuable as fenced land in the market, as is true with inventive ideas. And an inventor who lets the invention into the public domain should be able to generate a minimum value equivalent to the base worth, at least until the invention is replicated or recreated.[189] Given this, the rights associated with patents operate to create a zone of protection for the property with a view to prevent encroachment from third parties.

The above narrative posits exclusivity as a non-functional aspect of the grant. In doing so, it raises a fundamental question with respect to the correlative duty that such exclusivity imposes on the rest of the world. The term 'correlative duty' is used along the same lines as in property law where the grant of a right correlates to a duty of forbearance on others. But neither disclosure nor incentive to innovate fully explain the reason for society taking on the correlative obligation of forbearance from the property during the term. If disclosure from the specification was the only ultimate goal, such disclosure could be better achieved in many cases by simply letting the invention fall in the public domain without vesting the exclusive rights that are now associated with it. If incentive to innovate instead were the only goal, this objective could be served by mechanisms such as a prize, which is usually a more risk free one-time reward or recognition in celebration of the invention.[190] Exclusivity entails more than a prize or a reward,

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[189] Allison et al., *Valuable Patents*, 92 GEO. L.J. 435, 437 (2004) (highlighting that the value of the patent is different from the value of the invention). Importantly, exclusivity is not required functionally to increase the value of the invention.

[190] *See* Joseph E. Stiglitz, *Prizes, Not Patents*, PROJECT SYNDICATE (Mar. 6, 2007), https://www.project-syndicate.org/print/prizes--not-patents; *see also* Benjamin N. Roin, *Intellectual Property versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999, 1001-03

although mechanisms like awards and prizes can also be effective to further the objective of encouraging creativity.[191]

Specifically, a system styled to monetize the technological benefits of an invention could capture most of the functional value of exclusivity and may even eliminate some of the associated dangers. Even without patents, an invention that is successful in the market can incentivize competition. Inventions protected by trade secrets increase competition by reverse engineering or substitution. Such competition, in turn, incentivizes the original creator to continue capturing the benefits of lead-time advantages. Thus, patent incentives may be redundant in some circumstances because innovators may be motivated by market profits even without patent incentives. Considering this, the societal preference for the patent system at the cost of the forbearance duties leads to a conclusion that, save for the clear public benefit paradigm, there is limited justification for the society's self-imposition of a duty.

In considering the framework for rights and duties in patent law, a balance between rights and duties is important for the patent system to benefit the public. On the one hand, a patent regime that bears a low threshold for patentability may result in a large number of patents, likely to the detriment of the public domain. While such a system is likely to generate many patents, some with limited inventiveness, the value of each individual patent is likely to be limited by the lower levels of inventiveness barring exceptional circumstances. Also, the low inventiveness threshold makes it easier to find competing substitutes in the marketplace. Soon, as each of the patent holders embodying a low threshold of inventiveness compete, they will alter the norms relative to the others resulting in a rivalrous effect. Alternatively, each patent may be dependent on other patents or would have to be bundled together in order to generate adequate market value. Each such patent holder's exclusivity will be circumscribed by other patents. The best example of the above problem of low-value patents can be found in the

(2014); Marlynn Wei, *Should Prize Replace Patents? A Critique of the Medical Innovation Prize Act of 2005*, 13 B.U. J. SCI. & TECH. L. 25, 27-28 (2007).

[191] *See* Joseph E. Stiglitz, *How Intellectual Property Reinforces Inequality*, N.Y. TIMES (July 14, 2013), http://opinionator.blogs.nytimes.com/2013/07/14/how-intellectual-property-reinforces-inequality/ ("[T]here are alternatives. Advocates of intellectual property rights have overemphasized their role in promoting innovation. Most of the key innovations — from the basic ideas underlying the computer, to transistors, to lasers, to the discovery of DNA — were not motivated by pecuniary gain. They were motivated by the quest for knowledge.").

software industry.[192] As the number of patents on comparable and substitutable technology increases, there is an increasing tendency of corporations to accumulate software patents to create a portfolio.[193] That is, patent holders consolidate their property to maximize the benefits. This results in several patents with lower levels of inventiveness representing a potent business tool rather than pockets of innovation.

Under conditions detailed above, the value from each patent (or set thereof) is best generated when they are pooled together. Such consolidation can also have the benefit of minimizing litigations between holders of patents on comparable technologies. Thus, the trend today is to acquire a patent family, which is comprised of multiple patents that ultimately protect the same invention.[194] Within patent families each single patent may have limited value, but together as a patent family, they increase the bargaining parity of the patent holder.[195] In the telecommunication and mobile phone technology business, for example, Samsung is understood to hold about 31,524 patent families, Microsoft holds about 8,887, and Apple holds about 1,941.[196] Under these conditions, the market value of any one single invention is limited, and each patent holder's exclusivity is

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[192] *See, e.g.*, Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 52 (2005) (discussing how a portfolio of patents as opposed each individual patents adds to an aggregate value that is greater than individual worth of each of the patents); *see also* Doug Lichtman, *Aligning Patent Presumptions with the Reality of Patent Review: A Proposal for Patent Reform* 5-6 (The Brookings Inst., Discussion Paper No. 2006-10, 2006). *See generally* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 1-2 (Wesley M. Cohen & Stephen A. Merrill eds., 2003).

[193] *Cf.* John R. Allison & Ronald J. Mann, *The Disputed Quality of Software Patents*, 85 WASH. U. L. REV. 297, 304 (2007) (concluding that the difference between the patents obtained large firms and smaller firms are not substantial). The authors assert that the data does not support the need for patent reforms focused on a particular area of technology. The authors also conclude that patent reforms that increase the bar for patent filings may work to the detriment of smaller firms and inventors. *Id.*

[194] *See* Parchomovsky & Wagner, *supra* note 192, at 52.

[195] *Id.* at 35-36.

[196] *Id.* at 44; *see also Microsoft-Patsnap*, MICROSOFT (Feb. 2, 2016), http://www.patsnap.com /microsoft/ (formatting omitted) ("Microsoft has a total of 56,841 granted patents and 88,857 patent applications distributed into 46,972 patent families. Based on the countries of patent applications, the key markets for Microsoft are USA, European Patent Office and WIPO(PCT)."); *The Patent Wars: Apple versus Android*, THE CONVERSATION (Sept. 3, 2012), http://theconversation.com/the-patent-wars-apple-versus-android-9291; Reuven Brenner, *Must All Patents Last for 20 Years? A flexible system that recognizes the needs of different industries might lead to less legal conflict*, WALL STREET JOURNAL (Apr. 23, 2013), http://www.wsj.com/ articles/SB10001424127887324504704578413154212218668.

circumscribed by other patents. Each individual patent embodies limited inventiveness because of the low thresholds for protection that prevails in the first place. These conditions incentivize a larger number of arguably weaker patents.

However, the system produces patent portfolios that affect the public detrimentally in many important ways.[197] For example, recent studies have concluded that patent consolidation – grouping patents in "thickets" – increases transaction costs, reduces profits that derive from the commercialization of innovation and ultimately reduces incentives to innovate.[198] The resources required to create a portfolio and the consequential increase in bargaining parity of the portfolio owner increase the entry barrier, reduce competition in the market, and can affect small investors disproportionately.[199] The resulting inefficiencies affect the public detrimentally because patent protection is bestowed for materials with limited innovation.[200] In turn, the system results in allocating more power, sometimes unfairly, to holders of large patent portfolios.

A system that rewards innovations with a lower threshold of inventiveness can result in accumulating more but can also erode the incentive for inventors to reach their maximum creative potential, or worse, can create costs that result in blocking follow-on innovations. The protection for minor innovations increases the overall need for licensing fees, further impeding innovation. Such a system is a detriment to the public domain. Under such circumstances, the incentive of exclusive rights in reality becomes a burden on the public, preventing access to what might have been otherwise available and accessible to the public. Thus, overall, a system that facilitates low threshold of patentability may frustrate the purpose of incentivizing invention. Along the same lines, largess in the rights package can prevent the system from achieving the targeted objective of

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[197] *See* Parchomovsky & Wagner, *supra* note 192, at 52-54 (attempting to explain the current trend of holding families of patents each with diminishing worth but collectively increasing the bargaining strength of the holder using the theory of patent portfolio). The authors outline that the real value of patents lies in the aggregate value of the portfolio as differentiated from the value of each single patent. Such strategic collection of patent portfolio, the authors assert, presents an important array of advantages to the portfolio holder. *Id. See also* Ronald A. Cass, *Lessons from the Smartphone Wars: Patent Litigants, Patent Quality, and Software*, 16 MINN. J.L. SCI. & TECH. 1, 25-26 (2015).

[198] Bronwyn Hall et al., *Patent Thickets and First-time Patenting: New Evidence*, VOX (Apr. 23, 2016), *available at* http://voxeu.org/article/patent-thickets-and-first-time-patenting-new-evidence.

[199] *Id.*

[200] *See* Parchomovsky & Wagner, *supra* note 192, at 52-54.

incentivizing invention. Under these circumstances, the enormity of the rights package can lead to societal discontent with the system.[201]

Conversely, a legal system that confers limited power on the patent holder may be able to promote access to knowledge and innovation, even though it may not be able to capture all innovations under the private domain. The patent systems of several developing countries before the enactment of the TRIPS Agreement provide good examples.[202] Indian patent law allowed only process patents for pharmaceutical innovations with a view to improve competition. The process patent regime encouraged innovation in different methods of manufacturing known pharmaceutical products. This regime resulted in creating competing but similar products, increasing competition and thus making the product more accessible.[203] Process innovations became the critical first step for the genesis and growth of the Indian pharmaceutical industry. Similarly, a rule prohibiting product patents for chemicals was first introduced in the German Patent Law of 1877 to stimulate research in alternative methods of producing a product.[204] Within thirty years of enacting this rule, the German chemical industry became a European leader.[205] German scientists and research workers attributed the success to the various process innovations that promoted competition. Interestingly, research in Germany attributed the failure of the French chemical industry to the product patent system.[206] Importantly, providing exclusive rights to the process of production was considered a valuable inducement to the discovery of alternative processes.[207] The resulting increase in diversity of the products benefited consumers. Although regimes with only process protection for pharmaceutical drugs have typically been

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[201] *See, e.g.*, *Mayo*, 132 S. Ct. at 1305 (discussing the effects of raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements).

[202] *See, e.g.*, Indian Patents Act of 1970, 27 India A.I.R. Manual 450, (1979); *see also* Marrakesh Agreement Establishing the World Trade Organization Annex 1C, Apr. 15, 1994, 1869 U.N.T.S. 299. *See generally* Srividhya Ragavan, *A Patent Restriction On 'R & D: Infringers or Innovators*, 1 ILL. J.L. TECH & POL'Y 73 (2004).

[203] RAGAVAN, *supra* note 99, at 42; *see also* Indian Patents Act of 1970, *supra* note 197.

[204] RAGAVAN, *supra* note 99, at 58.

[205] *Id.*; *see also* Loi du 5 juillet 1844 sur les brevets d'invention [Law of July 5, 1844 on Patents for Inventions], PÉRIODIQUE ET CRITIQUE [D.P. III] [PERIODIC REVIEW]; Patentgesetz [Imperial German Patent Law], May 25, 1877, REICHSGESETZBLATT [RGBL].

[206] N. Rajagopala Ayyangar, *Report on the Revision of the Patents Law in India, 1959*, SCC ONLINE 23-24 (2013) [hereinafter Ayyangar Report].

[207] *Id.*; RAGAVAN, *supra* note 99, at 38.

faulted for having lesser rights, they should not be confused as lacking in innovation.[208]

For the patent system to be most efficient, the system should create a balance between rights and obligation.[209] As Waldron asserts, "[t]o say that rights are a means to an end is one thing; but the correlative proposition that some should be forced to bear sacrifices for the greater social good smacks dangerously of throwing Christians to the lions for the delectation of Roman society."[210] Justice Breyer captured this sentiment in *Mayo v. Prometheus*, opining,

> [p]atent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements.[211]

Reverberating similar sentiments, Justice Thomas in *Myriad* emphasized the importance of striking a "delicate balance between creating incentives that lead to creation, invention, and discovery and impeding the flow of information that might permit, indeed spur, invention."[212] Ghosh perhaps couches this concept with more precision when he asserts,

> While current intellectual property law assumes the primacy of the rights of owners (emphasizing the attachment to legal ownership), nuanced consequentialism would recognize the place of the intellectual property owner in a network of relationships which create duties and obligations. Sensitivity to the consequences of intellectual

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[208] *See generally* RAGAVAN, *supra* note 99.

[209] *See generally* MERGES, *supra* note 11, at 237-69. It is unlike the suggestion by Professor Merges of a Lockean sense of charity meant for the benefit of the *destitute*.

[210] Jeremy Waldron, *From Authors to Copiers: Individual Rights and Social Values in Intellectual Property*, 68 CHI.-KENT L. REV. 841, 862 (1993).

[211] *Mayo*, 132 S. Ct. at 1305.

[212] *Myriad*, 133 S. Ct. at 2108.

property rights is, to quote Professor Sen, sensitive 'to agencies and relations in evaluating what is happening in the world.'[213]

CONCLUSION

This paper attempts to capture the intrinsic core of patent law's structure as delineated in historical sources in an unorthodox manner. It asserts that patent law is a misfit within the traditional property regime. While patent law seems to struggle to define the outer limits of patent exclusivity, the paper shows how the current levels of exclusivity seem to lack support from the doctrinal construct of the philosophy behind exclusivity. In doing so, the paper highlights the source of exclusive rights to examine how a disconnect between the instrumental elements of patents and its targeted objectives has developed over time, leading to a rights-centric patent system. Understanding the objectives of the system is important for patent law to achieve its constitutional destiny. The paper does not propose a comprehensive theory of patent law. Instead, it presents the law of contracts as embodying a framework within which patent law can fit better. The paper concludes that patent law needs a more balanced approach to ensure that the rights and obligations inherent to the system work to achieve the targeted objectives.

[213] Ghosh, *supra* note 21, at 815.

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UN-BLURRING SUBSTANTIAL SIMILARITY: AESTHETIC JUDGMENTS AND ROMANTIC AUTHORSHIP IN MUSIC COPYRIGHT LAW

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Music copyright disputes have been in the limelight since long before George Harrison subconsciously ripped off the Chiffons. Yet, with copyright holders becoming ever more litigious, disputes over musical rights are revolving around increasingly narrow claims. While copyright law is meant to only protect the expression of an idea, rather than the idea itself, drawing the line is problematic and too often results in overly expansive definitions of "expression." Lacking any objective definitions of the terms, determining when an idea becomes expression depends entirely on how one defines "art." A recent case finding that pop-musicians Robin Thicke and Pharrell Williams infringed Marvin Gaye's 1970s funk song, "Got to Give It Up," by copying the amorphously defined "feel" and "sound" of the song, exemplifies the stifling affect our law is having on artists. After examining the evolution of the circuits' current, and varied copyright infringement tests, this note ultimately suggests a unified and more precise approach that utilizes not only experts who are well-versed in the specific genres of art at issue, but also analytic dissection that carefully considers only protectable elements when determining if works are "substantially similar."

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INTRODUCTION

By refusing to acknowledge[1] the aesthetic judgments inherent in determining copyright disputes,[2] American courts have plagued our copyright law with subjective bias[3] and doctrinal confusion. To avoid the appearance of impropriety,

[1] *See* Bleistein v. Donaldson Lithographing Co., 188 U.S. 239, 251 (1903) ("It would be a dangerous undertaking for persons trained only to the law to constitute themselves final judges of the worth of pictorial illustrations, outside of the narrowest and most obvious limits.").

[2] *See generally* Alfred C. Yen, *Copyright Opinions and Aesthetic Theory*, 71 S. CAL. L. REV. 247, 251, 285–86 (1998) (arguing that "judges necessarily make decisions of aesthetic significance in copyright" as implicit in determining whether elements are "public domain," or if they are "protected material." Moreover, substantiality rests on "how sensitive" courts are to the degree of quantitative and qualitative similarity between two works).

[3] *Id.* at 251 ("[S]ince no aesthetic perspective can be neutral and all-encompassing, aesthetic bias becomes inherent in copyright decisionmaking . . . .").

since at least 1903[4] courts have side-stepped clearly defining foundational concepts such as "originality,"[5] "authorship," and "infringement." As such, they have failed to provide a meaningful methodology for determining when a work infringes the copyright of another.[6] By instead relying on the impossibly vague "substantial similarity" test,[7] courts have crafted an impressionistic doctrine that has drifted far from copyright's original economic purpose of incentivizing creation.

While copyright infringement requires proof of copying, mere copying is not the end of the inquiry, as "[t]rivial copying is a significant part of modern life."[8] Thus, proof of copying, or "copying-in-fact," is only a threshold issue for proving infringement.

Copying-in-fact can be shown through direct evidence, such as testimony, but with witnesses and honest thieves often lacking, copying is most often shown by circumstantial evidence. Indirect proof of copying is provided by evidence creating an inference that the defendant copied – typically a combination of evidence of access to the plaintiff's work and similarities probative of copying. While courts allow expert analysis and dissection to aid them in inferring copying, the largely unguided impression of lay observers determines the more exacting question of misappropriation.[9]

Yet determining misappropriation requires an understanding of the "axiom of copyright law that the protection granted to a copyrightable work extends only

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[4] *See, e.g.*, Nichols v. Universal Pictures Corp., 45 F.2d 119, 121 (2d Cir. 1930); Brandir Int'l, Inc. v. Cascade Pac. Lumber Co., 834 F.2d 1142 (2d Cir. 1987); Carol Barnhart Inc. v. Economy Cover Corp., 773 F.2d 411, 415–18, 420 (2d Cir. 1985).

[5] *See* Olufunmilayo B. Arewa, *From J.C. Bach to Hip Hop: Musical Borrowing, Copyright and Cultural Context*, 84 N.C. L. REV. 547, 565(2006) ("Although originality is not explicitly included in the Intellectual Property Clause of the U.S. Constitution, it is a fundamental assumption of current copyright law that originality is implicitly mandated by the Constitution's references to 'authors' and their 'writings.'") (citations omitted); *see also* U.S. CONST. art. I, § 8, cl. 8 ("The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.").

[6] *See generally* Amy B. Cohen, *Masking Copyright Decisionmaking: The Meaninglessness of Substantial Similarity*, 20 U.C. DAVIS L. REV. 719, 720 (1987).

[7] H.R. REP. NO. 94-1476, at 61-62 (1976); S. REP. NO. 94-473, at 71 (1975) ("[A] copyrighted work would be infringed by reproducing it *in whole or in any substantial part*, and by duplicating it exactly or by imitation or simulation.") (emphasis added).

[8] Davis v. Gap, Inc., 246 F.3d 152, 173 (2d Cir. 2001).

[9] Shyamkrishna Balganesh, *The Questionable Origins of the Copyright Infringement Analysis*, 68 STAN. L. REV. 791, 805 (Forthcoming 2016).

to the particular expression of an idea and never to the idea itself."[10] Application of the "idea/expression" distinction requires delicate line-drawing to decide the appropriate "'level of abstraction' at which one defines the 'idea' that merges with the subject's expression."[11] But fact finders are unlikely to understand on their own which "ideas" are excluded or what elements fall into the category of "ideas." While jury instructions can theoretically work to inform jurors to exclude such elements, "in practice jurors aren't going to know what things are, for example, *scène à faire*[12] in the music industry, without some testimony on standard chord progressions."[13] Thus, jurors are not likely to understand such an ephemeral distinction between ideas and expression, especially when applied to areas in which they lack expertise, as is often the case with copyright.[14] Because the issue of misappropriation is so dependent on the interpretation of these underlying principles of copyright law, classifying the issue as purely a question of fact for the jury requires reconsideration.[15]

Courts recognize the need for expert analysis and dissection in determining infringement in cases involving computer software. Distinguishing computers as "complex" and having elements dictated by limited options, courts apply a special test to ensure only protected elements are considered for infringement purposes. Yet they proscribe such guidance when the "aesthetic arts" are at issue, failing to recognize traditions unique to genres, that all art is capable of being broken down into constituent elements, and that such elements are dictated by genre and functional constraints. Courts have assumed that art is intuitive, simply reflecting

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[10] Atari, Inc. v. N. Am. Phillips Consumer Electric Corp., 672 F.2d 607, 614-15 (7th Cir. 1982).

[11] MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 13.03[a][i] (2002).

[12] *Scène à faire* is the notion that certain similarities in the basic idea will require similarities in the expressions used to develop that idea. For example, "if two scenarios wish to treat the unprotected idea of police life in the South Bronx, one court has determined it would only be natural to depict 'drunks, prostitutes, vermin and derelict cars,' juxtaposed against hard drinking Irish cops chasing fleeing criminals." *Id.* (citations omitted).

[13] Mark A. Lemley, *Our Bizarre System for Proving Copyright Infringement*, 57 J. COPYRIGHT SOC'Y U.S.A.
719, 738 (2009) (alteration in original).

[14] *See infra* Part IIA (discussing how this need for, and lack of, special expertise in copyright makes the "ordinary observer" test a poor extension of the rationale underlying the negligence standard used in areas such as tort law).

[15] Balganesh, *supra* note 9, at 805 (explaining that the misappropriation inquiry requires procedural, substantive, and theoretical considerations).

emotions, and capable of being understood by anyone. Their narrow understanding of art comes from our law's founding.

Copyright arose in an era where the courts viewed creativity as coming from a place of pure autonomous genius,[16] but this romantic view of aesthetics is a relic of the past: a counteraction to the age of enlightenment and rationalization. The reality is that creative borrowing is almost unavoidable and results in widespread use of unprotected elements from preexisting works. Without expert guidance and the ability to dissect protectable and unprotectable elements, judges and jurors are "more likely to find infringement in dubious circumstances, because they aren't properly educated on the difference between protectable and unprotectable elements."[17]

Due to the prevalence of music copyright infringement suits, and the fact that music is more perceptively derivative than other media,[18] it seems disproportionately plagued by the courts' bias for traditional aesthetics. But music, like all arts, is inherently complex and technical,[19] and few "ordinary observers" know the elements and factors that go into its creation,"[20] especially with works of less familiar genres. Thus, fact finders are easily misled into finding substantial similarity based on unprotectable elements.[21]

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[16] *See generally* Arewa, *supra* note 5 (noting that American copyright law is founded on the unrealistic conception that creativity necessarily comes from a place of pure autonomous genius).

[17] Lemley, *supra* note 13, at 739 (citing Ann Bartow, *Copyrights and Creative Copying*, 1 U. OTTAWA L. & TECH. J. 77 (2003) (suggesting that this has been the result)).

[18] *See generally* Jeffrey Cadwell, *Expert Testimony, Scenes A Faire, and Tonal Music: A (Not So) New Test for Copyright Infringement*, 46 SANTA CLARA L. REV. 137 (2005) (arguing functional constraints make music prone to tendencies and commonalities).

[19] *See generally* Alice Kim, *Expert Testimony and Substantial Similarity: Facing the Music in (Music) Copyright Infringement Cases*, 19 COLUM.-VLA J.L. & ARTS 109, 124–125 (Fall 1994/Winter 1995) (arguing that music operates by such complexities and intricacies, especially in today's technological world as "all pieces of music, contain elements of 'melody, harmony, . . . rhythm [,] . . . [t]imbre (tonal quality), tone, pitch, tempo, spatial organization, consonance, dissonance, phrasing, accents, note choice, combinations, interplay of instruments, . . . bass lines, and the new technological sounds.'") (quoting Debra Presti Brent, *The Successful Music Copyright Infringement Suit: The Impossible Dream*, 7 U. MIAMI ENT. & SPORTS L. REV. 229, 248–49 (1990)).

[20] *See id.* at 124.

[21] Callie L. Pioli, *Copyright: Infringement v. Homage*, (September 17, 2015, 8:11 AM), http://www.mbbp.com/news/blurred-lines-copyright (noting that the lesson from the *Blurred Lines* decision is that "creating music 'reminiscent' of an era or paying homage to the genre-

While music may be uniquely crippled by our current copyright regime, the problems plaguing music copyright stem directly from a lack of guidance where it is arguably most needed: the technical issue of misappropriation.[22] With fact finders less likely to detect similarities attributable to common sources in unfamiliar aesthetic, the current system results in a prejudice against lesser-known aesthetics, and a bias for the traditional. [23] The result is far from encouraging aesthetic progress.

This paper will argue that to create a more encompassing[24] and objective copyright law, that fosters progress in all arts, it is vital to expand the role of analytic dissection and expert testimony to the misappropriation prong of the infringement test.

Part I of this paper provides background on the history of court treatment of music copyright and lays out the two major approaches to copyright infringement. In addition, this part outlines the foundational principle that only the expression of an idea is protectable. Part II illustrates how the tests have veered away from the original purposes and values underlying the inquiry. It argues that by relying on the ordinary observer test for misappropriation, the tests fail to accurately account for the idea-expression distinction. In outlining the problems facing music under our current copyright regime, this section shows how the problems with the audience test are particularly problematic for music, a medium in which the line between idea and expression is often not "spontaneous and immediate" to the ordinary observer.[25] The recent "Blurred Lines"[26] lawsuit serves to illustrate how the lack of

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creating greats of past decades may not hold as a defense to copyright infringement under the current substantial similarity framework.").

[22] *See* Cadwell, *supra* note 18, at 161; *see also* Kim, *supra* note 19, at 127 (arguing that an analogy between music and software does not seem inappropriate and thus proposing that the substantial similarity test does not suit the technical nature of music as well as permitting expert testimony would).

[23] *See generally* Arewa, *supra* note 5, at 581, 584-85 (arguing that in viewing classical composers as artistic geniuses, failing to appreciate their practice of borrowing from the past, and hip-hop artists as mere craftsmen, legal discourse is perpetuating culturally rooted prejudices against the "other," as most modern genres originated in African cultures).

[24] *Id.* at 587 ("this vision of musical authorship based upon notions of creativity, invention, originality and even genius is far too restrictive a representation of musical creation.").

[25] Harold Lloyd Corp. v. Witwer, 65 F.2d 1, 18 (9th Cir. 1933), *cert. denied*, 296 U.S. 669 (1933).

[26] Eriq Gardner, *'Blurred Lines' Jury Orders Robin Thicke and Pharrell Williams to Pay $7.4 Million*, HOLYWOOD REP. (March 10, 2015, 2:33 PM), http://www.hollywoodreporter.com/thr-esq/blurred-lines-jury-orders-robin-779445.2.

objectivity in our current law results in inconsistent application, thereby diminishing incentives to create new works. More broadly, this section considers that while the problems for music are often more noticeable than for other media, they merely expose the larger inaccuracies of the audience test. Finally, Part III considers proposals for creating a more guided and objective infringement analysis. Ultimately, this paper concludes that the best solution is adopting the test for computer software, the abstraction-filtration-comparison method (AFC),[27] as a uniform test for infringement.

Requiring careful dissection of unprotected elements by the court would ensure educated decisions, and reserving the intuitive question of whether the defendant copied those elements for the trier would preserve the economic rationale of the lay listener test.[28] Effectively reversing the analysis of proof "will likely result in greater attention to the limiting doctrines of copyright law"[29] and the evolution of reasoned rule of law.[30] By basing aesthetic nondiscrimination in objective and reasoned criteria, as opposed to the "anti-intellectual and book burning" philosophy[31] of visceral impressions, the courts can determine actual illicit copying while being receptive to unconventional aesthetics.[32]

I
HISTORICAL BACKGROUND OF MUSIC IN COPYRIGHT INFRINGEMENT LAW

While copyright law struggles to deal with the fine arts as a whole,[33] particular problems arise in the context of musical works. These issues are rooted

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[27] This test is currently reserved for computer software cases. *See* Computer Assocs. Int'l, Inc. v. Altai, Inc., 982 F.2d 693, 707 (2d Cir. 1992) ("Professor Nimmer suggests, and we endorse, a 'successive filtering method' for separating protectable expression from non-protectable material.").

[28] *Cf. id.*

[29] Lemley, *supra* note 13, at 741.

[30] Balganesh, *supra* note 9, at 855-58.

[31] Arnstein v. Porter, 154 F.2d 464, 478 (2d Cir. 1946) (Clark, J., dissenting) ("Further, my brothers reject as 'utterly immaterial' the help of musical experts as to the music itself (as distinguished from what lay auditors may think of it, where, for my part, I should think their competence least), contrary to what I had supposed was universal practice . . . .").

[32] *See generally* Robert Kirk Walker & Ben Depoorter, *Unavoidable Aesthetic Judgments in Copyright Law: A Community of Practice Standard*, 109 NW. U.L. REV. 343, 376 (2015) (proposing that experts brief the court on the aesthetic norms and traditions that inform the works at issue so that the hypothetical viewer is not limited to any specific aesthetic theory and can react sensitively to the nature of the work presented).

[33] *See* Barton Beebe, *Intellectual Property Law and the Problem of Aesthetic Progress, Inaugural Lecture of the John M. Desmarais Professorship of Intellectual Property Law*, NYU

in the history of copyright law. Many of the problems facing music copyright lie in the fact that creators are seeking protection under a scheme created for the distinct purpose of protecting works of literature.[34] However, these problems are not unique to music. American copyright law is based on a concept of authorship ill-suited to progress in general. This section will outline the evolution of our copyright infringement doctrine. In considering the historical application of the doctrine to musical works, this section analyzes the aesthetic norms embedded within judges' and jurors' findings of infringement.

A. Music's Initial Encounters in Early Legislation and Case Law

Article 1, Section 8 of the Constitution authorizes federal legislation "[t]o promote the Progress of Science and useful Arts,"[35] but gives little guidance in defining the scope of the copyright system. The original Copyright Act of 1790 extended protection only to maps, charts, and books.[36] Though musical compositions were routinely registered under the 1790 Act as "books,"[37] it was not until the Copyright Act of 1831 that Congress expressly extended protection to musical compositions. Congress's early failure to provide well-crafted protection for musical compositions is hardly surprising given the 1790 Act's roots in Great Britain's Statute of Anne, which covered only the distinct category of "books."[38]

With no other protection available against infringers, composers naturally came to seek protection of their works through copyright.[39] Yet utilizing a scheme

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LAW NEWS (Feb. 3, 2014), http://www.law.nyu.edu/news/barton-beebe-inaugural-desmarais-lecture.html (discussing the courts' failure to recognize that the framers intended to quarantine the fine arts from copyright law, as evident in the progress clause specifying "useful arts," and the resulting lack of a developed idea of what aesthetic expression means); *see also* Walker & Depoorter, *supra* note 32, at 344-45 (explaining how courts shy away from judging art for fear that they are "incompetent to do so") (citing Bleistein v. Donaldson Lithographing Co., 188 U.S. 239, 251 (1903) ("It would be a dangerous undertaking for persons trained only to the law to constitute themselves final judges of the worth of pictorial illustrations, outside of the narrowest and most obvious limits.")).

[34] Michael W. Carroll, *The Struggle for Music Copyright*, 57 FLA. L. REV 907, 934 (2005).

[35] U.S. CONST. art. I, § 8, cl. 8 (alteration in original).

[36] *See* Act of May 31, 1790, ch. 15, 1 Stat. 124.

[37] William F. Patry, *Copyright Law and Practice*, THE BUREAU OF NATIONAL AFFAIRS (2000), *available at* http://digital-law-online.info/patry/patry5.html.

[38] 8 Anne, ch. 19 (1710) (Eng.), http://www.copyrighthistory.com/anne.html.

[39] The first copyright action for a musical work, Bach v. Longman, 98 Eng. Rep. 1274, 1275 (K.B. 1777), was brought under the Statute of Anne by Johann Christian Bach on account of unauthorized editions, published by music publishers Longman & Lukey, of two Bach works, a

created for "written" works meant obtaining copyright protection solely with respect to the underlying composition, "the notated, written score, including the music and any lyrics."[40] While seemingly analogous, music as a performing art is "often related in some way to performance" and must be understood by reference to its context, that is, elements outside the composition.[41] Though federal law since 1976 has applied copyright protection to musical recordings, including some performance elements such as percussion, recordings are treated as distinct expressions with separate copyright protection.[42] Consequently, musical compositions are protected only within the restrictive framework of the "musical work," which is defined as a combination of melody and harmony.[43]

More problematically, courts analyzing music copyright cases tend to place undue weight on melody, rather than harmony and rhythm,[44] failing to consider the complexity of music and a realm of possible distinguishing features. Focusing on elements of music that "lend themselves to notation"[45] may seem adequate in analyzing works from European musical traditions, which typically have predominant harmonic and melodic structures,[46] but doing so fails to consider music in its totality. Because music is inherently relational,[47] our perception of musical works, and their meaning, is dependent on the context in which notes and pitches in the melody are played.[48] Elements such as timbre and spatial organization are also relevant to the way we hear music and to the similarities we perceive. Consequently, "originality is better viewed as a function of the interaction and conjunction of these elements than of any element alone."[49]

Neglecting to consider the totality of elements in musical works, while ill-suited even to classical traditions, most drastically affects works outside of Western traditions. The main aesthetic features of non-Western music often fall

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lesson and a sonata. "Bach brought the suits seeking to effect legal changes to provide composers with copyright protection equal to that of authors." Arewa, *supra* note 5, at 557–58.

[40] Arewa, *supra* note 5, at 568.

[41] *Id.* at 556.

[42] *See* 17 U.S.C. § 102(a)(7) (2000) (granting copyright protection to sound recordings).

[43] Paul Théberge, *Technology, Creative Practice and Copyright*, in MUSIC AND COPYRIGHT at 140 (Lee Marshall and Simon Frith eds., 2nd ed. 2004).

[44] Arewa, *supra* note 5, at 556.

[45] *Id.* at 625.

[46] *Id.*

[47] *Id.* at 556-57.

[48] *Id.* at 557.

[49] *Id.* at 626 n.445 (citing Aaron Keyt, Comment, *An Improved Framework for Music Plagiarism Litigation*, 76 CAL. L. REV. 421, 432 (1988)).

outside the confines of the court's emphasis on melody and notation. Most notably, hip-hop, which finds its roots in certain African musical traditions, features a dominant "oral tradition," evidenced in the practice of rapping, and complex rhythmic structures with less emphasis on melodic and harmonic structures. Moreover, such traditions predominately feature the element of musical borrowing through the practice of sampling, looping, and interpolation. These features are also found in other African American musical genres, including blues, jazz, rhythm and blues, gospel, Soul, rock, reggae, funk, disco, and rap, and are found mixed with all types of music today.[50] Electronic music producers are now producing hip-hop tracks,[51] and even pop-country artists are making rhythm-centric tracks that reference hip-hop culture. Not surprisingly, entering the arena puts artists at risk of facing a copyright suit. Taylor Swift recently faced a $42 million infringement claim for using the lyric "haters gone hate," a staple in hip-hop culture and music, [52] in her recent dance-pop track "Shake it Off."[53] Despite the prevalence of non-notational elements, copyright's bias for written work places works that do not fit the mold "at the bottom of the hierarchies of taste,"[54] making findings of original elements in allegedly infringing works more difficult to obtain.

Borrowing similarly conflicts with Western ideals of creativity and originality, with the result that music has historically been disvalued. Records from the time of the Statute of Anne's enactment are telling of the hostile attitudes facing music. While literature was held in high esteem for its educative role, music was seen as an unnecessary luxury that served merely as entertainment.[55] In *Pyle v. Falkener*,[56] an early case brought under the Statute of Anne, defendant publishers

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[50] *Id.* at 614.

[51] *See, e.g.*, LIVELOVEASAPVEVO, *A$AP ROCKY - Wild For The Night (Explicit) ft. Skrillex, Birdy Nam Nam*, YOUTUBE (Feb. 10, 2016), https://www.youtube.com/watch?v=1eWdbMBYlH4.

[52] Youyoung Lee, *OVER IT: It's Time To Retire The Word "Haters,"* THE HUFFINGTON POST: THE BLOG (June 25, 2013, 4:50 PM), http://www.huffingtonpost.com/youyoung-lee/over-it-its-time-to-retire-haters_b_3492129.html (citing as an example the song "Players Gon' Play," by the all-girl group 3LW).

[53] Michael Epstein, *Taylor Swift Is Being Sued for $42 Million for Singing "Haters Gonna Hate" in "Shake it Off,"* FLAVORWIRE (Nov. 2, 2015), http://flavorwire.com/545712/taylor-swift-is-being-sued-for-42-million-for-singing-haters-gonna-hate-in-shake-it-off.

[54] *See* Arewa, *supra* note 5, at 622.

[55] Carroll, *supra* note 34, at 949 (citing CHARLES BURNEY, A GENERAL HISTORY OF MUSIC (Dover 2d ed. 1957)); *see also id.* at 952 (arguing that by limiting protection to books, as opposed to single songs, the Statute of Anne was enacted only to protect "those who had advanced the cause of learning by producing books.").

[56] C33/442 London Public Record Office (1772), *reprinted in* Ronald J. Rabin & Steven

argued that, in contrast to works of literature, authorship of music required "a high standard of originality to qualify for protection under any legal theory."[57] Underlying their challenge was the commonly held notion that composers "merely borrowed" from "[o]ld [t]unes which had been [u]sed in [c]ommon by all persons for many years before…" and as such have no proprietary rights.[58]

Such disparaging views of music are less surprising when one considers the rise of the Romantic view of authorship in the nineteenth and twenties centuries.[59] Unlike the classical conception of authorship, which "conceives of art as imitating universal truths and ideas," and thus contemplates the evolutionary nature of art, the Romantic view conceptualizes the creation of art "as a process that reflect[s] the emotions and personality of the individual artist."[60] With the Romantic view informing cultural assumptions, originality often came to be defined as requiring independent creation, "which essentially appears to rule out or significantly limit borrowing."[61]

With the functional and genre constraints inherent to music,[62] tensions existed early on in applying copyright to musical works. Yet "use of existing works has historically been a core feature of the musical composition process"[63] and the artistic process in general. The courts' neglect to appreciate the reality of borrowing has often resulted in overbroad copyrights, extending protection to more than just the particular arrangement of the literal elements of a work.[64]

Zohn, *Arne, Handel, Walsh, and Music as Intellectual Property: Two Eighteenth-Century Lawsuits*, *in* 120 J. OF THE ROYAL MUSICAL ASS'N 112, 140-45 (1995).

[57] Carroll, *supra* note 34, at 950.

[58] *Id.* (citing *Pyle*, C33/442 London Public Record Office, at 143).

[59] Peter Jaszi, *Contemporary Copyright and Collective Creativity*, *in* THE CONSTRUCTION OF AUTHORSHIP: TEXTUAL APPROPRIATION IN LAW AND LITERATURE 29, 40 (Martha Woodmansee & Peter Jaszi eds., 1994) ("Eighteenth-century theorists . . . minimized the element of craftsmanship . . . in favor of the element of inspiration, and they internalized the source of that inspiration. That is, the inspiration for a work came to be regarded as emanating not from outside or above, but from within the writer himself.").

[60] Amy B. Cohen, *Copyright Law and the Myth of Objectivity: The Idea-Expression Dichotomy and the Inevitability of Artistic Value Judgments*, 66 IND. L.J. 175, 203 (1990); *see also* Arewa, *supra* note 5, at 566 n.80 (Romantic ideals emphasize "original ideas rather than 'successive elaborations of an idea or text by a series of creative workers.'").

[61] Arewa, *supra* note 5, at 566.

[62] At least music composed in the twelve-tone scale.

[63] Arewa, *supra* note 5, at 590.

[64] As a consequence, "inspired work was made peculiarly and distinctively the product – and the property – of the writer." *Id.* at 566-67 n.82.

Additionally, by failing to recognize distinguishing features of songs that lie outside the melody and notation, courts often find infringement based on unprotected elements. Genres that explicitly sample existing works, such as hip-hop, have been hit hardest. As a result, the courts are perpetuating a bias for traditional aesthetics at the expense of progressive and unfamiliar artistic movements.[65]

B. The Idea-Expression Distinction

Early on, courts using the idea-expression dichotomy to distinguish between unprotectable and protectable aspects of works did so on the basis of tangibility. Though the courts still use these terms in filtering out unprotectable elements, changing views on the nature of the artistic process have distorted the original tangibility basis, leading to ad hoc judicial determinations. With the rise of the Romantic view, artistic works in their entirety came to be regarded as reflecting the artist's contributions.[66] As a result, perceptions regarding the moral (and thus, intellectual property) rights of an artist expanded to include more than just the particular arrangement of the literal elements of a work.

Originally, American copyright law viewed "ideas" as "intangible, unexpressed concept[s] that existed only in the author's mind."[67] Courts deemed ideas unprotectable on an economic rationale because "in the absence of means of communicating them they are of value to no one but the author."[68] Therefore, copyright protected only the tangible[69] "expression," or the "arrangement of words which the author has selected to express the idea."[70] The rationale served the purposes of the intellectual property clause well, since free access to ideas is critical to the development of creative works.[71] Moreover, the right granted did not include a right over certain words used, because "they are the common property of

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[65] Arewa, *supra* note 5, at 592.

[66] Cohen, *supra* note 60, at 204.

[67] *Id.* at 201.

[68] Holmes v. Hurst, 174 U.S. 82, 86 (1899).

[69] *See, e.g.*, White-Smith Music Publ'g Co. v. Apollo Co., 209 U.S. 1, 17 (1908) (holding that a perforated piano roll used to create the sounds of a musical composition did not infringe the copyright in the underlying musical composition because "[a] musical composition is an intellectual creation which first exists in the mind of the composer. . . It is not susceptible of being copied until it has been put in a form which others can see and read. The statute has not provided for the protection of the intellectual conception apart from the thing produced . . . .").

[70] *Holmes*, 174 U.S. at 86.

[71] Cohen, *supra* note 60, at 206.

the human race."[72] This early approach was consistent under the classical conception of the creative process, which views the artist as portraying an intangible idea or truth which "cannot and should not be captured or controlled by one artist."[73]

However, with the rise of the Romantic view in the nineteenth and twenties centuries,[74] Congress no longer limited "expression" to the arrangement of the literal elements of the copyrighted work, but expanded it to include underlying "original" conceptual elements as well.[75] In 1909, Congress both enlarged the category of works eligible for protection and expanded the rights provided to copyright owners, including use of the work in a different medium.[76] Protection under the Act was no longer limited to the literal form or features of the expressed idea, but extended to elements of a work that are intangible and conceptual.[77] In applying the new act, the Supreme Court in *Kalem Co. v. Harper Bros.*[78] found the defendant's film to infringe upon the plaintiff's copyright in the book *Ben Hur* because the film expressed the same underlying idea, or plot, albeit in an entirely different medium.[79]

It became clear that balanced against the idea-expression distinctions is the countervailing consideration that copyright infringement cannot be limited to exact

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[72] *Holmes*, 174 U.S. at 86 ("[C]ertain words . . . are as little susceptible of private appropriation as air or sunlight[.]"); *see also* Johnson v. Donaldson, 3 F. 22, 24 (S.D.N.Y. 1880) ("A copyright secures the proprietor against the copying, by others, of the original work, but does not confer upon him a monopoly in the intellectual conception which it expresses.").

[73] Cohen, *supra* note 60, at 231.

[74] *Id.*

[75] *Id.* at 204–206 ("If art was no longer viewed as the formal expression of fundamental, abstract ideas, but rather as the expression of the individual feelings of the particular artist, then the view that copyright should protect only the author's specific way of expressing the ideas, but not those fundamental, abstract ideas themselves, had lost its philosophical basis.").

[76] Act of Mar. 4, 1909, ch. 320, § 1(b), (d), (e), 35 Stat. 1175 (providing the copyright owner with the exclusive right to transform the protected work into different formats, including the right to dramatize a nondramatic work, to translate a literary work or "to make any other version thereof," to perform works publicly, and to "make any arrangement or setting of it or of the melody of it in any system of notation or any form of record in which the thought of an author may be recorded and from which it may be read or reproduced.").

[77] Cohen, *supra* note 60, at 206 (citing Benedetto Croce's view that "the essence of artistic activity is not the
production of an external physical object, but an internalized aesthetic synthesis of impressions and sensations.").

[78] Kalem Co. v. Harper Bros., 222 U.S. 55 (1911).

[79] *Id.* at 63.

copying, "else a plagiarist would escape by immaterial variations."[80] The problem is one of line-drawing: at what point is a variation distinguishable enough to "sufficiently alter a work's substantial similarity to another so as to negate infringement," without extending protection to the underlying idea of the plaintiff's work?[81]

Views on the nature of art and the creative process have only continued to evolve and become more inconsistent with the idea-expression dichotomy.[82] The conceptual art movement advanced the rejection of any distinction between an artist's idea and the ultimate expression.[83] As conceptual artist Sol LeWitt stated, "the idea or concept is the most important aspect of the work. When an artist uses a conceptual form of art, it means that all of the planning and decisions are made beforehand and the execution is a perfunctory affair. The idea becomes a machine that makes the art."[84] In rejecting the Formalist tradition, which defined art by its form and structure, conceptual art judges art by what it contributes to the conception and definition of "art."[85] Even an unchanged item from the grocery store, like a box of Brillo soap pads,[86] can be art if framed in a new way.

With Romantic and neo-romantic views challenging classical aesthetic theory, no universally accepted philosophical or objective basis remains for distinguishing ideas from expression in works of art. Continuing to use the terms leaves courts to make infringement decisions on the basis of their own subjective assessments of a work's artistic value.[87] Judicial determinations of what constitutes the "idea" versus the "expression" have come to reflect personal assumptions and experiences. Courts tend to find elements of a work to be an "idea" when they are

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[80] Nichols v. Universal Pictures Corp., 45 F.2d 119, 121 (2d Cir. 1930).

[81] NIMMER, *supra* note 11, at § 13.03[a][i].

[82] *See* Cohen, *supra* note 60, at 207.

[83] *Id.* (citing JOHN DEWEY, ART AS EXPERIENCE 8, 49-52, 56, 64-65 (1934)).

[84] Sol LeWitt, *Paragraphs on Conceptual Art*, ARTFORUM (June 1967), http://radicalart.info/concept/LeWitt/paragraphs.html.

[85] *See id.*

[86] Take, for example, Andy Warhol's *Brillo Boxes*. By reframing the household-cleaning product as art, Warhol instilled in the Brillo box an entirely different meaning. Instead of representing a product or brand identity, Warhol's *Brillo Boxes* stood for the Pop Art movement's challenge to the dominant view of elitist aesthetics, and represented the idea that anything can be art. As philosopher Arthur Danto put it, the *Brillo Boxes* were the "end of art" as we know it because they marked the point at which art became so conscious of itself that it became apparent that in art "anything goes…that there were no stylistic or philosophical constraints." *Id.*

[87] *See* Cohen, *supra* note 60, at 232.

familiar with the work's aesthetic tradition and can recognize the elements as commonplace.[88] Conversely, courts are more likely to find elements of works in less familiar traditions to be original "expression," making them more inclined to find later uses infringing.[89] As the Ninth Circuit admitted, "'At least in close cases, one may suspect, the classification [of idea and expression] the court selects may simply state the result reached rather than the reason for it.'"[90] Thus, with changing views on the creative process, "it is no longer necessary or valuable or even possible to dissect a work of art to uncover the universal truths or ideas which must remain freely available to all future authors."[91]

Distinguishing between ideas and expression is perhaps most illusory in the context of music, due to the relatively limited number of compositional choices when compared with literary works.[92] Western music, at issue in most copyright suits, is primarily written in the tonal system, an organized and relational system of tones (*e.g.*, the notes of a major or minor scale) in which one tone becomes "the central point to which the remaining tones are related."[93] Because there are a limited number of possible pitch and harmonic relationships, options within tonal music are somewhat dictated by the system.[94] Moreover, because the tonal system is built on a hierarchy of predominate chords and pitches,[95] certain "patterns and tendencies are . . . common to virtually all musical works composed in the tonal

[88] *Id.* at 212; *see, e.g.*, Nichols v. Universal Pictures Corp., 45 F.2d 119 (2d Cir. 1930), *cert. denied*, 282 U.S. 902 (1931) (finding stories of star-crossed lovers too common to be protectable, despite both stories involving a relationship between a Jewish family and an Irish family, a secret marriage between the son and daughter of these two families, a conflict between the two fathers, and an ultimate reconciliation); Steinberg v. Columbia Pictures, 663 F. Supp. 706, 708–09 (S.D.N.Y. 1987) (discussing the plaintiff's fame and the popularity of his work in finding the defendant's work infringing); Cohen *supra* note 60, at 229 ("[A]nother factor that affects a court's determination of where to draw the line between idea and expression in a given case involving literary works is the relative commercial success of the works at issue and the reputations of their creators.").

[89] See, e.g., the recent *Blurred Lines* verdict discussed *infra* at Part II.C.1.

[90] Herbert Rosenthal Jewelry Corp. v. Kalpakian, 446 F.2d 738, 742 (2d Cir. 1982).

[91] Cohen, *supra* note 60, at 231.

[92] Cadwell, *supra* note 18, at 157; *see also* Arewa, *supra* note 5, at 556.

[93] BRUCE BENWARD & MARILYN SAKER, MUSIC: IN THEORY AND PRACTICE (7th ed., McGraw Hill 2003).

[94] *See generally* Cadwell, *supra* note 18, at 155–57.

[95] *Id. See generally* Carol L. Krumhansl & Lola L. Cuddy, *A Theory of Tonal Hierarchies in Music*, in MUSIC PERCEPTION 51 (M.R. Jones et al. eds., 2003).

system."[96] The distinction between these unprotectable ideas and the original expression thereof is difficult to see, and thus the room for bias is most apparent.[97]

C. Evolution of the Copyright Infringement Tests

Courts since the nineteenth century have attempted to separate the issue of copyright infringement into two issues. First, "Copying-in-Fact": did the defendant see and copy from the copyrighted work or did he create his work independently?; second, "Misappropriation": did the defendant appropriate too much of the protected work?[98] The first question is used as an evidentiary tool to infer copying from access or "striking similarity,"[99] while the second focuses on the liability issue.[100] The degree of similarity between the two works is relevant to both the inquiries;[101] the phrase "probative similarity" is often used in reference to the first inquiry, while "illicit similarity" is used for the second.

Courts in the 1900s maintained the distinction between the copying-in-fact and misappropriation inquiries. A "substantial similarity" test was used for the copying-in-fact inquiry to determine whether the degree of similarity between the defendant's and the plaintiff's work was substantial to the point of being probative of actual copying. [102] The focus was solely on whether the defendant had copied "the labors of the original author."[103] As such, before comparing the two works for

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[96] Cadwell, *supra* note 18, at 158.

[97] *Id.*

[98] *See* Yen, *supra* note 2, at 284.

[99] "Striking similarity" is similarity that is "so striking that the possibilities of independent creation, coincidence and prior common source are, as a practical matter, precluded." Selle v. Gibb, 741 F.2d 896, 897 (7th Cir. 1984).

[100] Cohen, *supra* note 6, at 724.

[101] *Id.* at 728.

[102] *Id.* at 724–27 (comparing the use of phrases such as "substantial identity" or "substantial copy" by the courts to "signify a degree or type of similarity that would be relevant" to proving whether the defendant had in fact used the plaintiff's work, versus the use of the adjective "substantial" in relation to the economic or aesthetic value of the copyright owner's work to determine whether the defendant could be liable for copyright infringement.). *Cf.* Arnstein v. Porter, 154 F.2d 464, 473 (2d Cir. 1946) (inquiring "whether defendant took from plaintiff's works so much of what is pleasing to the ears of lay listeners, who comprise the audience for whom such popular music is composed, that defendant wrongfully appropriated something which belongs to the plaintiff.").

[103] Cohen, *supra* note 6, at 725–26 ("The focus was not principally on how much or what aspects of the plaintiff's work defendant had borrowed, but on whether defendant had copied the plaintiff's work rather than doing his own work. The concern was with whether 'the labors of the original author are substantially to an injurious extent appropriated by another.'") (quoting

similarities, the court filtered out unprotected elements from the plaintiff's work, including those that were "well known and in common use."[104]

In determining misappropriation—that is, whether the defendant copied enough of the plaintiff's work to be held liable—courts looked to the economic or aesthetic value of what the defendant copied: if the portions extracted "embody the spirit and the force of the work…they take from it that in which its chief value consists."[105] In this context, courts often used the adjective "substantial" to refer to the qualitative value of what was copied.[106]

As precedent evolved, courts began to combine the structure of these two prongs. As a result, courts have often confused the economic purpose of the misappropriation prong: finding infringement based solely on quantitative similarity without taking account of the unprotected elements in the original work. The analysis of the two major copyright tests below outlines how this confusion arose and focuses on the problems the misappropriation prong are causing for copyright.

1. Second Circuit Copying/Unlawful Appropriation Test

In *Arnstein v. Porter*,[107] the litigious Ira B. Arnstein sued the American songwriter and composer Cole Porter, alleging that many of Porter's songs infringed the copyrights of songs written by Arnstein.[108] The Second Circuit

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Greene v. Bishop, 10 F. Cas. 1128, 1134 (C.C.D. Mass. 1858) (No. 5763)).

[104] Emerson v. Davies, 10 F. Cas. 615, 622 (C.C.D. Mass. 1845) (No. 4436) (noting, in comparing the similarities between tables in two arithmetic textbooks, that "[t]he question is not in what part of one or more pages the matter is found, but whether it is borrowed or pirated from the plaintiff, without any substantial alteration or difference."). The court went on to state that "[a] copy is one thing, an imitation or resemblance another…. It is very clear that any use of materials…which are well known and in common use, is not the subject of a copy-right, unless there be some new arrangement thereof." *Id.*

[105] *See* Story v. Holocombe, 23 F. Cas. 171, 173 (C.C.D. Ohio 1847) (No. 13497) (stating that infringement "does not depend so much upon the length of the extracts as upon their value.").

[106] Cohen, *supra* note 6, at 727 (citing Folsom v. Marsh, 9 F. Cas. 342, 348 (C.D.D. Mass. 1841) (No. 4901) (stating that infringement may exist "if so much is taken, that ... the labors of the original author are *substantially* to an injurious extent appropriated by another") (emphasis added).

[107] Arnstein v. Porter, 154 F.2d 464 (2d Cir. 1946). *See also* NIMMER, *supra* note 11, at § 13.03[a][i].

[108] *Arnstein*, 154 F.2d at 467. *See also* Cadwell, *supra* note 18, at 139 n.19.

conducted an influential bifurcated test,[109] which requires a plaintiff to prove (1) copying-in-fact and (2) illicit copying (unlawful appropriation) to establish infringement.[110]

i. Copying-in-Fact

The first prong of the *Arnstein* test is satisfied with the showing of (a) access; and (b) sufficient similarity, which is "probative" of copying: "The stronger the proof of similarity, the less the proof of access that is required."[111] Thus, if similarities are so "striking" so as to "preclude the possibility that plaintiff and defendant independently arrived at the same result," evidence of access may not be necessary.[112] Of course, the converse is not true because "access without similarity cannot create an inference of copying." [113]

To evaluate the likelihood of copying versus independent creation, expert testimony and "analytic dissection"[114] are admissible.[115] However, the two works are to be compared in their entirety, including both protectable and non-protectable material.[116]

ii. Unlawful Appropriation

Only if the threshold issue of copying-in-fact is shown does the court move to the question of misappropriation.[117] Having established copying-in-fact, the issue of unlawful appropriation is a question of fact. Therefore, the fact finder must determine whether the taking went so far as to constitute infringement under the "substantial similarity" test.[118] That is, would the ordinary observer, unless he set

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[109] Cadwell, *supra* note 18, at 139 n.19.

[110] ERIC C. OSTERBERG & ROBERT C. OSTERBERG, SUBSTANTIAL SIMILARITY IN COPYRIGHT LAW § 3.2.1.A (PLI 2015).

[111] *Arnstein*, 154 F.2d at 468. *See also* OSTERBERG, *supra* note 110, at § 3.1.1; Cohen, *supra* note 6, at 729 ("Although some dispute still exists as to whether the plaintiff must prove actual access or only opportunity for access, courts generally agree that showing some possibility of access is very much a part of the plaintiff's case.").

[112] *Arnstein*, 154 F.2d at 468.

[113] NIMMER, *supra* note 11, at § 13.03[a][i].

[114] A piece-by-piece examination of the works' constituent parts or elements. *See* OSTERBERG, *supra* note 110, at § 3.4.

[115] Cohen, *supra* note 6, at 731.

[116] NIMMER, *supra* note 11, at § 13.03[a][i].

[117] *Id.*

[118] *See* Castle Rock Entm't, Inc. v. Carol Pub. Group, Inc., 150 F.3d 132, 137 (2d Cir. 1998). *See also* OSTERBERG, *supra* note 110, at §§ 3-4.

out to detect the disparities, be disposed to overlook them and regard the aesthetic appeal of the two works as the same?[119] The second part of the *Arnstein* test is "related to the nineteenth century concern with the value of what the defendant had copied" as it asks whether the similarity "relates to material of substance and value in plaintiff's work."[120] However, the *Arnstein* test departs in some ways from earlier definitions of infringement by looking to the reaction of the "ordinary observer."[121]

In determining misappropriation, the *Arnstein* test looks to "the response of the ordinary lay hearer." That is, rather than making a purely subjective determination, the trier of fact is meant to determine the issue "in light of the impressions reasonably expected to be made upon the *hypothetical* ordinary observer."[122] Because the court reasoned that the value of the work lay solely in the opinion of its intended audience, it held that expert testimony on the "impression made on the refined ears of musical experts" was "utterly immaterial."[123] While seeming to realize the difficulty in discovering the views of the imaginary "ordinary observer,"[124] the court stated that expert testimony was permitted for the limited purpose of "assist[ing] in determining the reactions of lay auditors."[125]

Moreover, because the court determined that the value of the works lay in their final form as impressed upon the ordinary observer, it instructed that detailed analysis and careful dissection were inappropriate.[126] Therefore, according to *Arnstein*, works were to be considered in their entirety, again including both protectable and non-protectable material.[127] The trier was left to depend on "some visceral reaction" as the basis for determining misappropriation.[128]

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[119] OSTERBERG, *supra* note 110, at § 3.1.2 (citing Peter Pan Fabrics, Inc. v. Martin Weiner Corp., 274 F.2d 487, 489 (2d Cir. 1960)).

[120] Cohen, *supra* note 6, at 732.

[121] *Id.*

[122] Carol Barnhart, Inc. v. Econ. Cover Corp., 773 F.2d 411, 422 (2d Cir. 1985) (Newman, J. dissenting) (emphasis added).

[123] Arnstein v. Porter, 154 F.2d 464, 473 (2d Cir. 1946).

[124] *See* Yen, *supra* note 2, at 291 ("[D]ifficulties arise because the ordinary observer is not a real person whose views may be discovered.").

[125] *Arnstein*, 154 F.2d at 473.

[126] *Id.* at 468.

[127] NIMMER, *supra* note 11, at §13.03[a][i].

[128] Cohen, *supra* note 6, at 732.

If the case involves "comprehensive non-literal similarity"[129] – that is, similarity in the overall structure of the works – the trier must make a value judgment of "whether defendant took from plaintiff's works so much of what is pleasing to the ears of lay listeners, who comprise the audience for whom such popular music is composed, that defendant wrongfully appropriated something which belongs to the plaintiff."[130] In a case of "fragmented literal similarity," or verbatim copying of constituent elements, an analogous value judgment must be made, but here only with respect to the protectable portions of plaintiff's work that have been taken.[131] Dissimilarities between materials alleged to be infringing are "significant because they mitigate any impression of similarity."[132] Dissimilarities in other aspects of the defendant's work, except to the extent they create an overall different impression, "typically are not significant."[133] As Judge Learned Hand said, "no plagiarist can excuse his wrong by showing how much work he did not pirate."[134] Thus, if the defendant copies from the plaintiff's work, it does not matter if he adds significant material of his own,[135] resulting in what might be a transformative new work.

Consequently, under *Arnstein*, "[i]nstead of using some objective standards or criteria based on economic impact or quantity, courts [are] to determine infringement on an unpredictable, impressionistic basis."[136]

iii. Further Developments and Confusions of the *Arnstein* Test

Although the Second Circuit in *Arnstein* conducted two separate inquiries into the level of similarity between the two works,[137] namely to establish copying-in-fact and then to determine misappropriation, confusion ensued from the dual use of the term "substantial similarity." As a result of this confusion, in *Ideal Toy*

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[129] NIMMER, *supra* note 11, at § 13.03[a][i]. The terms "comprehensive non-literal similarity" and its counterpart, "fragmented literal similarity," emerge from this treatise but they have gained widespread judicial acceptance.

[130] *Id*. *See also Arnstein*, 154 F.2d at 473 (deeming it "an issue of fact which a jury is peculiarly fitted to determine.").

[131] NIMMER, *supra* note 11, at § 13.03[a][i].

[132] Eric Osterberg, *Copyright Litigation: Analyzing Substantial Similarity*, 1, 7 PRACTICAL LAW INTELLECTUAL PROPERTY & TECHNOLOGY, *available at* http://www.osterbergllc.com/wp-content/uploads/2013/09/Practical-Law-Article.pdf.

[133] *Id.*

[134] Sheldon v. Metro-Goldwyn Pictures Corp., 81 F.2d 49, 56 (2d Cir. 1936).

[135] Osterberg, *supra* note 132, at 7.

[136] NIMMER, *supra* note 11, at §13.03[a][i].

[137] Arnstein v. Porter, 154 F.2d 464, 468 (2d Cir. 1946).

Corp. v. Fab-Lu Ltd,[138] the Second Circuit essentially combined the issues into one subjective test. By misinterpreting the element of misappropriation identified in *Arnstein* as "merely an alternative way of formulating the issue of substantial similarity" rather than as an independent step, the Second Circuit stated that copyright infringement is shown solely by "substantial similarity" between the two works based on the reaction of the ordinary observer.[139] The court effectively reduced the test for prima facie copyright infringement to (1) access, and (2) misappropriation, thereby failing to consider copying-in-fact.[140] Therefore, the court rejected dissection, analysis, and expert testimony entirely and did not think it necessary to analyze the similarities between the works to determine the likelihood of independent creation.[141] By basing the entire copyright infringement inquiry on the subjective impression of those untrained in the arts, the court neglected to protect against a finding of infringement based on purely unprotectable and unoriginal elements. The *Ideal Toy* test fails to deal with the fundamental principle of copyright law that seeks to protect merely the expression of ideas rather than ideas themselves.[142] Unfortunately, *Ideal Toy*'s interpretation of the *Arnstein* test largely influenced the way modern courts use "substantial similarity" in determining infringement.[143]

Luckily, some courts have maintained the *Arnstein* two-part inquiry. In *Universal Athletic Sales Co. v. Salkeld*,[144] the Third Circuit restored *Arnstein*'s bifurcated approach in holding that a plaintiff must prove copying *and* "that

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[138] *See* Ideal Toy Corp. v. Fab-Lu Ltd., 266 F. Supp. 755 (S.D.N.Y. 1965), *aff'd*, 360 F.2d 1021 (2d Cir. 1966).

[139] *Id.* at 1022 (stating that the plaintiff need only show substantial similarity between the two works, which is present when "an average lay observer would recognize the alleged copy as having been appropriated from the copyrighted work.").

[140] *See* Cohen, *supra* note 6, at 733.

[141] *Id.* at 737.

[142] The idea-expression dichotomy is essential to copyright law, as only the expression of ideas is protectable. 17 U.S.C. § 102(b) (1982) (excluding from the subject matter of copyright "any idea, procedure, process, system, method of operation, concept, principle, or discovery.").

[143] Cohen, *supra* note 6, at 735 (deeming the court's test in *Ideal Toy* the "Traditional Approach") (citing Novelty Textile Mills v. Joan Fabrics Corp., 558 F.2d 1090, 1093 (2d Cir. 1977). *Novelty Textile Mills* found infringement because to lay eyes, the fabrics were "almost identical;" however, the court never analyzed the similarities to determine the likelihood of independent creation or the likelihood of copying.

[144] Universal Athletic Sales Co. v. Salkeld, 511 F.2d 904, 907 (3d Cir. 1975), *cert. denied*, 423 U.S. 863 (1975) ("[S]ubstantial similarity to show that the original work has been copied is not the same as substantial similarity to prove infringement.").

copying went so far as to constitute improper appropriation."[145] Moreover, the court recognized that "substantial similarity to show that the original work has been copied is not the same as substantial similarity to prove infringement."[146]

More inherently problematic is the fact that the *Salkeld* court maintained *Arnstein*'s limits on expert analysis and dissection in determining misappropriation.[147] As a result, the *Salkeld* test likewise fails to provide any objective standards or criteria for determining how much similarity is necessary to constitute misappropriation.[148]

Though courts instruct the fact finder to find misappropriation only if the defendant's work copies not merely the idea, but 'the expression of the idea,' this "vague formula" is a reformulation, not a solution, to the problem of determining "what sort of similarity short of the verbatim will constitute substantial similarity."[149] Thus, the ordinary observer continues to be left with "the impossible task of comparing only protected expression in determining substantial similarity without engaging in any thoughtful dissection or analysis of the works."[150]

2. Ninth Circuit: "Total Concept and Feel"

The Ninth Circuit's framework, laid out in *Sid & Marty Krofft Television Prods., Inc. v. McDonald's Corp*,[151] represents the second main approach to determining copyright infringement. Although not a music infringement case, the "extrinsic/intrinsic" test developed by the *Krofft* court has been influential in many copyright disputes, including those involving music.[152] In recognizing that the ordinary observer is unlikely to be able to separate idea from expression in comparing two works without dissection or analysis, the Ninth Circuit proposed its

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[145] Cohen, *supra* note 6, at 747 (citing *Salkeld*, 511 F.2d at 907).

[146] *Id.*

[147] *Id.*

[148] *Id.* at 737 ("By relying upon the ordinary observer test alone and thus rejecting dissection, analysis, and expert testimony, the courts were deprived of the evidence necessary to analyze properly the likelihood of independent creation.").).

[149] NIMMER, *supra* note 11, at § 13.03[A][1].

[150] Cohen, *supra* note 6, at 749; *cf.* NIMMER, *supra* note 11, at § 13.03[A][1][a] ("Obviously, no principle can be stated as to when an imitator has gone beyond the 'idea,' and has borrowed its 'expression.' Decisions must therefore inevitably be ad hoc.") (citing Peter Pan Fabrics, Inc. v. Martin Weiner Corp., 274 F.2d 487, 489 (2d Cir. 1960)).

[151] *See generally* Sid & Mart Krofft Television Prods., Inc. v. McDonald's Corp., 562 F.2d 1157 (9th Cir. 1977).

[152] Cadwell, *supra* note 18, at 150.

own two-step test that attempts to ensure that there is "substantial similarity not only of the general ideas but of the expressions of those ideas as well."[153] Though the test was later reformulated to include specific expressive elements during the extrinsic inquiry, as discussed in in Part I.ii.c., understanding the original formulation is key to examining its foundational flaws.

i. Extrinsic Test

The first step, or the "extrinsic" analysis, as originally cast by the *Krofft* court, was an objective comparison by the court for similarity in ideas.[154] Only if a substantial similarity of objective criteria under the "extrinsic" test is found do courts consider misappropriation under the "intrinsic" analysis.[155] Thus, the extrinsic test aims to limit protection to protectable elements by first filtering out unprotectable elements, including ideas, facts, and *scènes à faire*, and then determining whether the allegedly infringing work is "substantially similar to the protectable elements of the artist's work."[156]

According to the Ninth Circuit, in filtering out unprotected elements the extrinsic test incorporates the idea-expression dichotomy by limiting the scope of copyright protection to expression. As the court stated:

> By creating a discrete set of standards for determining the objective similarity of literary works, the law of this circuit has implicitly recognized the distinction between situations in which idea and expression merge in representational objects and those in which the idea is distinct from the written expression of a concept….[157]

Courts conducting the extrinsic test "must take care to inquire only whether the protectable elements, standing alone, are substantially similar."[158] Therefore, analytic dissection and expert testimony presented by the plaintiff on the

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[153] *See Krofft*, 562 F.2d at 1164 ("We believe that the court in *Arnstein* was alluding to the idea-expression dichotomy which we make explicit today."); *see also* Cohen, *supra* note 6, at 753 ("The Ninth Circuit recognized that the ordinary observer is unlikely to be able to separate idea from expression in comparing two works without dissection or analysis.").

[154] *Krofft*, 562 F.2d at 1164.

[155] *Id.* at 1165 (establishing that the question is whether the defendant took "so much of what is pleasing to the audience" to be held liable).

[156] OSTERBERG, *supra* note 110, at § 3-3-3.

[157] Shaw v. Lindheim, 919 F.2d 1353, 1360 (9th Cir. 1990).

[158] Cavalier v. Random House, Inc., 297 F.3d 815, 822 (9th Cir. 2002).

similarities between the plaintiff's work and defendant's work are recommended.[159]

In performing the analytic dissection, courts are instructed to list and analyze the "measurable, objective elements" of the works,[160] including "the type of artwork involved, materials used, and the subject matter."[161] For literary works, courts have listed such elements as "plot, theme, dialogue, mood, setting, pace, characters, and sequence of events."[162] Because these factors do not readily apply to visual works of art, the court looks to the "objective details of the appearance."[163] Without attempting to provide an exhaustive list of relevant factors, the court in Ninth Circuit listed such elements as "the subject matter, shapes, colors, materials, and arrangement of the representations."[164]

Though described as a factual question, because it bases the question on objective criteria rather than the response of the trier, the extrinsic test may often be decided as a matter of law.[165]

ii. Intrinsic Test

Much like the Second Circuit's ordinary observer test, the intrinsic test is entirely subjective and based on the "response of the ordinary reasonable person" to the "total concept and feel" of a work,[166] excluding expert testimony and dissection. Similar to the *Arnstein* court's language of "lay [persons], who comprise the audience,"[167] the *Krofft* court suggested that the fact finder's reaction be geared towards that of the intended or likely audience.[168] In a suit involving the

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[159] *Id.*

[160] *Shaw*, 919 F.2d at 1359.

[161] Cadwell, *supra* note 18, at 151.

[162] *Shaw*, 919 F.2d at 1359.

[163] McCulloch v. Albert E. Price, Inc., 823 F.2d 316, 319 (9th Cir. 1987) (noting that a conclusion that two works are "'confusingly similar in appearance' is tantamount to finding substantial similarities in the objective details of the [works].") (citing Litchfield v. Spielberg, 736 F.2d 1352, 1356 (9th Cir. 1984)).

[164] *Cavalier*, 297 F.3d at 826; *see also* Smith v. Jackson, 84 F.3d 1213, 1218 (9th Cir. 1996) (applying *Shaw*'s rule to musical motifs).

[165] *Cavalier*, 297 F.3d at 826.

[166] Sid & Mart Krofft Television Prods., Inc. v. McDonald's Corp., 562 F.2d 1157, 1164 (9th Cir. 1977).

[167] Arnstein v. Porter, 154 F.2d 464, 473 (2d Cir. 1946).

[168] *Krofft*, 562 F.2d at 1166–67. ("We do not believe that the ordinary reasonable person, *let alone a child*, viewing these works will even notice that Pufnstuf is wearing a cummerbund while Mayor McCheese is wearing a diplomat's sash.") (emphasis added).

characters in a children's television show, the court stated, "The present case demands an even more intrinsic determination because both plaintiffs' and defendants' works are directed to an audience of children."[169] Therefore, the court limited the inquiry to the understanding of a child and found substantial similarity despite noted differences. Without expert testimony to aid the trier in determining whether children might detect distinctions, the court relied on the triers' subjective belief that children would be unlikely to notice minor distinctions.[170]

iii. Further Developments and Confusions of the *Krofft* Test

In *Shaw v. Lindheim*,[171] the Ninth Circuit modified the extrinsic/intrinsic test in recognition of the fact that district courts were not limiting the extrinsic test to a comparison of ideas.[172] Recognizing that the similarity of ideas prong is often shown by "focusing on the similarities in the objective details of the works,"[173] the *Shaw* court explained that the extrinsic/intrinsic test is no longer divided by an analysis of ideas and expression.[174] Rather, the extrinsic test is an objective analysis of specific "manifestations of expression," while the intrinsic test is a subjective analysis of expression by the fact finder, which is no more than the lay observer's visceral reaction which is "virtually devoid of analysis."[175] Though the *Shaw* court recognized that the test was "more sensibly described as objective and subjective"[176] courts have confusingly continued to use the extrinsic/intrinsic language. Moreover, subsequent cases have left the analysis of improper appropriation to the jury analyzing the works as a whole.

In *Swirsky v. Carey*,[177] the Ninth Circuit applied the extrinsic/intrinsic test to a case involving musical works. Swirsky and his co-writer filed a copyright infringement suit claiming that Mariah Carey's song "Thank God I Found You"

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[169] *Id.*

[170] *See* Julie E. Cohen et al., *Copyright in a Global Information Economy*, COMPANION WEBSITE, http://coolcopyright.com/contents/chapter-5/sid-marty-krofft-television-productions-v-mcdonalds.

[171] 919 F.2d 1353 (9th Cir. 1990); *see also* Cavalier v. Random House, Inc., 297 F.3d 815, 822 (9th Cir. 2002).

[172] *Shaw*, 919 F.2d at 1357 (explaining that they were comparing "every element that may be considered concrete").

[173] Litchfield v. Spielberg, 736 F.2d 1352, 1356 (9th Cir. 1984).

[174] *See Shaw*, 919 F.2d at 1357.

[175] *Id.*

[176] *Id.*

[177] Swirsky v. Carey, 376 F.3d 841, 844–45 (9th Cir. 2004).

plagiarized their song "One of Those Love Songs."[178] The court rejected the district court's approach to the extrinsic test, which involved a "measure-by-measure comparison of melodic note sequences."[179] The Ninth Circuit felt comparing notes would fail to consider other relevant elements such as "harmonic chord progression, tempo, and key" as "it is these elements that determine what notes and pitches are heard in a song and at what point in the song they are found."[180] The court expressly refused to announce precisely which elements the court should consider, explaining in dicta that the copyright framework is difficult to apply to aesthetic works such as music which are "not capable of ready classification into . . . constituent elements" the way literary works can be classified into "plot, themes, mood, setting, pace, characters, and sequence of events."[181]

The Ninth Circuit's opinion in *Swirsky* is also relevant for its proposition that substantial similarity can be found based on a combination of elements, "even if those elements are individually unprotected."[182] For example, in *Three Boys Music Corp. v. Bolton*,[183] the Ninth Circuit upheld the jury's finding that two songs were substantially similar due to the presence of the same five individually unprotectable elements: "(1) the title hook phrase (including the lyric, rhythm, and pitch); (2) the shifted cadence; (3) the instrumental figures; (4) the verse/chorus relationship; and (5) the fade ending."[184] Even though courts filter out unprotected elements such as expression that are commonplace within a genre, they reconsider these elements in examining whether there is a unique combination of elements.[185] However, the protection granted to a unique combination of elements is "thin," applying only to the combination itself, not the individual elements, and protecting only against "virtually identical" copying.[186]

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[178] *Id.* at 843.

[179] *Id.* at 847.

[180] *Id.* at 848.

[181] *Id.* at 849 n.15 (quoting Metcalf v. Bochco, 294 F.3d 1069, 1073 (9th Cir. 2002) (quoting Kouf v. Walt Disney Pictures & Television, 16 F.3d 1042, 1045 (9th Cir. 1994))).

[182] *Id.* at 848.

[183] Three Boys Music Corp. v. Bolton, 212 F.3d 477 (9th Cir. 2000).

[184] *Id.* at 485.

[185] *Swirsky*, 376 F.3d at 850; *see also* Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 349 (1991) (extending copyright protection to the original selection and arrangement of otherwise uncopyrightable components).

[186] Apple Computer v. Microsoft Corp., 35 F.3d 1436, 1442, 1447 (9th Cir. 1994).

II
THE ROOTS, FLAWS, AND LEGACY OF *ARNSTEIN*

Though *Arnstein* remains the majority approach to analyzing copyright infringement,[187] the opinion has attracted much criticism. This part will begin by detailing the flaws of *Arnstein*, and its progeny, including *Krofft*. Arguing that *Arnstein* lacks objectivity by relying on the "impression" of the lay observer and limiting the use of expert testimony,[188] this section will consider courts' classification of misappropriation as a subjective factual question for the jury, rather than as a legal question with its own standard. This part will argue that the treatment of the "aesthetic arts" as incapable of technical analysis is the root of its subjective treatment of misappropriation. Finally, this part will argue that in relying on the general public, untrained in artistic assessment, the courts risk finding infringement based on similarities that are attributable to common sources.[189]

A. Problems with Arnstein *and the Ordinary Observer*

Without detailed analysis, filtering out unprotectable ideas, or guidance from experts on the artistic merits of the works at issue, little assurance remains that jurors will decide the issue of misappropriation in keeping with the law. This section will explore why relying on the reaction of laymen is problematic in the context of copyright law. While jury instructions attempt to solve the problem, this part will examine why such abstract guidance is often more confusing than helpful, as judges themselves seem baffled by the blurry line of where an idea ends and its expression begins.

While the ordinary observer test attempts to utilize the "reasonable person" standard found in other areas of the law, its application to copyright is not analogous. In areas such as tort law, the trier is capable of placing himself in the defendant's shoes to assess the defendant's actions.[190] In copyright, because the trier often lacks the defendant's artistic background, the trier cannot reasonably put himself in the defendant's shoes to consider whether he would have been constrained to copy from the plaintiff in order to achieve the given result.[191]

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[187] Dawson v. Hinshaw Music Inc., 905 F.2d 731, 733 (4th Cir. 1990) (describing *Arnstein* as "the source of modern theory"); *see also* Lemley, *supra* note 13, at 719.

[188] Arnstein v. Porter, 154 F.2d 464, 468 (2d Cir. 1946).

[189] As Professor Nimmer suggests, conversely, it may also cause very real appropriation to go undetected. NIMMER, *supra* note 11, at § 13.03[E][2].

[190] *Id.*

[191] *Id.*

Consequently, the trier is asked to assess the defendant's actions as if he is an "average lay observer" reacting to whether the defendant's work *appears* to have been copied from the plaintiff's work.[192] Yet copyright is meant to protect artists from the theft of the fruits of their labor, not from the "impression" of theft.[193] While the "spontaneous and immediate" impression of theft is "important evidence," it cannot be the end-all-be-all test.[194] Given the complexities of copyright law,[195] the ordinary observer simply is not capable of accurately detecting very real appropriation.[196]

While the ordinary observer test has logical value in protecting the artist's interest in the potential fruits of his labor by looking to the response of the specific market from which those fruits would derive,[197] its methodology for making that determination is lacking. One problem is that it is not clear the trier has knowledge of what constitutes the "lay listener's" response,[198] especially considering the multitude of possible reactions even among a "target" audience.[199] While expert testimony is permitted to inform the fact finder on the views of the target audience, it is questionable whether qualifying as a music expert establishes "an expertise in the aural perceptions of a lay hearer."[200] Put another way, "whether an expert,

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[192] *Id.*

[193] *Id.*

[194] *Id.*

[195] *See* Balganesh, *supra* note 9, at 794 ("Copyright's infringement analysis has been variously described as 'bizarre,' 'mak[ing] no sense,' 'viscid,' and 'problematic.'"); *see also* Whelan Assocs., Inc. v. Jaslow Dental Lab., Inc., 797 F.2d 1222, 1232 (3d Cir. 1986) (noting the doubtful value of the ordinary observer test in cases involving complex subject matter unfamiliar to most members of the public).

[196] Especially when applied to complex works, such as computer software and music and with complicating circumstances of the transformation of a work into a different medium. NIMMER, *supra* note 11 at § 13.03[E][2].

[197] *Id.*; *cf.* Hein v. Harris, 175 F. 875, 876 (C.C.S.D.N.Y. 1910) (explaining that the ultimate inquiry is whether the average person's ear would find the two melodies substantial similar because the pecuniary value of a composition rests in the public taste).

[198] Michael Der Manuelian, *The Role of the Expert in Music Copyright Infringement Cases*, 57 FORDHAM L. REV. 126, 131 (1988) (describing how the trier must determine, not his own personal reaction to the similarities between the two works, but the reaction of the "average lay hearer."); *see id.* at n.145 (citing *Copyright Infringement Actions: The Proper Role for Audience Reactions in Determining Substantial Similarity*, 54 S. CAL. L. REV. 385 (1981) ("[Q]uestioning value of lay observer test when copyrighted matter is targeted for a particular, identified audience")).

[199] Cohen, *supra* note 6, at 765.

[200] Manuelian, *supra* note 198, at 133.

highly educated in the field of music theory, analysis, and history, can in fact hear again as a lay listener is speculative at best."[201]

Prohibiting expert dissection and analysis on the ultimate issue of misappropriation deprives the trier of information that may be helpful in hearing the music through the ears of the "audience for whom such popular music is composed."[202] As Professor Nimmer pondered:

> If what is to be protected is literary theft, and not the impression of literary theft *per se*, why, we may wonder, must the view be "uncritical," and why must there be no suggestion and pointing to similarity, if that suggestion would prove helpful to the trier in seeing that all or a part of plaintiff's work formed the basis for all or a part of defendant's work?[203]

Experts could note similarities dictated by the particular type of work at issue that are "most likely insignificant to the ears of the targeted audience familiar with that form or type of work,"[204] thereby helping to ensure that infringement is not found based on common sources or coincidence,[205] and conversely, ensuring that very real appropriation does not go undetected.[206] As Justice Clark, dissenting in *Arnstein*, noted, the jury is not "'pre-eminently fitted to decide questions of musical values,' which are different from an ordinary fact-finding exercise."[207]

Perhaps the outcome in *Arnstein*, and thus the bases of our modern law, can be explained by the views of Justice Frank, who wrote for the majority. Frank believed that some judicial decisional processes "like the artistic process, involve[d] feelings that words cannot ensnare" since they contain "overtones inexpressible in words."[208] For Frank, music was the prime example "of a hunch that was intrinsically incapable of disaggregation."[209] He wrote, "a melody does not result from the summation of its parts; thus to analyze a melody is to destroy it.

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[201] *Id.*
[202] *Id*. at 146.
[203] NIMMER, *supra* note 11, at § 13.03 [E][2].
[204] Manuelian, *supra* note 198, at 146.
[205] *Id.* at 145.
[206] NIMMER, *supra* note 11, at § 13.03 [E][2].
[207] Balganesh, *supra* note 9, at 810 (citing Arnstein v. Porter, 154 F.2d 464, 479 (2d Cir. 1946) (Clark, J. dissenting)).
[208] *Id.* at 845.
[209] *Id.*

It is a basic, primary unit."[210] Similar language is found in opinions today, including the Ninth Circuit case *Swirsky* cited earlier.

Attempting to break down what was underlying Frank's opinion, one commentator argued that the *Arnstein* court's exclusion of expert testimony and dissection seemed rooted in the court's fact-skepticism and unwillingness to entrust the explanation of similarities to experts, preferring instead a "subjective determination," perhaps in the hopes that a lay-jury trial would confirm the judge's own subjective hunches.[211]

While courts typically rely on lay jurors to apply the law to the facts of a case at hand,[212] it seems naïve to believe jurors are capable of understanding the complexities of copyright law, particularly the ever elusive idea-expression distinction.[213] Federal judges themselves have found the doctrine difficult to apply,[214] and for good reason as "precision in marking the boundary between the unprotected idea and the protected expression . . . is rarely possible."[215] Determining what is an "idea" versus an "expression" requires more than mere application of the law; it requires interpretation of the law and consideration of policy. Even with a basic understanding of copyright law, applying the doctrine to music is still more difficult. "What of a song's music is 'idea' and what is 'expression'?"[216]

While jury instructions attempt to inform jurors of the law,[217] in practice instructions are often an inconsistent, "confusing welter of legal jargon" that may wrongly suggest that any copying, including copying of an idea, counts as

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[210] *Id.*

[211] *Id.* at 846.

[212] *Id.* at 810. This was a practice Justice Clark said he generally promoted, unlike his adversary Justice Frank (citing Judge Frank's two extrajudicial writings).

[213] *Id.* at 800; *see also* NIMMER, *supra* note 11, at § 13.03 [E][2] ("[T]he idea/expression dichotomy…depends on the level of abstraction at which one defines the "idea" that merges with the subject expression).

[214] Manuelian, *supra* note 198, at 139.

[215] *Id.* (citing Franklin Mint Corp. v. National Wildlife Art Exch., Inc., 575 F.2d 62, 65 (3d Cir. 1978)).

[216] *Id.*

[217] *See, e.g.*, Williams v. Bridgeport Music, 2:13-cv-06004-JAK-AGR (2015), *available at* http://www.scribd.com/doc/258437531/Blurred-Lines-jury-instructions#scribd (hereinafter, Blurred Lines Jury Instructions).

infringement.[218] Moreover, clarity in keeping the two different "substantial similarity" inquiries distinct, both in purpose[219] and procedure, is often lacking. Because both the *Arnstein* and *Krofft* tests forbid expert testimony on the ultimate issue of misappropriation, fact finders will often have to consider expert analysis and dissection on alleged similarities during the copying-in-fact or extrinsic inquiries, but somehow disregard such testimony on the misappropriation or intrinsic inquiry.[220] "Especially in complex cases, [it is] doubt[ful] that the 'forgetting' can be effective when the expert testimony is essential to even the most fundamental understanding of the objects in question."[221] Moreover, courts often fail to clearly explain the two-step inquiry and the need to disregard testimony presented on the first issue in determining the second.

For example, consider a well-known music plagiarism case, *Selle v. Gibb*,[222] where the plaintiff, a part-time musician and composer, sued the Bee Gees, alleging that the Bee Gees' "How Deep is Your Love" infringed the copyright of his song, "Let It End."[223] Without evidence of access, Selle sought to establish copying-in-fact by showing substantial similarity between the two songs, relying heavily on expert testimony.[224] Yet in making the misappropriation determination, the jury was neither instructed to disregard the expert's testimony on substantial similarity, nor informed of the two distinct steps of the *Arnstein* test.[225] Instead, the

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[218] Wendy Gordon, "How the jury in the 'Blurred Lines' case was misled," THE CONVERSATION (March 17, 2015, 5:47 AM), http://theconversation.com/how-the-jury-in-the-blurred-lines-case-was-misled-38751; *see, e.g.*, Balganesh, *supra* note 9, at 794 ("[T]he Ninth Circuit chose to "withdraw" its model jury instructions on the analysis recognizing that no amount of abstract guidance could resolve the indelible complexity that the [copyright infringement] analysis routinely engenders,").

[219] Gordon, *supra* note 218 ("Instruction 28 makes it looks like "substantiality" only matters for proof of the first criterion – 'Did they copy?' But if a juror thinks she already has the answer to that first question – from evidence such as Thicke's own words to GQ – she might conclude that she doesn't need to assess 'substantiality' as well. (That is, she might ignore the second criterion.) So, again, it could look to a careful juror as if any copying of the Gaye composition brings liability.").

[220] *See* Manuelian, *supra* note 198, at 139.

[221] *Id.* at 145.

[222] Selle v. Gibb, 741 F.2d. 896 (7th Cir. 1984).

[223] *See* Manuelian, *supra* note 198, at 140.

[224] *Id.* (citing *Gibb*, 741 F.2d at 901).

[225] *Id.* at 143, n.137 ("The instructions to the jury do not distinguish the similarities evidencing copying
from the substantial similarity from which "the average person would recognize 'How Deep Is Your Love' as having been appropriated from parts of 'Let It End.'") (citing *Gibb*, 741 F.2d at 1079).

jury instructions combined the copying-in-fact and misappropriation steps, explaining that "[t]o prove substantial similarity plaintiff must establish...that the average person would recognize [defendant's song] as having been appropriated from parts of [plaintiff's song]."[226]

Consider also the jury instructions in the recent "Blurred Lines" trial. Judge Kronstadt's first instruction to the jury on the copyright infringement standard said that any copying of original elements is unlawful:

> Anyone who copies original elements of a copyrighted work during the term of the copyright without the owner's permission infringes the copyright....[If] 1. the Gaye Parties are the owner of a valid copyright; and 2. the Thicke Parties copied original elements from the copyright work….your verdict should be for the Gaye Parties.[227]

According to this instruction alone,[228] whether the copied element is an unprotectable idea is irrelevant. In attempting to explain the extrinsic/intrinsic analysis, Kronstadt further suggested that copying an idea can count as infringement. Kronstadt instructed the jury to consider similarities in ideas, as well as expression, on the extrinsic test, but he failed to tell the jurors to disregard any similarity in ideas when considering the "concept and feel" during the misappropriation inquiry.[229] Following this questionable guidance seems to be the exact mistake the jury made in finding that Robin Thicke and Pharrell Williams infringed the copyright in Marvin Gaye's song "Got to Give it Up" by creating their stylistically similar song, "Blurred Lines."[230]

Fundamentally, the problem with the audience test is that by wholeheartedly relying on the lay juror, the test erroneously treats the question of misappropriation as a pure question of fact. Infringement is far less intuitive, and more complex, than ordinary negligence. Just as the testimony of medical experts is necessary in negligence cases in the context of medical malpractice, copyright is dependent on a technical analysis of works which jurors know little about. Determinations of

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[226] *Id.* at 144.

[227] *See* Gordon, *supra* note 218 (citing Instruction 27); *see also* Blurred Lines Jury Instructions, *supra* note 217 at 28.

[228] Gordon, *supra* note 218 (alluding to Blurred Lines Jury Instructions at 31, where eventually Instruction No. 30 corrects this mistake, noting the jury "must not consider in your comparison (1) ideas, as distinguished from the expression of those ideas" but stating "[n]onetheless, the distorted message of Instruction 27 echoes throughout.").

[229] *Id.*

[230] *See* NIMMER, *supra* note 11, at §13.03[A][1].

infringement necessarily involve ad hoc line-drawing that affects artistic incentives and the public's access to art works. While it is possible to limit and tailor the test, as it stands, it has been disappointingly inaccurate and has been often used as a "verbal formula to explain results otherwise reached."[231]

B. Krofft: Reconciling Arnstein and the Idea Expression Dichotomy?

While the court in *Krofft* seemed to recognize the problems with the *Arnstein* test in its failure to ensure copyright infringement was only found on a similarity of expression, the Ninth Circuit neglected to explain how its own test would resolve any of the problems presented by the Second Circuit approach.[232] In laying out vague criteria for defining ideas versus expression, the Ninth Circuit left lower courts and artists to their own devices in figuring out where to draw the line.[233] The court itself noted that the extrinsic test is "turbid waters." "Nevertheless," it continued, "the test is our law and we must apply it."[234] Applying the test to artistic works is even more problematic. As the court said in *Swirsky*, "the extrinsic test provides an awkward framework to apply to copyrighted works like music or art objects, which lack distinct elements of idea and expression."[235]

By failing to state whether a lack of substantial similarity in ideas is relevant for copying or misappropriation, or both,[236] the extrinsic/intrinsic test fails to isolate the issue of copying from the issue of misappropriation. Focusing on the idea-expression distinction improperly frames the question. Similarity of ideas found during the extrinsic inquiry may be probative of copying, but such similarity does not prove copying of protected expression. Furthermore, the Ninth Circuit never made clear how the ordinary observer could determine if there is a similarity of expression while refraining from dissection and analysis. If anything, fact finders in the Ninth Circuit are left with less expert guidance than in the Second Circuit, as the Second Circuit at least allowed testimony to inform the trier of the intended audience's likely views rather than leaving them guessing.

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[231] *Id.* at §13.03[E][b] (suggesting that the courts discard the audience test entirely and adopt the abstraction-filtration-comparison method used in cases involving infringement of computer programs and factual compilations.).

[232] Cohen, *supra* note 6, at 757.

[233] *Id.* at 754-755.

[234] Swirsky v. Carey, 376 F.3d 841, 848 (9th Cir. 2004) (citing Metcalf v. Bochco, 294 F.3d 1069, 1071 (9th Cir. 2002)).

[235] *Swirsky*, 376 F.3d at 848.

[236] Cohen, *supra* note 6, at 745 n.81.

As in other jurisdictions using the term, courts applying *Krofft* struggle to define "substantial." The focus ranges from audience confusion,[237] to the substantiality relative to the overall work,[238] to the aesthetic or financial value of the portion of the work copied.[239] In the *Krofft* decision itself, because the works at issue were directed at children, the court focused on the impact of the "total concept and feel" of the works "upon the minds and imaginations of young people."[240] Thus, some courts adopting the extrinsic/intrinsic framework utilize an "intended audience" test for works that appeal to an audience with "specialized expertise,"[241] therefore allowing the use of expert testimony. Yet such works have been narrowly construed and usually only include computer software.[242] Most courts applying the Ninth Circuit test determine the likelihood of audience confusion by simply comparing the "total concept and feel" of the works to the ordinary observer as determined by jurors with no specialized training or expertise.[243]

Courts that look to the value of the elements at issue criticize the "total concept and feel" approach for failing to maintain the idea-expression distinction during the misappropriation analysis. As the Ninth Circuit stated in *Cooling Systems & Flexibles, Inc. v. Stuart Radiator*,[244] "What is important is not whether there is substantial similarity in the total concept and feel of the works . . . but whether the . . . amount of protectable expression in Cooling Systems' catalog is

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[237] *Id.* at 742.

[238] *Id.*

[239] Thus, in the music context, taking the "heart" of a song, or the portion that makes the song appealing and valuable, is a substantial taking. *See id.*; Campbell v. Acuff-Rose Music, Inc., 510 U.S. 569 (1994) (overturning the district court's finding of infringement where the defendant used the "heart" of the plaintiff's song under the fair use defense); Arnstein v. Porter, 154 F.2d 464, 468 (2d Cir. 1946) (asking "whether defendant took from plaintiff's works so much of what is pleasing to the ears of lay listeners, who comprise the audience for whom such popular music is composed, that defendant wrongfully appropriated something which belongs to the plaintiff."); Eisenman Chem. Co. v. NL Indus., 595 F. Supp. 141, 146 (D. Nev. 1984) (holding that the defendant's manual copied "virtually verbatim" from the plaintiff's manual and thereby appropriated the plaintiff's labor and skill to publish a rival work).

[240] Sid & Marty Krofft TV Prods. v. McDonald's Corp., 562 F.2d 1157, 1166 (9th Cir. 1977).

[241] NIMMER, *supra* note 11, at § 13.03[E][4].

[242] *Id.*

[243] Cohen, *supra* note 6, at 756; *see, e.g.*, Three Boys Music v. Bolton, 212 F.3d 477, 485 (9th Cir. 2000) (upholding the jury's determination that the defendant's song has a substantially similar "total concept and feel" to the plaintiff's song); *see also* OSTERBERG, *supra* note 110, at 3-37.

[244] Cooling Sys. & Flexibles, Inc. v. Stuart Radiator, 777 F.2d 485 (9th Cir. 1985).

substantially similar to the equivalent portions of [the defendant's] catalog."[245] The court in *Cooling Systems* stated that the intrinsic test must take into consideration the nature of the elements that were allegedly infringed,[246] reasoning that "the fewer the methods of expressing an idea, the more the allegedly infringing work must resemble the copyrighted work in order to establish substantial similarity. . . ."[247] Yet the court continued to prohibit the aid of dissection, analysis, and expert testimony, failing to explain how an ordinary observer lacking expertise could make such a determination.[248]

C. The Modern Music Dilemma

While creators of musical works have struggled to extend copyright beyond its natural borders since the Statute of Anne was enacted, the inexact fit of music in our copyright doctrine has only become more obvious with the invention and popularity of sampling technology. Since the advent of digital sampling technology in the 1960s, the art of taking a portion, or sample, of a sound recording and repurposing it to make a different song has become engrained in nearly every popular musical genre.[249] Yet, after the industry-shattering decisions in *Grand Upright Music, Ltd. v. Warner Brothers Records Inc.*,[250] and *Bridgeport Music, Inc. v. Dimension Films*,[251] which resulted in a bright-line rule against *de minimis* copying of even three notes of a sound recording,[252] artists need to seek licensing

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[245] *Id.* at 493.

[246] Cohen, *supra* note 6, at 756–57.

[247] *Cooling Sys.*, 777 F.2d at 491.

[248] Cohen, *supra* note 6, at 757.

[249] *See, e.g. How Hip-Hop Works*, STUFF YOU SHOULD KNOW: THE PODCAST, http://www.stuffyoushouldknow.com/podcasts/hip-hop-works/ (tracing the birth of hip-hop to Jamaica, where DJs began using two turntables at once to play extended doctored versions of popular songs that isolated the percussive breaks, while "toasting" or rapping over the beat).

[250] Grand Upright Music, Ltd. v. Warner Brothers Records Inc., 780 F. Supp. 182 (S.D.N.Y. 1991) (ruling that sampling without permission can qualify as copyright infringement in holding rapper Biz Markie liable for sampling Gilbert O'Sullivan's song "Alone Again (Naturally)" in his song "Alone Again.").

[251] Bridgeport Music, Inc. v. Dimension Films, 410 F.3d 792 (6th Cir. 2005) (holding that the Beastie Boys' three note sampling of George Clinton's song "Get Off Your Ass and Jam" infringed the sound recording and creating a bright line rule that de minimis analysis does not apply to sound recordings).

[252] *Id.* at 801; *see generally* Mark R. Carter, *Applying the Fragmented Literal Similarity Test to Musical-Work and Sound-Recording Infringement: Correcting the* Bridgeport Music, Inc. v. Dimension Films Legacy, 14:2 MINN. J. L. SCI. & TECH (2013) (arguing that courts should engage in an analysis of the quantitative and qualitative significance of a sampled sound recording rather than creating a bright line rule); *cf.* Lesley Grossberg, *A Circuit Split at Last:*

rights to sample a sound recording. However, the costs to do so are often prohibitive, both in terms of negotiating fees and contacting often-elusive copyright owners.[253] Consequently, many artists have turned to re-creating segments of prior musical compositions for use in their own works, a practice known, at least in the hip-hop industry, as "interpolation."[254] Though creative borrowing of this type is deeply embedded in art history, after the *Blurred Lines* verdict it seems songs that interpolate prior works are also at risk of extinction.

While we may be lacking strong evidence that copyright actually encourages creativity,[255] copyright can suppress the creation of works of a specific nature.[256] After *Grand Upright* put "the fear of God" in recording companies, artists releasing a record on a major label were forced to clear every sample used.[257] As a result, songs composed of various samples from multiple sources were no longer possible. Records like *Paul's Boutique* by the Beastie Boys, which is almost entirely composed of 104 samples, would be "financially and bureaucratically impossible" today.[258] Each sample would have to be cleared by obtaining two

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Ninth Circuit Recognizes De Minimis Exception to Copyright Infringement of Sound Recordings (June 21, 2016), https://www.copyrightcontentplatforms.com/2016/06/a-circuit-split-at-last-ninth-circuit-recognizes-de-minimis-exception-to-copyright-infringement-of-sound-recordings/ (a recent circuit split arose after the Ninth Circuit ruled in *VMG Salsoul, LLC v. Ciccone*, 824 F. 3d 817 (9th Cir. 2016), that the *de minimis* exception to copyright infringement applies to sound recordings. Though *Salsoul* may offer hope to samplers by tipping "the weight of the authorities heavily on the side of recognizing a *de minimis* exception," litigious copyright holders can still find a favorable forum in circuits bound by *Bridgeport*. Moreover, it remains to be seen if courts will extend *Salsoul* to use of the underlying composition.).

[253] *See* NEIL WEINSTOCK NETANEL, COPYRIGHT'S PARADOX 21 (2008).

[254] MICKEY HESS, IS HIP HOP DEAD?: THE PAST, PRESENT, AND FUTURE OF AMERICA'S MOST WANTED MUSIC 106 (2007); interpolation allows the artist to simply pay the holder of the rights in the composition, usually a songwriter, without needing to pay the artist and the record company as well.

[255] Copyright's failure to encourage creativity may simply be proof that its protection is overreaching, since creative incentives and normative protections exist regardless of the law as it stands. *See, e.g.*, Jodie Griffin,
The Economic Impacts of Copyright, PUBLIC KNOWLEDGE, https://www.publicknowledge.org/files/TPP%20Econ%20Presentation.pdf (last accessed Feb. 7, 2016) ("evidence suggests 'most sound recordings sell in the ten years after release.'").

[256] Arewa, *supra* note 5, at 630.

[257] *Id.*

[258] Joe Fassler, *How Copyright Law Hurts Music, From Chuck D to Girl Talk*, THE ATLANTIC, Apr. 12, 2011, http://www.theatlantic.com/entertainment/archive/2011/04/how-copyright-law-hurts-music-from-chuck-d-to-girl-talk/236975/ ("Capitol Records would lose 20 million dollars on a record that sold 2.5 million units.").

different licenses from two different rights holders: the owner of the sound recording and the owner of the underlying composition. To make matters more complicated, additional licenses are needed if the sampled song contains samples itself, as is increasingly the case today.

While artists can obtain a compulsory license to create a cover of a prior song, using only a portion of a song while substantially altering "the melody or fundamental character of a work" falls outside of the range of the statutory license,[259] even though doing so entails more originality and less substantial similarity.[260] Newcomers are back in the position of having to seek permission and pay whatever rights holders demand,[261] or face the risk of hefty legal judgments and court costs.

For well-known songs, the costs to license are often as high as 100% of the royalties generated by the new song, and sometimes higher. Mark Ronson, a music producer and sampling guru, analogizes the process of creating his debut album, *Here Comes the Fuzz*, to the process of producing the fictional musical in the play, *The Producers.* In creating the track, "Ooh Wee," Ronson wanted to sample two different songs by two different artists: a drum sample from Dennis Coffey's song "Scorpio," and a string sample from a cover of Boney M's song "Sunny." Collectively, the owners of the rights wanted 125% of the song's royalties. Believing the samples to be necessary to the "emotional effect" and "toughness of the beat," Ronson said he had to do it: "I had to pro-rate my entire album down so I

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[259] Arewa, *supra* note 5, at 638; *see also* 17 U.S.C. § 115(a)(2) (2000) (requiring that the compulsory licensing arrangement not change the basic melody or fundamental character of the work).

[260] *See* HESS, *supra* note 254, at 106 ("Dr. Dre, one of hip hop's biggest producers, says that he prefers [sheet music] interpolation to sampling because working from sheet music allows him more control of the sound: he can ask studio musicians to play it the way he wants it.").

[261] Guy Raz & Mark Ronson, *Why Would More Than 500 Artists Sample The Same Song?*, NPR (June, 2014, 9:57 AM), http://www.npr.org/2014/06/27/322721353/why-would-more-than-500-artists-sample-the-same-song. Explaining the process of seeking sampling rights, producer Mark Ronson said,

> Basically, you go to the person that wrote it, or maybe the person that owns that song now – because it could have been sold, the rights to it, years ago. You have to play them *your* song, and then you guys kind of come to agreement about how much you're going to give them. I mean, if you use a tiny two seconds of a Led Zeppelin song, it doesn't matter how important it is to your song – you can pretty much guarantee you're going to give up 100 percent of your publishing to Jimmy Page and Robert Plant. *Id.*

could rob this song to pay that guy…."[262] In hindsight, the decision may have made his career, as the song ended up being the lead single and a chart-topper.[263]

Rights holders can always refuse clearance entirely, as they often do. When musician and producer Danger Mouse put out *The Grey Album*, which splices together samples from *The White Album*[264] by the Beatles with an a cappella version of *The Black Album* by rapper Jay-Z, the recording company that holds the Beatles' copyright was able to prevent the album's distribution, despite approval from both Jay-Z and the surviving members of the Beatles.[265]

Since *Grand Upright*, it has become largely impossible to create songs using more than one or two samples. As a result, industry practice and the sound of hip-hop music abruptly changed. Artists turned to heavily interpolating a few samples per song, particularly from artists who are amenable to having their music sampled. Dr. Dre's production style, which was highly influential in spawning an entire era in hip-hop, changed from outright sampling to heavily interpolating the 1970s funk band, Parliament.[266] Dre's style changed hip-hop forever, as G-funk, defined by Parliament's influence, became the most popular genre in hip-hop during the 1990s.[267]

While some artists are still producing heavily-sampled albums, it seems only those with the most obvious fair use defense are confident enough to do so without a license, perhaps recognizing the strength of their defense and realizing record companies would rather not risk setting bad precedent.[268] The D.J. Gregg Gillis, better known as Girl Talk, is perhaps the most notorious sampler; he uses hundreds of small samples on a single album, never licenses anything, generates tons of publicity, and is never sued. As Gillis put it, with so many samples, "[i]t would

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[262] *Id.*

[263] The song charted at number 15 on the UK Singles Chart. Billboard, May 26, 2007.

[264] This is the commonly used name for their LP, *The Beatles*.

[265] Jillian C. York, *The Fight to Protect Digital Rights Is an Uphill Battle, but not a Silent One*, THE GUARDIAN (Apr. 24, 2010, 12:38 AM) http://www.theguardian.com/commentisfree/2014/apr/24/the-fight-to-protect-digital-rights-is-an-uphill-battle-but-not-a-silent-one.

[266] Dr. Dre, *'The Chronic' at 20: Classic Track-By-Track Review*, BILLBOARD (Dec. 15, 2012), http://www.billboard.com/articles/review/1537948/dr-dre-the-chronic-at-20-classic-track-by-track-review.

[267] *See P-Funk*, RATE YOUR MUSIC, https://rateyourmusic.com/genre/P-Funk/ (last visited Sept. 20, 2015).

[268] Mike Masnick, *Why Hasn't The Recording Industry Sued Girl Talk?*, TECHDIRT (July 8, 2009, 8:32 AM), https://www.techdirt.com/articles/20090707/0237205466.shtml.

take you hundreds of hours of work and hundreds of thousands of dollars to clear the rights to this album even if you *wanted* to."[269] Yet, Girl Talk's business is not without harm. Both iTunes and a CD distributer refused to carry his most recent album, *Night Ripper*, because of legal concerns.[270]

While Girl Talk might feel confident in his defense, anyone using a sample in a more qualitatively and quantitatively significant way is likely to fear settlement fees, or worse, high statutory damages. Even with a seemingly good defense, those with less fame than Girl Talk, or Pharrell Williams, are less likely to take the risk. When part of the beauty of digital sampling technology lies in its removal of bars to entry, allowing a twenty-year-old kid to create a critically acclaimed album with cheap technology,[271] cases like *Grand Upright* and "Blurred Lines" leave the next Dr. Dre on the margins.

Although Dr. Dre's debut album immortalized Parliament's style as an entire hip-hop genre in and of itself, and the release of "Blurred Lines" landed "Got to Give it Up" back on the Billboard 200 after a decade's long hiatus,[272] the courts have ignored the economic reality of homage and have placed it on par with theft. A justified reason for deeming musical borrowing as theft is lacking when artists of all mediums, from classic literature to appropriations art, have borrowed from their predecessors without anyone taking notice, or under the defense of "fair use."[273] One rationale is that our copyright law is based in the romantic conception of

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[269] Alex Mayyasi, *The Economics Of Girl Talk*, PRICENOMICS (Apr. 11, 2013) (quoting David Post, *Girl Talk:*, VOLOKH CONSPIRACY (Nov. 19, 2010, 7:10 PM), http://volokh.com /2010/11/19/girl-talk/), http://priceonomics.com/post/47719281228/the-economics-of-girl-talk.

[270] Eryc Eyl, *Ripper Offer*, THE PITCH (Oct.4, 2007, 4:00 AM), http://www.pitch.com/ kansascity/ripper-offer/Content?oid=2187141.

[271] *See, e.g.*, Mayyasi, *supra* note 269 (stating Girl Talk's main instrument is a laptop); RZA, *RZA on Gear*, SKULL THEFT (citing *So You Wanna Be a Record Producer*, RAP PAGES, Mar. 1995), http://skulltheft.tumblr.com/post/256038796/rza-on-gear (last visited Feb. 10, 2016) (describing early hip-hop producers, like RZA of the group Wu-Tang Clan, who used basic sampling equipment, stating "'[b]ack in '89…all I had was a four-track, some turntables, and a drum machine.'").

[272] Keith Caulfield, *Billboard 200 Chart Moves: Marvin Gaye Sales Up 246% After 'Blurred Lines' Trial*, BILLBOARD (Mar. 20, 2015), http://www.billboard.com/articles/columns/chart-beat/6509353/marvin-gaye-got-to-give-it-up-sales.

[273] *See, e.g.*, Cariou v. Prince, 714 F. 3d 694 (2d Cir. 2013); Campbell v. Acuff-Rose Music, Inc., 510 U.S. 569 (1994) (finding the defendant's use of plaintiff's song to be fair use because the new work was a parody); Bill Graham Archives v. Dorling Kindersley Ltd., 448 F.3d 605 (2d Cir. 2006) (finding defendant's use of the plaintiff's music posters in a biographical coffee table book to be fair use because of the new purpose).

authorship, that is, the notion that the author has the right to control the context of his work and should be able to object to "her work [being] sampled and added into a work she finds repugnant."[274] However, applying moral rights arguments to the issue does not serve the Intellectual Property Clause's purpose of striking a balance between economically incentivizing the production of creative works and maintaining public access to those works.[275]

The current tests do not adequately balance the impact of copyright on creativity. Rather, courts focus more on the potential harm to the plaintiff's market[276] than on assuring "access to the raw materials that artists need to create in the first place."[277] Progress and culture depend on the accumulation of aesthetic works. By granting property rights in creative building blocks and requiring new works to be wholly different from prior works, the courts are treating the arts like science and technology, where progress means improving. However, progress in the arts is valued for reasons beyond efficiency. Society benefits from the accumulation of artistic works and the mere experience of making them.[278] "Culture . . . is a social phenomenon. It is not the creation of one or another artist, but of many doing somewhat similar things."[279] The *scènes à faire* doctrine is one way of protecting free access to artistic materials. But with jurors unable to appreciate the balance of these competing interests, we risk skewing it in a way that stifles creativity.

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[274] George Howard, *Should There Be a Compulsory License for Derivative Works?*, TUNECORE (Apr. 17, 2013), http://www.tunecore.com/blog/2013/04/should-there-be-a-compulsory-license-for-derivative-works.html.

[275] H.R. REP. NO. 60-2222, at 7 (1909), *reprinted in* 6 LEGISLATIVE HISTORY OF THE 1909 COPYRIGHT ACT, Part S (E. Fulton Brylawski & Abe Goldman eds., 1976).

[276] Nicole K. Roodhuyzen, *Do We Even Need a Test? A Reevaluation of Assessing Substantial Similarity in a Copyright Infringement Case*, 15 J. L. & POL'Y, 1375, 1418-19 (2008), http://brooklynworks.brooklaw.edu/cgi/viewcontent.cgi?article=1217&context=jlp.

[277] Jennifer Jenkins, *The "Blurred Lines" of the Law*, CENTER FOR THE STUDY OF THE PUBLIC DOMAIN, http://web.law.duke.edu/cspd/blurredlines/ (last visited Oct. 16, 2016).

[278] Beebe, *supra* note 33 (explaining that aesthetic progress doesn't mean that the works of Picasso are better than cave drawings).

[279] Simon Waxman, *'Blurred Lines' Ruling Makes Influence Illegal*, AL JAZEERA AMERICA (Apr.l 4, 2015, 2:00AM), http://america.aljazeera.com/opinions/2015/4/blurred-lines-ruling-makes-influence-illegal.html.

1. Scènes à Faire *In Music: "Blurred Lines" as a Case in Point*

Credited as a Billboard's Song of the Summer for 2013,[280] and the best-selling single of 2013,[281] it is no wonder the controversies over Robin Thicke and Pharrell Williams's song "Blurred Lines" made so many headlines. The song was controversial from its release date, featuring arguably misogynistic, "rapey" lyrics,[282] and a music video that was removed from, and then censored on, YouTube for violating the site's policies regarding nudity.[283] Then came the copyright controversy. Marvin Gaye's family accused Thicke and Williams of copying the "feel" and "sound" of Gaye's "Got to Give It Up," [284] the song Thicke even publicly noted as the influence for "Blurred Lines."[285] Therefore, the issue in the "Blurred Lines" case revolves around whether Thicke and Williams illegally interpolated original elements of Marvin Gaye's musical composition.

In response to the allegations, Thicke and Williams sought a declaratory judgment that "Blurred Lines" did not infringe upon "Got to Give It Up."[286] When that failed, and inevitably backfired with the Gaye family filling a cross-complaint, the plaintiffs moved for summary judgment, claiming that the eight alleged similarities between the songs are based on elements of Gaye's sound recording

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[280] Gary Trust, *Robin Thicke's 'Blurred Lines' Is Billboard's Song of the Summer*, BILLBOARD (Sept. 5, 2013), http://www.billboard.com/articles/news/5687036/robin-thickes-blurred-lines-is-billboards-song-of-the-summer.

[281] Stuart Dredge, *Global Music Sales Fell in 2013 Despite Strong Growth for Streaming Services*, THE GUARDIAN (March 18, 2014 9:00 AM), http://www.theguardian.com/technology/2014/mar/18/music-sales-ifpi-2013-spotify-streaming (reporting that "Blurred Lines" sold 14.8 million units in track downloads and equivalent streams).

[282] Geeta Dayal, *The Music Club, 2013*, SLATE (Dec. 19, 2013, 2:44 PM), http://www.slate.com/articles/arts/the_music_club/features/2013/music_club_2013/robin_thicke_s_blurred_lines_it_s_sexist_and_awful.html (citing lyrics like "I know you want it" and "I hate these blurred lines").

[283] *'Blurred Lines' Banned by YouTube as Robin Thicke's Video Features Nude Models*, HUFFINGTON POST (April 1, 2013 5:28 PM), http://www.huffingtonpost.com/2013/04/01/blurred-lines-banned-by-youtube-robin-thicke-nude-models_n_2994676.html.

[284] Zoe Chace, *Robin Thicke's Song Sounds Like Marvin Gaye. So He's Suing Gaye's Family*, NPR PLANET MONEY (Aug. 19, 2013, 1:05 PM), http://www.npr.org/sections/money/2013/08/19/213471083/robin-thickes-song-sounds-like-marvin-gaye-so-thicke-is-suing-gayes-family.

[285] Eriq Gardner, *Robin Thicke Sues to Protect 'Blurred Lines' from Marvin Gaye's Family (Exclusive)*, THE HOLLYWOOD REP. (Aug. 15, 2013, 6:13 PM), http://www.hollywoodreporter.com/thr-esq/robin-thicke-sues-protect-blurred-607492.

[286] *Id.*

that are not part of the copyright that Gaye's family claims to own.[287] According to the Gaye family's expert report, these eight "substantially similar features" include: (1) the signature phrase; (2) hooks; (3) hooks with backup vocals; (4) the core theme in "Blurred Lines" and the backup hook in "Got to Give It Up"; (5) backup hooks; (6) bass melodies; (7) keyboard parts; and (8) unusual percussion choices.[288] The family's expert also alleged that the songs share similar "departures from convention such as the unusual cowbell instrumentation, omission of guitar and use of male falsetto."[289]

Though most of these elements are not part of the underlying composition, and the melodies of the two songs are arguably completely different ("one's minor and one's major. And not even in the same key"[290]), the court found that the Gaye family made a sufficient showing of substantial similarity to satisfy the extrinsic test and the issue went to trial.[291] The jury found against Thicke and Williams with a judgment topping $7.3 million, one of the largest ever in music copyright history.[292] While Thicke's and Williams's fortune and fame seem unlikely to be tarnished, with each of them earning over $5 million for the song itself, [293] the verdict shows how misguided results can be under our infringement tests. In misapplying the already confusing Ninth Circuit test for substantial similarity, the court protected musical style and genre under the guise of protecting an original combination of elements. As one composer and producer put it, the court "made it illegal to reference previous material. . . . I'm never going to come up with

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[287] Williams v. Bridgeport Music, Inc., No. LA CV13-06004 JAK (AGRx), 2014 WL 7877773, at *18-19 (C.D. Cal. Oct. 30, 2014).

[288] Frankie Christian Gaye and Nona Marvisa Gaye First Amended Counterclaims Preliminary Expert Report for Defendants at ¶ 9, 43, Williams v. Bridgeport Music, Inc., No. CV13-06004-JAK (AGRx) (C.D. Cal. Oct. 30, 2013) [hereinafter Counterclaim].

[289] Emily Miao & Nicole E. Grimm, *The Blurred Lines of Copyright Infringement of Music Become Even Blurrier as the Robin Thicke v. Marvin Gaye's Estate Lawsuit Continues*, MBHB ACCESS MEDIA (Winter 2014) (quoting Counterclaim, *supra* note 288), http://www.mbhb.com/pubs/xpqPublicationDetail.aspx?xpST=PubDetail&pub=271.

[290] *Pharrell Denies 'Blurred Lines' Copies Marvin Gaye: 'It's Completely Different*,' BILLBOARD (Sept. 13, 2013), http://www.billboard.com/articles/news/5695041/pharrell-denies-blurred-lines-copies-marvin-gaye-its-completely-different.

[291] Miao & Grimm, *supra* note 289.

[292] Lauretta Charlton, *A Copyright Expert Explains the 'Blurred Lines' Ruling*, VULTURE (Mar. 11, 2015, 3:11 PM), http://www.vulture.com/2015/03/what-the-blurred-lines-ruling-means-for-music.html.

[293] Eriq Gardner & Austin Siegemund-Broka, *'Blurred Lines' Trial Reveals How Much Money Robin Thicke's Song Made,* HOLLYWOOD REP. (Mar. 3, 2015, 10:54 AM), http://www.hollywoodreporter.com/thr-esq/blurred-lines-trial-reveals-how-778884.

something so radically different that it doesn't contain references to something else."[294] While the creators of "Blurred Lines" have already decided to appeal the verdict,[295] if it is upheld, artists on the margin, who are less willing to take on legal fees and whose work is less in tune with romantic authorship, will be discouraged from "creating any new songs that evoke the feel of the music that inspired them in their youth." Further, "with the length of copyright we have these days, artists who want to feel confident that their musical influences are in the public domain are going to have to go all the way back to ragtime."[296]

The verdict reached is procedurally problematic for a few reasons. Under the current Ninth Circuit test, the court erred in allowing the jury to hear excerpts of the sound recordings for "Got to Give It Up" and "Blurred Lines,"[297] which contained elements that are not part of Gaye's written composition and, therefore, not part of his copyright.[298] Though the background chatter, party noise, and percussion, are common to both songs and contribute to the instinctive feeling that "Blurred Lines" "reminds" us of "Got to Give It Up," they are totally irrelevant to the issue of substantial similarity.[299] Yet, these elements seemed to sway the jury in reaching its verdict.

Many, if not all, of the elements in "Got to Give It Up" are unoriginal staples in funk music, from the walking down funky bass line to the falsetto and melisma

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[294] Kit Walsh, *The Blurred Lines Copyright Verdict is Bad News for Music*, ELECTRONIC FRONTIER FOUNDATION (Mar. 11, 2015), https://www.eff.org/deeplinks/2015/03/blurred-lines-copyright-verdict-bad-news-music (quoting Gregory Butler).

[295] Amar Toor, *Robin Thicke and Pharrell Appeal 'Blurred Line" Copyright Ruling*, THE VERGE (Dec. 9, 2015, 3:30 AM), http://www.theverge.com/2015/12/9/9877706/robin-thicke-pharrell-blurred-lines-marvin-gaye-appeal.

[296] Walsh, *supra* note 294; *see also* Toor, *supra* note 295 ("The verdict handicaps any creator out there who is making something that might be inspired by something else….This applies to fashion, music, design . . . anything. If we lose our freedom to be inspired we're going to look up one day and the entertainment industry as we know it will be frozen in litigation. This is about protecting the intellectual rights of people who have ideas.") (quoting Pharrell Williams).

[297] Ed Christman, *'Blurred Lines' Verdict: How It Started, Why It Backfired on Robin Thicke and Why Songwriters Should Be Nervous*, BILLBOARD (Mar. 13, 2015), http://www.billboard.com/articles/business/6502023/blurred-lines-verdict-how-it-started-why-it-backfired-on-robin-thicke-and.

[298] Williams v. Bridgeport Music, Inc., No. LA CV13-06004 JAK, 2014 WL 7877773, at *10 (C.D. Cal. Oct. 30, 2014) ("[T]he lead sheets are deemed to define the scope of Defendants' copyrighted compositions.").

[299] Kal Raustiala & Christopher Jon Sprigman, *Squelching Creativity*, SLATE (Mar. 12, 2015, 12:27 PM), http://www.slate.com/articles/news_and_politics/jurisprudence/2015/03/_blurred_lines_verdict_is_wrong_williams_and_thicke_did_not_infringe_on.html.

hook,[300] but Judge Kronstadt, applying the extrinsic test on summary judgment, held that a genuine issue of material fact existed either on the similarity to protectable elements, or on the similarity to an original combination of elements.[301] To show that the allegedly infringing elements are unprotectable *scènes à faire*, the defendants' expert cited multiple prior songs that used many of the same allegedly infringing elements.[302] Judge Kronstadt still ruled that the testimony was not sufficient, citing *Swirsky* for the idea that the defendants failed to show that the plaintiff's work is "more similar" to prior works than it is to the defendants' work.[303] Yet the issue in *Swirsky*, and here, was whether the individual *elements* are *scènes à faire*, not whether the works as a whole are unoriginal.[304] Thus, Kronstadt's reliance on *Swirsky*'s "more similar to prior works" language is misplaced, and bypasses actual consideration of the protectability of the elements themselves.[305] The court thereby failed to dispose of the issue of whether the defendants copied original elements on summary judgment, leaving the question to the jury.

In erroneously applying the "more similar" to prior works test to the works as a whole, Kronstadt further failed to consider the actual test for copying a combination of unprotectable elements: whether the works are "virtually identical." As Pharrell and Thicke argued, the requirement for originality in a combination of unoriginal elements is much more stringent than the usual "some minimal level of creativity."[306] The elements need to be "numerous enough and their selection and arrangement original enough that their combination constitutes an original work of authorship."[307] Furthermore, infringement can only be found if the defendant's work is "virtually identical" to the copyrighted work.[308] While

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[300] *See infra*, note 302.

[301] *Williams*, 2014 WL 7877773, at *19.

[302] *Id.* at *4, *13, and *15 (including "Low Rider" by War from 1975, "Superfly" by Curtis Mayfield from 1972 and "Funkytown" by Lipps Inc. from 1980).

[303] *Id*. at *19.

[304] Swirsky v. Carey, 376 F.3d 841, 850 (9th Cir. 2004).

[305] Kronstadt confuses the issue of whether the elements themselves are protected versus the issue of whether the work as a whole is a unique combination of unprotected elements, applying the test for the former in attempting to determine the latter, thereby failing to decide either issue.

[306] Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 358 (1991).

[307] Satava v. Lowry, 323 F.3d 805, 811 (9th Cir. 2003).

[308] Apple Computer, Inc. v. Microsoft Corp., 35 F.3d 1435, 1439, 1442 (9th Cir. 1994), *cert. denied*, 513 U.S. 1184; *see also* Mattel, Inc. v. MGA Entm't, Inc., 616 F.3d 904, 915-917 (9th Cir. 2010) (finding that the district court erred in applying the substantial similarity standard for unprotectable elements, as opposed to the heightened virtually identical standard, in comparing

many might say the two songs sound similar, with entirely different melodies and lyrics, one cannot maintain that the songs are "virtually identical," especially when the misappropriation inquiry is supposed to be based solely on the written melodies, chords, and lyrics.[309] Even still, copying that is virtually identical may fall within the merger doctrine – that is, it may be an unavoidable product of using the same idea, which as discussed above is not a protectable interest.[310]

Because Judge Kronstadt determined that Pharrell and Thicke failed to meet the stifling burden of "more similar" to prior works on summary judgment, the final decision went to the jury to be based on their spontaneous reaction unguided by musicologists and uninstructed by the court on the "virtually identical" standard. Thus, the simple instinct that "Blurred Lines" felt like "Got To Give It Up" determined the verdict, regardless of the law. Yet, if the "feel of a work is sacrosanct," many songs would be illegal for simply being a part of a "derivative and rigid genre," as is often the case in music.[311]

When genres and subgenres have been inspired by one song, privatizing common elements can only do harm. Musicians like Marvin Gaye still have the incentive to create, especially with the notoriety and revitalized publicity that comes with a new artist referencing an old song. A reference from today's stars can make a music legend. Snoop Dogg's cover of Slick Rick's 1985 hit "La Di Da Di," and Notorious B.I.G.'s sample of it in "Hypnotize Me," made Slick Rick's song the most sampled rap song of all time. Dr. Dre's use of the drum-break from The Wintons' "Amen, Brother" started a narrative that led this little known band to have arguably the most sampled song of all time. The Amen Break has been used in over 1,700 songs and has become the basis for drum-and-bass and jungle music.[312]

Despite the notoriety and financial benefits of being sampled, by looking to our skewed notions of authorship, both judges and juries alike are trigger-happy to find copyright infringement when there is so much as a waft of homage. Their

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defendant's "Bratz" dolls to Mattel's iconic Barbie because "small plastic dolls that resemble young females is a staple of the fashion doll market").

[309] Chris Richards, *It's Okay if You Hate Robin Thicke but the 'Blurred Lines' Verdict is Bad for Pop Music*, WASH. POST (March 11, 2015), https://www.washingtonpost.com/news/style-blog/wp/2015/03/11/the-blurred-lines-of-the-blurred-lines-verdict/.

[310] NIMMER, *supra* note 11, at § 13.03[B][3][d], [B][3][c].

[311] Waxman, *supra* note 279 (citing bluegrass as an example).

[312] Landon Proctor, *Video Explains the World's Most Important 6-Sec Drum Loop*, YOUTUBE (Feb. 21, 2006), https://www.youtube.com/watch?v=5SaFTm2bcac.

intentions are well wrought in a desire to protect the "genius" of artists loved by generations. However, that desire is based on notions of fairness, and copyright was never meant to protect artists' moral rights in their works. Incentives to create have always been the only concern, balanced against maintaining public access to creative works. Yet "discussions of copyright and its goals frequently conflate the compensatory and control aspects of copyright on the incentive side."[313]

If we expand the copyright in an original selection and arrangement to find infringement when any song includes just some of its elements, the blurry standard determining how many elements count as copying will result in risk-averse content creators. When nothing is truly original or avant-garde in music, the safe route in creating content is not clearly laid out either. Even if artists can be completely progressive, it is not clear they will be rewarded for doing so. Popular content is popular for a reason, and the benefits of creating it will be limited to the lucky first comers who hold a monopoly on elements they did not even create simply because they strung them together first. The success of "Blurred Lines" might be due, at least in part, to its ability to incorporate so many nostalgic funk clichés at once, all in the context of a modern pop song. Moreover, the enjoyment derived by the public from having an expanse of options to choose from will be lost. Of course, the effects of prohibiting "inspired works" will touch on industries beyond music, covering the fine arts, dance, and anything covered by copyright.

III
CONSIDERING DISSECTION AND REVERSED QUESTIONS OF LAW AND FACT

When copyright infringement is meant to prohibit the copying of protectable elements of a work, it seems that the audience test, unguided as it is, can "play no useful role" in fulfilling the goals of copyright law.[314] Expert testimony and analytic dissection are necessary to maintain the distinction, both at the copying and misappropriation stages of the inquiry. More specifically, courts should be informed fully of the broader contexts within which specific artistic works are created.

While some courts recognize *Arnstein*'s limits and allow expert testimony when works are of a "highly technical nature," thus far only computer software has met this characterization.[315]

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[313] Arewa, *supra* note 5, at 628.
[314] NIMMER, *supra* note 11, at § 13.03[E][1][b].
[315] *Id.* at § 13.03[E][4].

The courts' unwillingness to see "aesthetic arts, such as music, visual works or literature" as sufficiently complex to warrant the aid of expert guidance is merely an artifact of indoctrinated opinions on the nature of aesthetics. Yet with culture becoming ever more aware of its recombinant nature,[316] and the arts becoming increasingly technical in the age of digitalization, it is necessary to alter the current infringement tests in order to encompass varying artistic theories.

Courts need to act as gatekeepers, preventing an onslaught of needless and threatening litigation by deciding whether there is a cognizable claim of misappropriation and identifying the unprotectable elements in a work before sending the intuitive issue of copying to the trier. There have been many scholarly suggestions for reforming the two-part test. This part considers adoption of a proposal first suggested by Nimmer and expanded by Professor Lemley: extending the "abstraction-filtration-comparison" (AFC) test for computer software to all cases deciding copyright infringement.[317]

First adopted by the Second Circuit in *Computer Associates v. Altai*,[318] the AFC test requires the court to identify which aspects of the program constitute its expression versus ideas ("abstraction"), remove from consideration unprotectable ideas ("filtration"), and only then compare whether the defendant copied the protectable elements ("comparison").[319]

Following *Altai*, the AFC test was widely adopted in determining substantial similarity in the non-literal aspects of computer programs. However, as Nimmer notes, "there is no reason to limit it to that realm."[320] In fact, the AFC method is more consistent with the Supreme Court's definition of infringement (along with ownership of a valid copyright) as the "copying of constituent elements of the work that are original."[321] Whether expert testimony is permitted, and to what extent, is left to the discretion of the district court.[322] This approach allows the court flexibility in determining the necessity of expert testimony depending on the

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[316] *See* Erin Geiger Smith, *What's the (Fair) Use?*, NYU LAW MAG. (2014), http://blogs.law.nyu.edu/magazine/2014/whats-the-fair-use/ (discussing the "latest incarnation of the Internet…the phenomenon of user-generated content" and Barton Beebe's views that "[o]pening up the conversation about aesthetic progress and what it means could lead to tweaks to copyright law that are more in line with today's hands-on approach to cultural commentary.").

[317] NIMMER, *supra* note 11, at § 13.03[F][1]; *see also* Lemley, *supra* note 13, at 734.

[318] Computer Assocs. Int'l, Inc. v. Altai, Inc., 982 F.2d 693, 713 (2d Cir. 1992).

[319] NIMMER, *supra* note 11, at § 13.03[F].

[320] *Id.*

[321] Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 361 (1991).

[322] Altai, 982 F.2d at 713.

complexity and nature of the works at issue. A court might therefore determine that the issue of substantial similarity in a case involving generic pop songs would best be determined by lay jurors, but in most cases where songs mix genres and traditions, the court would need the testimony of experts well versed in the nature of the art at issue.

Given that nearly every circuit already permits expert testimony on both prongs of the copyright infringement test in software cases,[323] adopting the AFC test wholeheartedly seems like a more feasible path to altering the current framework than other suggested reforms.[324] In fact, the Tenth Circuit already applies the AFC test for all copyright infringement cases, and the Sixth Circuit uses a variation of the Tenth Circuit test.[325] As discussed above, expanding the role of analytic dissection and expert testimony will result in better maintenance of the idea-expression distinction and respect for the limits to copyright protection. Moreover, allowing expert testimony in guiding the jury will solve the problem of juries having trouble disregarding the testimony they hear on the copying-in-fact prong in deciding misappropriation.

Professor Lemley suggests a further change: reserving the issue of misappropriation to the court as a question of law, to be determined on summary judgment. The role of the jury would be preserved in leaving the intuitive issue of whether the defendant copied as a question of fact.[326] According to Lemley, this seems to be the "practical import" of the AFC test.[327] Reversing the judge-jury role would better serve the interests of copyright, as the issue of which elements are protectable and unprotectable in any given work implicates substantial policy considerations and interpretation of the law better suited for a judge well-versed in the law.

Moreover, by providing written judicial opinions, this altered framework would allow a reasoned jurisprudence to develop on the issue of which elements are protected. The transparency and predictability of the law would allow artists a safe harbor and guaranteed protections in creating new works, thereby preventing the chilling effects of a potentially devastating lawsuit.

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[323] Lemley, *supra* note 13, at 726, 733.
[324] *Id.*
[325] OSTERBERG, *supra* note 110, at § 3.
[326] Lemley, *supra* note 13, at 741.
[327] *Id.*

Taking reform a step further, Professor Balganesh suggests reversing the order of the test.[328] That is, have the court determine misappropriation as a question of law on summary judgment, filter out what is sent to the jury, and then have the jury determine the question of copying-in-fact of "protected expression." The jury would still hear evidence on the issue of "protected expression," including expert testimony on whether elements are *scènes à faire* or original in the area or genre, and even on the ultimate issue of similarity between the works and probative similarity. The jury would also hear the judge's own dissection from the first step.[329] Balganesh argues that reversing the framework would encourage disposition on summary judgment, providing judges with a real gate-keeping role.[330] Moreover, it removes the subjectivity of the audience test, which he argues was based in mere skepticism towards rules, judges, and the law.[331]

While reversing the ordering might offer the benefit of preventing the judge's determination of misappropriation from improperly influencing the jury's probative similarity analysis, almost every court has adopted some version of the *Arnstein-Krofft* test,[332] which might make it difficult to persuade courts to do exactly the opposite.

At least preliminarily, extending the AFC approach seems more feasible and the need for dissection and expert testimony most ripe. Allowing the judge to determine the question of misappropriation as a matter of law, while preserving the issue of copying-in-fact for the jury, removes the inherent subjectivity and messiness of the audience test while complying with the constitutional mandate of jury trials in copyright lawsuits.[333] Furthermore, it uses juries for the role they are best suited for: the intuitive and fact-dependent question of whether the defendant copied.

On both questions, expert testimony can aid the court in understanding the nature of the work at issue. The controversy over sampling, for example, focuses on the taking rather than the contribution. Yet, experts in musicology know that sampling can be transformative. As D.J. Shadow put it, sampling is a way to reintroduce a person's music to people "in a completely different context than the

[328] Balganesh, *supra* note 9, at 859.
[329] *Id*.
[330] *Id*. at 860.
[331] *Id.* at 849.
[332] Lemley, *supra* note 13, at 725.
[333] U.S. CONST. amend. VII.

way they originally intended."[334] Mark Ronson similarly explained that through sampling artists insert themselves in a narrative and push that narrative forward.[335]

An expert might testify that sampling extends an African American oral tradition known as "signifying," a type of word play that draws attention to the cultural significance of the words.[336] For example, an expert could explain that the Beastie Boys' line "I shot a man in Brooklyn just to watch him die" places Johnny Cash's line "I shot a man in Reno just to watch him die" in a new setting – a hip-hop anthem called "Hello Brooklyn" – thereby removing the ideas of consequences and regret found in the context of Cash's murder ballad.[337] An expert could note that while sampling might intuitively seem like theft, it is no more so theft than quoting a passage from another book in a novel.[338] Rather, sampling is a form of textual revision and a literary device through which text speaks to text.[339] Through sampling, 2 Live Crew relied on repetition of the key elements of "Oh, Pretty Woman" to achieve a parody of the song.[340]

Our current framework for copyright infringement fails to inform courts of the artistic merits behind our most illustrative and progressive artistic movements. In perpetuating the courts' biases, copyright is its own worst enemy, stifling innovation where it is most likely to happen: on the margins.

CONCLUSION

Though the problems with copyright pose unique problems for music, these problems reflect the larger difficulties in our current copyright law. Our infringement doctrine inhibits progress by making "substantial similarity" the end-all-be-all test. The generalized focus on substantial similarity leaves homages and similarities inherent in the genre subject to findings of infringement because the law, like our culture, sees derivative works as unworthy. But what is originality? As music producer and sampling guru Mark Ronson said in an interview with NPR: "Well, what's the T.S. Eliot quote, which apparently he even stole from

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[334] *DJ Shadow On Sampling As A 'Collage Of Mistakes*,' NPR (Nov. 17, 2012 7:04 PM), http://www.npr.org/2012/11/17/165145271/dj-shadow-on-sampling-as-a-collage-of-mistakes.

[335] Raz & Ronson, *supra* note 261.

[336] HESS, *supra* note 254, at 98.

[337] *Id.* at 99.

[338] Fassler, *supra* note 258 (noting that author David Shields's novel, *Reality Hunger*, is made up of passages from other books, but musicians can't make a record made up from other records).

[339] HESS, *supra* note 254, at 98.

[340] *Id.* at 99.

Picasso, about 'Genius steals...?' 'Good artists borrow, great artists steal.'"[341] How we define "Progress of Science and useful Arts" is rooted in the dominant cultural beliefs of aesthetic value, but innovation comes with embracing progressive ideas and more of them.[342] The law needs to protect a new kind of originality, one that might not fit the Romantic mold, but that re-conceptualizes and re-frames preexisting works and provides listeners with a different experience than the original. The most important question should be what the newcomer added: how they took influences to make something new, because progress never involves creating something from nothing.

[341] Raz & Ronson, *supra* note 261.
[342] *See* Beebe, *supra* note 33.

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THE CHALLENGING ECONOMICS OF THE COMPANION DIAGNOSTICS INDUSTRY: A COMPELLING CASE FOR INVIGORATED PATENT PROTECTION

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Diagnostic tests are a core component of modern health care practice: they determine a patient's susceptibility to developing cancer and other disorders; they diagnose biological conditions; they monitor the progress of disease; and they can assess the risk of disease recurrence. Ensuring their innovative growth is therefore an important issue in innovation policy. While legal scholarship addresses much about the relevance of patents and other forms of intellectual property protection for diagnostic methods as a general matter, far less attention has been paid to a distinct class of diagnostic tests that deserves its own innovation policy debate: companion diagnostic tests. This note seeks to draw more attention to the economic challenges facing the companion diagnostics industry. It begins by providing the necessary background to understand what companion diagnostic tests are, and why they are vital to the future of modern healthcare. It then explores the unique underlying incentive structure amongst the key industry stakeholders, revealing how the incentives of these stakeholders are misaligned in ways that impede the industry's growth. Relying on empirical data from case studies collected in pharmacology and biotechnology business literature, this note ultimately argues that the microeconomics of the companion diagnostics industry present a compelling case for invigorated patent protection of companion diagnostic tests.

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INTRODUCTION

Diagnostic tests are a core component of modern health care practice: they determine a patient's susceptibility to developing cancer and other disorders; they diagnose biological conditions; they monitor the progress of disease; and they can assess the risk of disease recurrence.[1] Ensuring their innovative growth is therefore an important issue in innovation policy. While legal scholarship addresses much about the relevance of patents and other forms of intellectual property protection for diagnostic methods as a general matter,[2] far less attention has been paid to a distinct class of diagnostic tests that deserves its own innovation policy debate: companion diagnostic tests.

This note seeks to draw more attention to the unique economic challenges facing the companion diagnostics industry.[3] Part I provides the necessary background to understand what a companion diagnostic test is, and why it is vital to the future of modern health care. It presents the fundamental problem this note addresses, which is the sub-optimal growth that the companion diagnostics industry is currently experiencing. Part II focuses on why the industry faces challenging economics, relying on discussion and empirical case studies from pharmacology and biotechnology business literature. Part II.A introduces the key stakeholders in companion diagnostic test development. Part II.B argues that the empirical results of case studies suggest that one specific development pathway for companion diagnostics, referred to as the "co-development pathway," is most conducive to economic growth for the industry as a whole. Part II.C explains how the incentives of the stakeholders in the companion diagnostics industry are misaligned in ways that impede pursuit of the preferable co-development pathway.

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[1] *See infra* Part I.B (defining diagnostic tests more specifically and elaborating on their importance to clinical health care practice).

[2] *See, e.g.*, Christopher M. Holman, *The Critical Role of Patents in the Development, Commercialization and Utilization of Innovative Genetic Diagnostic Tests and Personalized Medicine*, 21 B.U. J. SCI. & TECH. L. 297 (2015); Eldora L. Ellison & David W. Roadcap, *Diagnostic Method Patents – Not All Hope Is Lost*, 22 NO. 15 WESTLAW J. INTELL. PROP. 1 (2015); Rebecca Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. SCI. & TECH. L. 256 (2015); Note, *Diagnostic Method Patents and Harms to Follow-On Innovation*, 126 HARV. L. REV. 1370 (2013); Daniel K. Yarbrough, *After Myriad: Reconsidering the Incentives for Innovation in the Biotech Industry*, 21 MICH. TELECOMM. & TECH. L. REV. 141 (2014).

[3] The authors who have addressed companion diagnostics specifically in the legal literature have yet to analyze the complicated underlying economic structure of industry. *See, e.g.*, Alison Hill, Comment, *Ambiguous Regulation and Question Patentability: A Toxic Future for In vitro Companion Diagnostic Devices and Personalized Medicine?*, 2013 WIS. L. REV. 1463 (2013) (addressing the application of FDA regulations and patentability standards to companion diagnostic tests).

Part II.D addresses how recently-proposed FDA guidance on diagnostics testsmight affect the economics of the companion diagnostics industry. Finally, Part III argues that the microeconomics of the companion diagnostics industry present a compelling case for invigorated patent protection of companion diagnostic tests.

I
BACKGROUND

A. Personalized Medicine Is the Future of Healthcare

Imagine you have been diagnosed with early onset of a disease. Your doctor prescribes an expensive drug therapy that your insurance only partly covers, but you decide to pursue the treatment anyway because to you, health comes first. Weeks pass, but the disease shows no decline in progress. You wonder whether the drug is even working, and whether it ever will. The sad truth is that it probably isn't working, and it probably ever won't.

This predicament is common because a given drug, on average, is only effective in 30% to 40% of the prescribed patient population.[4] One esteemed academic geneticist has suggested that over 90% of drugs work for less than half of those prescribed them.[5] This problem is largely attributable to immense genetic variation across individuals.[6] Genetic variation affects how drugs are absorbed and distributed; how they act on their targets; how they are metabolized; and how they are eventually excreted, all of which influence the efficacy and toxicity of drugs administered to patients.[7] This forms the basis of the study of pharmacogenetics and pharmacogenomics, both of which, at the risk of oversimplification, assess

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[4] Jakka Sairamesh & Michael Rossbach, *An Economic Perspective on Personalized Medicine*, 7 THE HUGO JOURNAL 1, 2 (2013) (defining an "ineffective drug" as one where the costs from adverse events outweigh the benefits); *see also* Culbertson et al., *Personalized Medicine: Technological Innovation and Patient Empowerment or Exuberant Hyperbole?*, 8(3) DRUG DISCOVERY WORLD 18 (2007) (finding that the efficacy of a drug can vary from 30% to 75% depending on the drug class and therapeutic use).

[5] Steve Connor, *Glaxo Chief – "Our Drugs Do Not Work On Most Patients"*, THE INDEPENDENT (London), Dec. 13, 2011, *available at* http://www.rense.com/general69/glax.htm (interviewing Allen Roses, an academic geneticist from Duke University and worldwide vice-president of genetics at GlaxoSmithKline).

[6] *See generally* Ashraf G. Madian et al., *Relating Human Genetic Variation to Variation in Drug Responses*, 28(10) TRENDS GENETICS 487 (2012) (summarizing the evidence accumulated over the last three decades of how genetic variation plays a major role in drug response variability).

[7] *Id.*

genetic characteristics of individuals and sub-populations to determine whether a drug will trigger a great response, bad response, or no response in a particular person.[8] This is accomplished not only by analyzing an individual's genes, but also by analyzing the downstream biochemical and molecular processes that are influenced by genetic variation and that play important roles in managing the body's response to drugs.[9] These distinct genetic, biochemical, and molecular characteristics of individuals are broadly referred to as "biomarkers," and studying them informs how clinical care management can be maximized and tailored to subpopulations of patients.[10]

The efforts of scientists to understand and develop innovative applications from the presence, absence, or level of expression of specific biomarkers, to improve health outcomes for patients, is the foundation of "personalized medicine." Personalized medicine represents the modern aspiration of a health care system that is predictive, preventive, personalized and participatory,[11] where every patient receives the right drug, at the right dose, at the right time.[12]

B. Companion Diagnostics Are An Essential Component of Personalized Medicine

The tools that scientists use to ascertain differences in biomarkers across patient populations are known as *in vitro* diagnostic devices. These are medical devices used to test human samples *outside* the living body, in test tubes (hence the name *in vitro*).[13] For example, many women undergo testing of the *BRCA1* and

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[8] More specifically, pharmacogenetics is a field that explains how different people respond to a given drug in different ways. Pharmacogenomics explains the role of differences in the level of *expression* of given genes (i.e., how 'active' genes are), which also influences drug responses. DEVARAJAN THANGADURAI & JEYABALAN SANGEETHA, BIOTECHNOLOGY AND BIOINFORMATICS 37 (2015).

[9] Madian, *supra* note 6, at 487.

[10] Elizabeth Drucker & Kurt Krapfenbauer, *Pitfalls and Limitations in Translation from Biomarker Discovery to Clinical Utility and Personalised Medicine*, 4 THE EPMA JOURNAL 1, 2 (2013).

[11] Sairamesh & Rossbach, *supra* note 4, at 1.

[12] U.S. Food and Drug Administration, *Paving the Way for Personalized Medicine: FDA's Role in New Era of Medical Product Development*, http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PersonalizedMedicine/UCM372421.pdf. A more rigorous definition of personalized medicine would be "the use of genetic or other biomarker information to improve the safety, effectiveness, and health outcomes of patients via more efficiently targeted risk stratification, prevention, and tailored medication and treatment-management approaches." THANGADURAI & SANGEETHA, *supra* note 8, at 37.

[13] *In vitro* is Latin for "in glass" and is a term of art for conducting tests on components of an organism isolated from or outside of their biological surroundings, such as in a test tube. OXFORD DICTIONARIES, http://www.oxforddictionaries.com/us/definition/american_english/

BRCA2 genes to inform them of their risk of developing breast and ovarian cancers; these tests are completed by *in vitro* diagnostic devices.[14] *In vitro* diagnostic devices can also be used to diagnose disease, to inform the selection of treatment plans, to monitor the progress of disease, and to assess the risk of disease recurrence.[15]

This note is about one category of *in vitro* diagnostic devices in particular: companion diagnostics. Companion diagnostics are the class of *in vitro* diagnostic devices that assess the likely safety and efficacy of a particular drug in a particular patient.[16] They accomplish this by assessing *pharmacodynamic* biomarkers – genetic, biochemical, and molecular characteristics that help predict the outcome of a drug's interaction with its target.[17] This enables scientists and physicians to identify segments of a patient population in which a drug will be most effective, ineffective, or even harmful. Companion diagnostic tests, through their analysis of biomarkers, can also inform the optimal dosages of drugs for different sub-segments of the relevant population.[18] Companion diagnostics ("CDx's") are thus an essential component of personalized medicine because they are the vehicle for

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invitro. In contrast, "in vivo" testing is carried out in a living organism such as electrocardiography or diagnostic imaging (for example, X-rays). For a denser definition of *in vitro* diagnostic devices, see 21 C.F.R. § 803.3.

[14] National Institute of Health, *BRCA1 & BRCA2: Cancer Risk and Genetic Testing*, NATIONAL CANCER INSTITUTE, http://www.cancer.gov/about-cancer/causes-prevention/genetics/
brca-fact-sheet#q1 (last visited Apr. 22, 2016).

[15] *In Vitro Diagnostics*, U.S. FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm (last updated Oct. 24, 2016).

[16] *Companion Diagnostics*, U.S. FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm407297.htm (last updated Oct. 5, 2016).

[17] Drucker & Krapfenbauer, *supra* note 10, at 2. Pharmacodynamic biomarkers aren't limited to genetic information. The other "biochemical and molecular characteristics" referred to include proteins, metabolites, essential elements, and tracers since all these molecules can affect drug action. Amit Agarwal et al., *The Current and Future State of Companion Diagnostics*, 8 PHARMACOGENOMICS AND PERSONALIZED MED. 99 (2015).

[18] Zivana Tezak et al., *FDA and Personalized Medicine: In Vitro Diagnostic Regulatory Perspective*, 7 PERSONALIZED MED. 517, 522 (2010). For example, the drug Warfarin, which is used to treat blood pressure, is metabolized at different rates depending on what version of the *CYP2C9* gene a patient possesses. A CDx for Warfarin enables physicians to identify the 30% of European and Caucasian populations that metabolize Warfarin at a slower rate, and therefore require a lower dose, to avoid internal bleeding. Simon Sanderson et al., *CYP2C9 Gene Variants, Drug Dose, and Bleeding Risk in Warfarin-Treated Patients: A HuGEnet™ Systematic Review and Meta-Analysis*, 7 GENETICS IN MEDICINE 97 (2005).

ascertaining the selection of the right drug, at the right dose, at the right time, for the right person.[19]

The benefits of more sophisticated methods of drug treatment selection attributable to CDx testing are plenty. Companion diagnostic testing can enhance the lifespan of patients, preventing them from undergoing therapies that are ineffective or cause harmful side effects. [20] "HercepTest," the first broadly-marketed companion diagnostic whose companion is the breast cancer drug trastuzumab (sold as "Herceptin"), identifies the 25-30% subpopulation with overexpression of the *HER-2* gene for which Herceptin is uniquely effective.[21] The CDx "HLA-B*5701," used alongside HIV treatment with the drug Abacavir, singles out the 10% of patients that will experience adverse reactions, saving the health care system costs from hospitalizations caused by these adverse side effects.[22]

The more recently developed "Cobas 4800 BRAF V600E mutation test" illustrates how CDx's ensure that drugs that are effective in smaller segments of the population still make their way to market. The actual benefit of this test's companion drug, Zelboraf, in an unselected clinical population would have been around 50%, and therefore insufficient to obtain FDA approval.[23] Armed with the knowledge from the Cobas 4800 CDx that Zelboraf appeared to be more effective in patients with a certain mutation, *only* those patients with the mutation were

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[19] Stephen Naylor & Toby Cole, *Overview of Companion Diagnostics in the Pharmaceutical Industry*, DRUG DISCOVERY WORLD, http://www.ddw-online.com/personalised-medicine/p92845-overview-of-companion-diagnostics-in-the-pharmaceutical-industry-spring-10.html (last visited Feb. 22, 2016) (acknowledging widespread agreement that a companion diagnostic provides biological and/or clinical information that enables better decision making about the use of a potential drug therapy).

[20] *E.g.*, Christopher P. Leamon & Mike A. Sherman, *The Rise of Companion Diagnostics: A Step Towards Truly Personalized Medicine*, ONCOLOGY BUSINESS REVIEW (OBR) GREEN, https://obroncology.com/obrgreen/article/The-Rise-of-Companion-Diagnostics-A%20Step-Towards-Truly-Personalized-Medicine (last visited Mar. 1, 2016).

[21] Remarkably, the HerceptTest is now also used to identify those in the 22% subpopulation of patients with *stomach* cancer that are eligible for treatment with Herceptin. *Dako: FDA approval of Diagnostic Tests Provides Hope for Patients with Stomach Cancer*, THOMSON-REUTERS, http://www.reuters.com/article/idUS47201+21-Oct-2010+MW20101021 (last visited Apr. 22, 2016).

[22] A.R. Hughes, *Pharmacogenetics of Hypersensitivity to Abacavir*, 8 THE PHARMACOGENOMICS JOURNAL 365 (2008). *See also* Leamon & Sherman, *supra* note 20 (acknowledging the benefit of CDx's at reducing health care costs by minimizing incidences of adverse reactions); Sairamesh & Rossbach, *supra* note 4 (same).

[23] Edward Blair et al., *Aligning the Economic Value of Companion Diagnostics and Stratified Medicines*, 2 J. PERS. MED. 257, 261 (2012).

selected for the Phase III trial. The results demonstrated a tremendous clinical benefit over chemotherapy.[24] In 2015, Zelboraf was the 391st-biggest drug in the world, with sales of $219 million, an unobtainable achievement were it not for the CDx.[25] Evidently, the economic gains that can be realized from CDx's are substantial.[26]

C. Scientific Progress of Companion Diagnostic Development Outpaces Economic Progress

The science and business literature expresses disappointment and dissatisfaction with CDx economic growth,[27] even though the science underlying CDx's has transformed dramatically since the launch of the HercepTest in 1998, and especially after the completion of the human genome product in 2003.[28] Acknowledgment of the potential of CDx's and personalized medicine is juxtaposed with statements that the use of CDx's "is currently constrained;"[29] that their progress has been "slower than expected;"[30] that their potential has "yet to be

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[24] *Id.*

[25] Drug Analyst, Equity Research, *Zelboraf*, DRUGANALYST CONCENSUS DATABASE, http://consensus.druganalyst.com/Roche/Zelboraf (last visited Apr. 22, 2016).

[26] *But see* Gregory Zaric, *Cost Implications of Value-Based Pricing for Companion Diagnostic Tests in Precision Medicine*, PHARMACOECONOMICS, http://link.springer.com/article/10.1007%2Fs40273-016-0388-x (2016) (finding in some scenarios analyzed that companion diagnostic tests will lead to an increase in healthcare costs).

[27] *E.g.* Lisa M. Meckley & Peter J. Neumann, *Personalized Medicine: Factors Influencing Reimbursement*, 94 HEALTH POL. 91, 97 (2010) (concluding from six case studies that "the hype of personalized medicine technologies has outpaced its evidentiary support to date"); Mark D. Hughes, *Molecular Diagnostics Market Trends and Outlook*, ENTERPRISE ANALYSIS CORPORATION, http://www.eacorp.com/images/PDFS/Molecular%20Diagnostics%20IVD%20Article%20v21%20MEK%20-%20Reprint%20FINAL.pdf (last visited Mar. 3, 2016) (describing pharmacogenetics as a "disappointment" from the perspective of molecular diagnostic vendors despite initial enthusiasm about sales).

[28] *See e.g.*, Drucker & Krapfenbauer, *supra* note 10 (noting that thousands of putative biomarkers have been identified and published, dramatically increasing the opportunities for developing more effective therapeutics); James Buchanan et al., *Issues Surrounding the Health Economic Evaluation of Genomic Technologies*, 14 PHARMACOGENOMCIS 1833 (2013) (acknowledging the promise of new genetic diagnostic technologies).

[29] Dee Luo et al., *A Quantitative Assessment of Factors Affecting the Technological Development and Adoption of Companion Diagnostics*, 6 FRONTIERS IN GENETICS 1 (2016).

[30] Adrian Towse et al., *Understanding the Economic Value of Molecular Diagnostic Tests: Case Studies and Lessons Learned*, 3 J. PERSONALIZED MEDICINE 288 (2013).

fully realized;"[31] that "significant opportunity remains untapped;"[32] and that there exist "several operational challenges."[33] In fact, as of 2014, CDx's made up only 3% of the worldwide market for *in vitro* diagnostics.[34] They account for a small percentage of today's health insurance expenditures.[35] Many have yet to gain widespread adoption,[36] and few CDx-drug pairs have been approved since Herceptin's breakthrough.[37] Forecasts show this trend will continue.[38] In the meantime, society is left with a plethora of commonly used and costly therapeutic agents that are ineffective in a high percentage of patients prescribed them, even though the science says the health care industry could know better.[39] Scientific challenges do undoubtedly remain,[40] but the consensus is loud and clear that the growth rate of CDx's is sub-optimal and disappointing in light of how far the science has progressed. The obstacles responsible for this less-than-optimistic view of CDx-driven personalized medicine are *not* scientific; they are economic.

II
COMPANION DIAGNOSTIC DEVELOPMENT FACES CHALLENGING ECONOMICS

This Part explores the economic challenges of the CDx industry, drawing from the results of several case studies from the pharmacologic literature that examine the most successful CDx's on the market. Part A introduces the key stakeholders in CDx development, and begins to reveal how the stakeholders'

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[31] Mark R. Trusheim et al., *Quantifying Factors for the Success of Stratified Medicine*, 10 NATURE REVIEWS: DRUG DISCOVERY 817 (2011).

[32] Robert McCormack et al., *Co-development of Genome-Based Therapeutics and Companion Diagnostics*, 311 J. AMER. MEDICAL ASSOC. 1395 (2014).

[33] Sairamesh & Rossbach, *supra* note 4, at 2; Jerel Davis et al., *The Microeconomics of Personalized Medicine*, MCKINSEY & COMPANY, http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-microeconomics-of-personalized-medicine. (last visited Feb. 22, 2016).

[34] Agarwal et al., *supra* note 17, at 106 (2015).

[35] *E.g.*, Joshua Cohen et al., *Clinical and Economic Challenges Facing Pharmacogenomics*, 13 PHARMACOGENOMICS J. 367 (2013) (purporting to explain why there is a lack of comprehensive reimbursement of CDx's).

[36] Hughes, *supra* note 22; Naylor & Cole, *supra* note 19 (companion diagnostics have been "cautiously adopted"); Sairamesh & Rossbach, *supra* note 4, at 2 ("[O]nly a few personalized medicine based diagnostic tests have achieved high levels of clinical adoption.").

[37] Drucker & Krapfenbauer, *supra* note 10, at 44; Luo et al., *supra* note 29, at 2-3.

[38] Cohen et al., *supra* note 35.

[39] *E.g.* McCormack et al., *supra* note 32 (calling attention to the fact that many commonly-used and costly agents don't have validated CDx tests and are ineffective in large number of patients).

[40] *E.g.* Drucker & Krapfenbauer, *supra* note 10, at 3 (identifying challenges in developing biomarkers for CDx tests that are of high sensitivity and specificity).

incentives are misaligned. Part B examines the important distinction between *co-developed* CDx's (CDx's that are developed in tandem with their companion drug), and *post-approval* CDx's (CDx's that are developed after their companion drug has been put on the market). It argues that co-developed CDx's are economically and socially preferable to post-approval ones, and that stimulating CDx-drug co-development is a necessary step to move the CDx industry forward as a whole. Part C presents the challenges in incentivizing diagnostic companies and drug companies to engage in the requisite collaboration for CDx-drug co-development.

A. The Interests of the Stakeholders Are Diverse

The key stakeholders in the CDx industry are the payers, diagnostic developers, drug companies, the regulators, and healthcare providers.

1. The Payers

The payers possess power in the CDx industry because, ultimately, their reimbursement policies allow or restrict access to the market.[41] Payers include governmental and private organizations that manage reimbursement of healthcare costs. They vary in their size, scope, and management of patient care.[42]

Companion diagnostics may pose large potential cost savings to payers by eliminating payments for ineffective drugs and reducing the costs associated with adverse events.[43] But this is no guarantee.[44] Consider the overall cost savings to payers as a function of: (1) the cost of the treatment decision in the absence of the CDx; (2) the cost of the treatment decision made in light of the CDx; (3) the probability that the CDx will change the treatment decision; and (4) the cost of administering the CDx.[45] Permutations of these variables reflect some interesting results. Most obviously, if the CDx has a low probability of changing a patient's

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[41] *See generally* P.M. Danzon, *Pricing and Reimbursement of Biopharmaceuticals and Medical Devices in the USA*, 3 ENCYCLOPEDIA OF HEALTH ECONOMICS 127 (2014) (providing an overview of payer reimbursement for drugs and medical devices in the USA); *see also* P. Deverka, *Pharmacogenomics, Evidence, and the Role of Payers*, 12 PUB. HEALTH GEN. 49 (2009).

[42] Eric Faulkner et al., *Challenges and Development and Reimbursement of Personalized Medicine-Payer and Manufacturer Perspectives and Implications for Health Economics and Outcomes Research*, 15 VALUE HEALTH 1162, 1163 (2012).

[43] *E.g.*, Davis et al., *supra* note 33 (estimating that CDx's save $600 to $28,000 per patient).

[44] *See* Faulkner et al., *supra* note 42 (qualifying the fact that payers recognize the potential advantages of personalized medicine with the notion that they are cautious regarding the potential downsides of the CDx approach).

[45] *See* Davis et al., *supra* note 33.

treatment decision (for example, the CDx reveals that only 10% of a patient subpopulation should avoid an expensive drug therapy), the cost savings to the payer will be less than if the CDx revealed that 50% of the patient population should avoid the drug therapy. Whether either of these scenarios presents a net savings to the payer, however, will depend on the cost of the new treatment decision. If a CDx reveals that either 10% or 50% of a patient subpopulation should avoid a particular drug therapy because it will be ineffective or cause adverse side effects, the cost of the alternative treatment could still be significantly higher. And while the cost of the tests themselves are not prohibitive (some are priced as low as $40 per test; many cost under $300 per test, and few cost over $1000 per test),[46] the consequences of reimbursing every eligible member of the patient population, compared to the savings when only a few patients benefit, are uncertain.[47] The savings to payers presented by CDx's are therefore variable.

The quality of clinical utility evidence available is also a key factor in payer decision-making.[48] Clinical utility evidence is the body of evidence that showcases the added value of a CDx to treatment management, as compared with treatment management without a CDx. The more the CDx has been clinically tested, the more evidence is available to assure a payer that the variations in biomarkers revealed by the CDx actually lead to overall health care savings in the patient population.[49]

Analyzing cost savings to payers is also complicated by the high rate of customer turnover for commercial payers in the United States.[50] This factor is most relevant to patients diagnosed with a long-term disease: a payer might cover the cost of an initial screening and CDx that reveals which drug therapy will be most optimal if and when the disease begins to progress. If that patient leaves the payer before the disease begins to progress, the payer will not see the benefit in the reduction of cost of the patient's future treatments.[51]

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[46] Cohen et al., *supra* note 35, at 387.

[47] *Id.*

[48] *See infra* Part II.B.1 for further discussion on the importance of the quality of clinical utility evidence to payer decision-making, and the consequences arising from the difficulties in assessing clinical utility.

[49] Paul Engstrom et al., *NCCN Molecular Testing White Paper: Effectiveness, Efficiency and Reimbursement*, 9 J. NAT'L COMPREHENSIVE CANCER NETWORK (Supl. 6) S1 (2011)

[50] Sairamesh & Rossbach, *supra* note 4, at 3.

[51] *Id.* (turnover also makes it less attractive to reimburse *prophylactic* tests that minimize likelihood of disease occurring later in life).

All of these factors lead payers to behave variably and unpredictably. [52] Payers will differ in terms of which CDx's and drugs they choose to cover and when, with some enforcing strict coverage rules, and others extending more room for medical providers to determine what they deem to be the appropriate care for their patients.[53]

2. The Diagnostic Developers

Diagnostic test developers range from modest research labs to large companies. Across the entire range, significant obstacles exist in the way of profitability.[54]

Generally, the potential revenues to be generated from a CDx are not substantial. Diagnostics are valued and paid for at far lower levels compared to their companion drugs. While common drug treatments cost between $15,000 and $149,000 per patient in the United States, the CDx's range from $40 to $2,000 per test.[55] One economic simulation of a co-developed CDx using favorable assumptions for the diagnostic developer[56] found the expected net present value (eNPV) of CDx tests to be 2-4% of the eNPV of their corresponding drugs.[57] The difficulty in reaping large revenues from CDx's is augmented by the fact that few diagnostic developers have a large enough sales force to educate healthcare providers about ordering the appropriate CDx.[58]

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[52] *See infra* Part II.D for further discussion of the variability of payer decision making.

[53] For example, the payer company Aetna, does not cover *CYP2C9* testing for Warfarin, citing the lack of clinical and cost-effectiveness evidence in their "Policy on Pharmacogenomic Testing" as a reason for not covering the test, while the payer Cigna does cover the test. Meckley & Neumann, *supra* note 27, at 94.

[54] *E.g.* Davis et al., *supra* note 43; McCormack et al., *supra* note 32 (describing the financial position of diagnostic companies as "fragile").

[55] Joshua P. Cohen & Abigail E. Felix, *Personalized Medicine's Bottleneck: Diagnostic Test Evidence and Reimbursement*, 4(2) J. PERSONALIZED MED. 163 (2014); Agarwal et al., *supra* note 17 (emphasizing that the potential revenue from a "blockbuster" CDx is rarely over $100 million while annual sales of the companion drug can reach up to ten times that amount).

[56] These were that the drug company would absorb most of the diagnostic development costs and that the diagnostic company would receive net $200 payer reimbursement per test. Trusheim et al., supra note 31, at 829.

[57] *Id.*

[58] Agarwal et al., *supra* note 17; *see also* McCormack et al., *supra* note 32 (noting that the financial position of diagnostic companies for developing a CDx is often fragile); Leeland Ekstrom et al., *Well Begun Is Half Done: Success Factors for Companion Diagnostic Launch*, in PERSONALIZED MEDICINE, THE PATH FORWARD, 28 (McKinsey & Company, eds. 2013).

Beyond the difficulties in obtaining a revenue stream, the development costs of a CDx are substantial, varying widely based on which of two possible classes of CDx's the developer chooses to pursue. The first class of CDx a developer may pursue includes commercial CDx testing kits ("commercial CDx's"). As the name implies, these CDx's are developed with the intention of being commercialized and broadly marketed to other labs, to physicians, and to the public through direct-to-consumer marketing.[59] Companion diagnostics can be co-developed alongside a particular drug and used in the drug's clinical trials, or they can be developed "post-approval;" that is, after their corresponding drug has been FDA approved for market. The CDx's in the second class are "laboratory developed CDx's" ("LDT-CDx's"). These are CDx's that are manufactured and offered within a single laboratory and are *not* sold as commercial products in the marketplace. Instead, they are sold as services, with the diagnostic developing lab being the sole performer of the CDx (unlike commercial CDx's, which can be performed by all entities to which the CDx is marketed).[60] LDT-CDx's are most often not co-developed with drugs, since co-developed CDx's are typically commercially marketed with their companion drug.

The development costs for a commercial CDx are far greater than for an LDT-CDx, primarily because the FDA imposes costlier regulatory hurdles for commercial CDx's.[61] The FDA has actually exercised its enforcement discretion with regard to LDT-CDx's, which are only subject to minimal regulation by the Center for Medicaid and Medicare Services (CMS).[62] Developers pursuing commercial CDx's thus face greater upfront expenses. It is perhaps not surprising that the value of commercial CDx's in the market is far less than that of LDT-

[59] For example, a diagnostic company that owns several clinical laboratories may develop a CDx in one of its labs and then transfer the CDx to several clinical labs within its network. This would be a considered a commercial CDx. U.S. Food & Drug Admin., Draft Guidance for Industry, Clinical Laboratories, and FDA Staff: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) (Oct. 3, 2014), http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm416685.pdf [hereinafter, FDA Guidance for LDTs].

[60] For example, a laboratory will use peer-reviewed articles and its own instruments to develop a testing protocol that will be verified and validated within the lab. Once validated, the CDx can be used by the lab to provide clinical diagnostic results for health care providers. *Id.* LDT-CDx's are sometimes developed as novel CDx's for post-approval drugs on the market, but more often, they are developed as copies of co-developed CDx's.

[61] The additional cost of obtaining FDA approval for a CDx as compared to an LDT-CDx can range from $24–$75 million. Frost & Sullivan, *Opportunities and Growth Strategies for the APAC IVD Industry*, SLIDESHARE, http://www.slideshare.net/FrostandSullivan/diagnostic-world-asia-apac-ivd-outlook-2010 (last visited Feb. 29, 2016).

[62] Agarwal et al., *supra* note 17.

CDx's: in 2012, the value of commercial CDx's was $405 million and the value of LDT-CDx's was $1.17 billion.[63]

Difficulties in obtaining payer reimbursement further complicate the business model of a diagnostic developer. Payer reimbursement is essential to assist in covering the extensive upfront costs just described, but the amount of time to payer coverage is unpredictable as previously alluded to in Part II.A.1 and further discussed in Part II.B. The same is true for the time until physicians adopt the tests. The diagnostic developer must consider *ex ante* what minimum economic data and evidence of clinical utility will be necessary to obtain payer reimbursement, and how to get past potential barriers in the adoption of the tests by medical providers.[64]

In summary, CDx development is more capital-intensive compared to other diagnostic tests, and the diagnostic developer faces a high degree of uncertainty in securing returns which depend heavily on the regulatory requirements at play and payer reimbursement practices.

3. The Pharmaceutical Companies

Pharmaceutical companies are wholly distinct from diagnostic developers. The latter employ completely different technology in their development platforms compared to the former. The business models and economics of the pharmaceutical industry are equally distinct from diagnostics, as each industry develops products with different life cycles and timelines, customers, and regulatory requirements.[65] The top priorities for a pharmaceutical company are to obtain as much value as possible after market launch of their drugs, and, to a lesser extent, reduce development costs.[66]

Decisions to pursue CDx development versus conventional "treat-all" approaches are complex, and depend on many factors including the size of the patient population, the class of disease the drug targets, the degree of payer management of the target indication, and the potential for value differentiation. [67]

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[63] *Id.*

[64] Faulkner et al., *supra* note 42, at 1166.

[65] Maham Ansari, *The Regulation of Companion Diagnostics: A Global Perspective*, 47 THERAPEUTIC INNOVATION & REGULATORY SCIENCE 405, 406 (2013).

[66] *See* Davis et al., *supra* note 33 (claiming that the potential to generate greater value after marketing is more important for the economics of pharmaceutical companies than making development more productive).

[67] Faulkner et al., *supra* note 42, at 1165.

Each of the above factors is further influenced by whether the CDx is co-developed with its companion drug, or developed post-approval. Co-development of a CDx with its companion drug has several benefits for a pharmaceutical company.[68] The CDx can significantly reduce the costs of clinical trials because if the drug company knows in advance which patient subpopulation is most likely to benefit from it, it can tailor the trial to that specific subpopulation. This increases the chance of demonstrating drug efficacy and of obtaining approval, and can decrease the amount of time it takes to get the drug to market.[69] At the same time, however, there is a risk that a suitable diagnostic will not be approved for use in clinical trials with the drug or be discovered at all.[70] Other studies have explored additional factors suggesting that savings in CDx co-development for drug companies may be offset by other costs associated with using a CDx in clinical trials.[71]

Post-approval CDx's have the potential to take a well-known drug therapy on the market that is a second-line or third-line treatment option for the general population, and turn it into a first-line treatment for a select group of patients.[72] The drug Tarceva is a good example. Since its CDx was approved in 2013, Tarceva's forecast changed to projections of increased growth over the next five years.[73] Post-approval CDx's, on the other hand, have the potential to divide the treatable population of patients into sub-segments, thereby decreasing the number

[68] *See infra* Part II.B.1 for further dissection of the incentives of drug companies to engage in CDx co-development.

[69] Davis et al., *supra* note 33; Drucker & Krapfenbauer, *supra* note 10, at 3; Sairamesh & Rossbach, *supra* note 4, at 3; Leamon & Sherman, *supra* note 20. For example, Pfizer's drug Zalkori was able to obtain FDA approval in a lightning-fast 1.8 years with the assistance of its co-developed CDx, the ALK Break Apart FISH Probe Kit. Agarwal et al., *supra* note 17. The drugs Tarceva and Iressa, which were *not* initially approved with a CDx, took 5.3 and 7.0 years respectively. *Id.*

[70] *E.g.* Davis et al., *supra* note 33. For further discussion on the risks associated with CDx co-development to a diagnostic developer see *infra* Part II.B.2.

[71] Sairamesh & Rossbach, *supra* note 4, at 4 (noting that co-development might increase costs and delay drug developments since clinical trials must frequently be larger when CDx's are employed and that this is more likely to occur when the drug's mechanism of action is less well-understood); Mark R. Trusheim, *Economic Challenges and Possible Policy Actions to Advance Stratified Medicine*, 9 PERSONALIZED MEDICINE 413, 414 (2013) (listing other factors that offset the potential gains of co-development).

[72] Agarwal et al., *supra* note 17.

[73] *Id.* The increase in sales growth is modest, but it is so rare for a drug to experience faster growth eight years after its initial launch, that the example is worth nothing.

of patient customers.[74] A post-approval CDx also has the potential to direct segments of the patient population to a competitor's product, a drug company's worst nightmare. Ultimately, the potential costs and benefits of post-approval CDx's for drug companies are also difficult to ascertain.

The incentives of drug companies to engage in CDx co-development with diagnostic developers, and the advantages and disadvantages posed by the development of post-approval CDx's, are discussed in greater detail in Part III. For now, it is simply worth noting that the incentive structures are complicated and that there is clear potential for the incentives of drug companies and diagnostic developers to point in opposite directions.

4. The Regulators

As noted earlier, the FDA regulates commercial CDx's, and has exercised its enforcement discretion for LTD-CDx's, leaving their regulation in the hands of the CMS.[75] The CMS and the FDA have different regulatory goals. The FDA addresses "the safety and effectiveness of the diagnostic tests themselves and the quality of the design and manufacture of the diagnostic tests."[76] The CLIA regulates "the quality of the clinical testing process itself, mostly by assessing the quality of the clinical laboratory."[77]

The FDA's regulatory oversight of commercial CDx's is more substantial than the CMS's regulatory oversight of LDT-CDx's. The CMS only evaluates LDT-CDx's for their analytical validity, which is the ability of a CDx to measure the biomarker it is intended to measure.[78] The FDA evaluates the analytical validity of commercial CDx's, but it also evaluates the tests' *clinical* validity – the ability of the test to predict the likelihood of a clinical outcome from its measurement of a biomarker.[79] In addition, commercial CDx's are subject to pre-market review, systematic adverse event reporting, and a process for corrections or

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[74] Davis et al., *supra* note 33; Sairamesh & Rossbach, *supra* note 4, at 4 (noting that CDx's divide the market of treatable patients into groups and clusters thereby reducing market share of the patient population).

[75] Amanda Sarata & Judith Johnson, *Regulation of Clinical Tests: In Vitro Diagnostic (IVD) Devices, Laboratory Developed Tests (LDTs), and Genetic Tests*, Congressional Research Service Report 11 (2014). The Clinical Laboratory Improvement Amendments Act (CLIA) of 1988 provides the CMS with authority to regulate clinical labs that carry out diagnostic testing. 42 U.S.C. § 263(a).

[76] Sarata & Johnson, *supra* note 75, at ii.

[77] *Id.* at 11.

[78] *Id.*

[79] *Id.*

recalls.[80] This discrepancy in the level of regulatory overseeing between LDT-CDx's and commercial CDx's, and between *all* laboratory-developed tests (LDTs) and commercial diagnostic tests for that matter, has attracted significant attention in light of the increasing complexity of LDTs and their expansion from academic institutions to commercial ones.[81] The FDA has developed "serious concerns" regarding the lack of independent review of the evidence of clinical validity of LDTs generally, including LDT-CDx's.[82] Consequently, it issued a draft guidance in the Federal Register in October 2014 to begin regulating LDTs on a risk-based approach.[83] If the guidance were to become final, LDT-CDx's would be classified under the highest-risk category and in effect would be subject to the same regulatory standards as commercial CDx's.[84] The economic implications of the current regulatory overseeing regime as well as the FDA's recent proposal are discussed in Part III.

5. The Medical Providers

Economically, CDx's can have a positive or negative impact on medical providers depending on what the results of the test suggest for further treatment. Under the current procedure-based reimbursement for providers, physicians are incentivized to use CDx's that will increase, rather than decrease, the number of subsequent procedures a patient requires.[85] Where diagnostic tests make existing procedures unnecessary, doctors might be disinclined to perform them. Providers are likely to wait some time to ascertain the effects of a CDx on treatment procedures before deciding whether it is in their economic interest to use the test. Providers might not pay much attention to companion diagnostics at all if they aren't committed to molecularly-guided therapeutic decisions.[86] Educating

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[80] *Id.*

[81] *See, e.g.*, Report of the Secretary's Advisory Committee on Genetics, Health and Society, *U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services*, http://oba.od.nih.gov/oba/sacghs/reports/sacghs_oversight_report.pdf (April 2008).

[82] *See, e.g.*, Office of Public Health Strategy and Analysis, FDA, *The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies* (Nov. 16, 2015) (examining events involving 20 LDTs with inaccurate results that placed patients at risk).

[83] U.S. Dep't of Health and Human Services, FDA, Center for Devices and Radiological Health, *Framework for Regulatory Oversight of Laboratory Developed Tests* (LDTs), Draft Guidance, Oct. 2014 [hereinafter FDA Draft Guidance].

[84] *Id.* at 23-27.

[85] Sairamesh & Rossbach, *supra* note 4, at 6; Davis et al., *supra* note 33.

[86] Ildar Akhmetov et al., *Market Access Advancements and Challenges in "Drug-Companion Diagnostic Test" Co-Development in Europe*, 5 J. PERSONALIZED MED. 213, 224 (2015).

providers on newly-developed CDx's is therefore critical to clinical adoption of CDx's and their commercial success.

The subsequent sections take on the more complicated task of analyzing how the stakeholders' incentives interact in the context of developing CDx's along the various pathways, and the economic consequences for the CDx industry that flow therefrom.

B. Co-Developed Companion Diagnostics Are More Conducive to CDx Microeconomic Growth

This Part argues that CDx's that are co-developed with their companion drugs provide greater economic and social benefit over post-approval CDx's, drawing on the empirical findings of case studies of CDx-drug pairs on the market for support.

1. CDx Co-Development Leads to Better Evidence of Clinical Utility & Greater Patient Access

Clinical utility refers to the body of evidence that showcases the added value of a CDx to treatment management.[87] A CDx may accurately measure a biomarker (i.e., be analytically valid), and from that measurement, a CDx may accurately predict how a particular subpopulation will respond to a drug (i.e., be clinically valid). But that doesn't necessarily mean that the benefit of this knowledge outweighs the costs of developing the CDx; that is, that the CDx has strong clinical utility. To ascertain the latter, controlled studies must be conducted.

Case studies find that the quality of clinical utility and cost-effectiveness evidence for CDx's is highly variable, and often very weak.[88] For instance, the 2013 Cohen et al. study analyzed data from the Cost Effective Analyses ("CEA") Registry, a publically-available database of over 2,000 different cost-utility analyses published in peer-reviewed journals, for eight CDx-drug pairs.[89] It found that the quality and quantity of both the clinical and cost-effectiveness studies in the registry varied significantly, with "surprisingly few CEAs show[ing] conclusive evidence as to whether [the companion diagnostic] represents 'good value' to society."[90] Likewise, in 2014, Cohen et. al. and Towse et al. found a

[87] Engstrom et al., *supra* note 49, at S-3.

[88] Cohen & Felix, *supra* note 55; Cohen et al., *supra* note 35; Meckley et al., *supra* note 27; Towse et al., *supra* note 30.

[89] Cohen et al., *supra* note 35.

[90] Cohen & Felix, *supra* note 55, at 386.

dearth of evidence concerning the comparative clinical effectiveness of CDx-drug combinations.[91]

Nevertheless, the CDx's from the case studies demonstrate that the greatest clinical utility evidence base is typically found for CDx's that were co-developed rather than developed post-approval.[92] Because the FDA doesn't actually assess a CDx's clinical utility (the FDA only assesses analytical and clinical validity),[93] the fact that co-developed CDx's have a better clinical utility evidence base is not due to the fact that they are FDA regulated and commercially marketed.[94] In fact, seven of the eight post-approval CDx's in the Cohen, 2014 study, for example, were indeed FDA approved and sold as commercial CDx's.[95]

Co-developed CDx's are supported by greater evidence of clinical utility because they are a core component of their companion drugs' clinical trials. For *drugs* to be FDA-approved, clinical utility must be established in Phase III,[96] and when a CDx is co-developed with its companion drug, the CDx-drug pair are tested together in Phase III.[97] Therefore, co-developed CDx tests generate evidence of their clinical utility automatically from their use in clinical trials (that is, the clinical utility of the CDx is self-evident when it is used to select the patients in the study and the drug is proven effective in those patients).[98]

Since post-approval CDx's stand alone in their development, they do not partake in the clinical trial process that drugs do. So demonstrating clinical utility for a post-approval test requires generating evidence distinct from the drug itself. The case studies illustrate that randomized control trials are the best route to demonstrate clinical utility for the sake of obtaining payer reimbursement.[99] Diagnostic companies are often not in in the financial position to be able to accommodate these studies,[100] which would explain why the evidence base of post-approval tests is weak. But when a diagnostic developer collaborates with a drug company, the drug company will typically sponsor the costs of the clinical trials,

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[91] *Id.*; Towse et al., *supra* note 30, at 169 (finding only four studies in the CEA registry that included a CDx in analyzing the cost-effectiveness of the corresponding drug).

[92] Cohen & Felix, *supra* note 55, at 171; Cohen et al., *supra* note 35, at 380; Towse et al., *supra* note 30, at 297-99.

[93] Sarata & Johnson, *supra* note 75.

[94] Meckley & Neumann, *supra* note 27, at 96.

[95] Cohen & Felix, *supra* note 55, at 167.

[96] McCormack et al., *supra* note 32, at 1396.

[97] *Id.*

[98] Meckley & Neumann, *supra* note 27, at 94.

[99] *Id.* at 97.

[100] Towse et al., *supra* note 30; Davis et al., *supra* note 33.

since the clinical utility of the test might be necessary for the drug to obtain approval and achieve its full value.[101] Therefore, co-development in effect subsidizes the costs of generating clinical utility evidence of a CDx for a diagnostic developer, and enhances the value of the clinical trial process.

Ultimately, the impact of a stronger clinical utility evidence base on the payers and medical providers opens the door for greater market access to CDx's. Case studies that examine payer reimbursement practices, and that survey payers to ascertain the influence of different kinds of evidence on reimbursement decisions, find that evidence of clinical utility and cost-effectiveness are the top priorities in deciding whether to reimburse a CDx.[102]

The lack of evidence on clinical utility would understandably make payers insecure and hesitant to immediately cover CDx's. This is supported by the survey data from payers across multiple studies which has found that a large majority question the clinical utility of CDx tests, often viewing the conclusiveness of test evidence to be inadequate. [103] Reimbursement, while variable, is generally limited and slow, with payers sometimes refusing to reimburse diagnostics that the FDA explicitly requires.[104] Even for co-developed CDx's that include better evidence of clinical utility, however, the variability in payer response suggests that methods for incorporating this evidence into economic evaluations are inconsistent. Consequently, critics have called for health technology assessment agencies and payers to implement more explicit decision criteria, guidelines, and policies over the economic evaluation of CDx's.[105] Despite the overwhelming consensus that the

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[101] Blair et al., *supra* note 23, at 258–59; Meckley & Neumann, *supra* note 27, at 97.

[102] Meckley & Neumann, *supra* note 27, at 91-92 (conducting six case studies of CDx tests and examining the practices of five different payers and finding the strength of the evidence of the test to be the strongest predictor of reimbursement); Cohen et al., *supra* note 35, at 383 (surveying payers and finding that among the 12 that responded, clinical utility was unanimously ranked as the most strongly considered criteria in making coverage decisions).

[103] For example, the commercial payer Aetna does not cover *CYP2C9* testing for Warfarin, citing the lack of clinical and cost-effectiveness evidence in their "Policy on Pharmacogenomic Testing" as a reason for not covering the test, while the payer Cigna does. Meckley & Neumann, *supra* note 27, at 94. *See also* Cohen & Felix, *supra* note 55, at 169 (surveying payers and finding that among the eleven that responded, the largest majority questioned the clinical utility of the CDx tests in the study over any other criteria); Faulkner et al., *supra* note 42, at 1164-66 (noting skepticism of the efficacy of CDx's to predict responses to therapy and uncertainty of the necessity of a CDx slows reimbursement).

[104] *E.g.*, Cohen et al., *supra* note 35, at 382-84 (finding that three out of the twelve payers who completed the survey do not provide reimbursement for the *KRAS* CDx explicitly required by the FDA for use with the colon cancer drug cetuximab).

[105] Faulkner et al., *supra* note 42.

evidence base establishing linkage between diagnostic testing and positive health outcomes must be strengthened,[106] it is clear that pursuing co-development will lead to better evidence of clinical utility and payer reimbursement, thereby increasing patient and provider access to CDx's.

2. Co-Development Uses Resources More Efficiently

CDx-drug co-development provides significant opportunity to use the resources of both companies more effectively by reducing the development costs of the CDx and corresponding drug, and increasing the likelihood of therapeutic success and improved cost-effectiveness.[107] Co-development allows both companies to streamline their research[108]: as the pharmaceutical company narrows in on the selection of a lead compound, and the diagnostic company narrows in on corresponding biomarkers, each side will learn from each other's research developments.[109] Both will then make better-informed decisions that they would not have otherwise made in isolation. The compound and diagnostic method ultimately selected will jointly run through Phase III (and potentially earlier phases as well),[110] increasing the chances that the drug will have a significant enough benefit in the clinical trial population to be approved, and generating evidence of clinical utility for the diagnostic developer. This illustrates the "regulatory efficiency" of tying the drug and CDx together at the outset.[111] If the CDx and drug both pass FDA approval, patients for whom the drug is effective will have received a cure they might not have were it not for the presence of the CDx, and at a faster speed, with a faster turnaround of payer coverage.[112]

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[106] *E.g.* Meckley & Neumann, *supra* note 27 (arguing that evidence on the impact of CDx testing on actual patient outcomes is lacking).

[107] *E.g.* Cohen & Felix, *supra* note 55, at 171; Luo et al., *supra* note 29, at 2. The FDA's 2014 guidance document regarding CDx's also recommends that the CDx be co-developed especially where it is essential for the safe and effective use of the product. U.S. Food and Drug Administration, *In Vitro Companion Diagnostic Devices*: *Guidance for Industry and Food and Drug Administration Staff*, http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM262327.pdf (Aug. 6, 2014).

[108] Leamon & Sherman, *supra* note 20.

[109] *Id.*

[110] *See* Cohen et al., *supra* note 35, at 379 (claiming that a CDx intended to inform uses of a drug in development should be studied in parallel in Phases I or II).

[111] Dorothea K. Thompson, *From Research to Clinical Application: Challenges in Regulating Companion Biomarker Tests for "Personalized" Drugs*, 1 J. PHARMACEUTICAL ANALYTICS & INSIGHTS 1 (2016).

[112] This embodies the example of the Cobas 4800 Mutation CDx, used with the drug Zelboraf, discussed in Part I.

Comparatively, post-approval CDx's can inform patients that a drug they might have been prescribed will be ineffective, cause adverse side effects, or should be taken at a different dose. Co-developed CDx's do the same for their corresponding drug, in addition to helping ensure that the most effective drugs for certain populations that would not necessarily have ever made it to market, do. Further, as more drugs are co-developed with a CDx, the number of drugs in need of a post-approval CDx only goes down. Therefore, co-developed CDx's ultimately capture more value than post-approval ones, and are the key to driving personalized medicine forward.

C. A Misalignment of Stakeholder Incentives Impedes Necessary CDx Co-Development

Despite the economic benefits of co-development just described, the number of post-approval CDx's is larger than the number of co-developed CDx's.[113] Ultimately, this reflects a lack of willingness on the part of drug and diagnostic companies to collaborate. This Part presents the obstacles and deterrents of co-development for each stakeholder, which reveals how their underlying incentives are misaligned.[114] It argues that based on the empirical evidence from the case studies, the drug companies have a greater incentive to engage in CDx co-development, while diagnostic companies have a greater incentive to focus on post-approval CDx's, primarily LDT-CDx copies of co-developed CDx's already on the market.

1. Disparate Business Models Hinder Co-Development

A popular assertion in the pharmacologic and biotech business literature is that economic collaboration between drug and diagnostic developers is undermined by their different business models.[115] As noted above, each stakeholder employs

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[113] Joshua Cohen, *Overcoming Regulatory and Economic Challenges Facing Pharmacogenomics*, 29 NEW BIOTECHNOLOGY 751-56 (2012); Drucker & Krapfenbauer, *supra* note 10; Thompson, *supra* note 111.

[114] That the incentives of drug companies and diagnostic companies are misaligned when it comes to CDx development is a frequently-held position in the pharmacologic and biotech business literature. *See generally* Thompson, *supra* note 111.

[115] This difference in business models has led many authors in the pharmacologic and biotech business literature to claim that the incentives of the stakeholders in the CDx industry are misaligned. *See e.g.*, Agarwal et al., *supra* note 17; Davis et al., *supra* note 33; Sairamesh & Rossbach, *supra* note 4, at 2-4; Faulkner et al., *supra* note 42, at 1163-67. Scientific factors can and do still slow co-development as well, mostly in situations where the drug's mechanism of action is poorly understood. Leamon & Sherman, *supra* note 20. However, that does not change the fact that economic growth still lags behind the science.

completely different technology in its development platforms, produces a different class of products, and has different development timelines, costs, rates of return, customers, and regulations.[116] Few have endeavored to empirically test how these differences in drug and diagnostic business models impact their collaboration, but at least two studies shed light on the question.[117]

Luo et al. selected nine successful CDx-drug pairs, and quantitatively assessed the impact of factors pertinent to drug and diagnostic companies that influence their calculus in deciding whether to collaborate.[118] The priority factors selected for drug companies were drug prices, drug efficacy, patient responses, and patient subpopulation; CDx price and CDx sensitivity were the priority factors selected for the diagnostics.[119] The study found no significant relationship between the economic factors for the two industries.[120] For example, the CDx price did not significantly correlate with any of the factors that impact drug development; high-risk, high-benefit drugs that are priced high to reflect their greater development costs may only require cheap and simple CDx's to accurately stratify the patient population. And moderate-risk or low-risk drugs might require CDx's that are more complex and expensive to develop to accurately segment the patient population. These findings thus support the view that the disparate business models of the CDx and pharmaceutical industries are a legitimate obstacle to CDx-drug co-development.[121]

2. For Drug Companies, Co-Development Is Economically Preferable Over Post-Approval CDx Development

Despite the potential ability of CDx co-development to reduce development costs for drug companies discussed in Part II.B, research has suggested that CDx's may sometimes do little to improve drug development productivity and might actually increase overall costs.[122] Some of these scenarios are now considered.

As a general matter, additional complexities associated with running clinical trials with a CDx include "recruiting special patients at additional sites, executing

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[116] Peter Collins, *Personalized Medicine: From Biomarkers to Companion Diagnostics*, GEN: GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (March 27, 2013), http://www.genengnews.com/gen-articles/personalized-medicine-from-biomarkers-to-companion-diagnostics/4820/.

[117] *See* Luo et al., *supra* note 29. The second case study was completed at MIT by Trusheim et al., *supra* note 31, and is discussed *infra* Part II.C.1.

[118] Luo et al., *supra* note 29.

[119] *Id.* at 3.

[120] *Id.* at 6.

[121] *See supra* note 109 and accompanying text.

[122] Davis et al., *supra* note 33.

the clinical protocols, demonstrating effects in biomarker-negative patients, and analyzing biomarker data."[123] These can reduce the savings associated with smaller clinical trials.[124] There is also the risk that a suitable CDx will not be adequately developed.[125] If so, the associated costs will not be offset by any savings in clinical trials. Similarly, if a CDx is used in clinical trials but the drug still fails to be approved, the CDx will not have conferred a benefit to the drug company. It is also possible that a drug will be co-developed with a CDx in its early phases, but that later trials reveal that the drug performs well enough in the broader population to obtain FDA approval without the CDx.[126] The CDx, then, will have been unnecessary to achieve FDA approval, and the development costs of the CDx will not be offset. This is what happened with the drug ponatinib,[127] though it is not a common occurrence given the reduced odds of a drug being effective enough in the broader patient population. Nevertheless, these factors conceivably influence a drug company's calculus in deciding whether to collaborate with a diagnostic company for CDx co-development.

The economic risks associated with co-development for a drug company pale in comparison with the risks of the development of post-approval CDx's. In co-development, the risks previously described are offset by the potential gains achieved by obtaining FDA approval for a drug for segments of the patient population, when the drug would be incapable of obtaining FDA approval for the broader population.[128] But novel post-approval CDx's are developed by diagnostic companies for drugs that have *already* obtained FDA approval.[129] What a new post-approval CDx ultimately accomplishes, then, is the stratification of the patient population that reveals those who are *not* ideal responders, patients that would have been prescribed the drug prior to the arrival of the post-approval CDx. This

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[123] Trusheim, *supra* note 71; *see also* Trusheim et al., *supra* note 31, at 827 (explaining that the need to screen more patients with a CDx increases the complexity of clinical trials and may lengthen the duration of the study).

[124] Trusheim, *supra* note 71.

[125] Trusheim et al., *supra* note 31, at 827.

[126] Heather Thompson, *Companion Diagnostics from a Business Perspective*, MDDI: MED. DEVICE & DIAGNOSTIC INDUSTRY (MARCH 8, 2013), http://www.mddionline.com/article/companion-diagnostics-business-perspective.

[127] *See id.* Phase I results of the ponatinib trial suggested the drug may be more effective in patients with a particular mutation. Phase II showed better results in the subpopulation with the mutation, but on the whole, stratifying would not be required for the clinical trial results to meet the primary end point for all patients. The FDA submission for pre-market approval of the CDx was therefore withdrawn by the drug company. *Id.*

[128] Thompson, *supra* note 126.

[129] *See supra* Part II.A.2.

undeniably benefits the public. For the drug company, however, the post-approval CDx in effect divides the treatable population into smaller segments, reducing the drug's sales and the market share of the relevant patient population.[130] Economic theory would predict that the drug company would increase its price in response, to make up for this decrease in revenues, and that payers would correspondingly pay the higher price, reflecting the greater drug's greater efficacy with the CDx and the resulting savings from fewer patients taking the drug.

This does not appear to occur in practice, however. A study from the Massachusetts Institute of Technology that quantitatively analyzed economic value to drug and diagnostic companies in case studies of co-developed and post-approval CDx's illustrates the point.[131] In 2006, the drug panitumumab was FDA approved with a co-developed CDx for patients with metastatic colorectal cancer and *EGFR* overexpression (the biomarker measured by the CDx).[132] A year later, an additional CDx developed by an independent diagnostic company, showed that the drug was actually ineffective in a subset of this *EGFR* over-expressing subpopulation, and thus the patient population to which the drug could subsequently be marketed decreased.[133] Reimbursement levels did *not* rise to reflect the higher efficacy in the smaller selected subpopulation, causing the drug developer to suffer a loss in revenues[134] – perhaps a disappointing outcome to those who despise market inefficiencies, and a pleasing outcome for those hostile towards corporate America. Either way, this pricing inflexibility on the part of payers might reflect the externality of renegotiating drug prices, or might also reflect payer skepticism regarding the cost savings attributable to CDx's, as discussed in Part II.[135]

The increased risk in revenue reduction attributable to the development of post-approval CDx's by third parties would seem to provide an incentive for drug companies to engage in CDx co-development. By doing so, they increase the accuracy of their business projections, and increase the likelihood of capturing potential losses in revenues from CDx stratification in the drug price, by negotiating *ex ante* with payers as opposed to *ex post*.[136]

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[130] *See supra* note 70 and accompanying text.

[131] Trusheim et al., *supra* note 31.

[132] *Id.* at 822.

[133] *Id.*

[134] *Id.* at 823.

[135] *See supra* Part II.A.1.

[136] The quantitative study by Trusheim suggested that price negotiations with drug companies prior to when a drug is FDA-approved have greater flexibility for the drug company. *See* Trusheim et al., *supra* note 31.

3. For Diagnostic Developers, Post-Approval CDx Development Is Economically Preferable to Co-Development

Diagnostic developers face many disincentives in collaborating with drug companies for CDx-drug co-development. Despite CDx companies conducting business on vastly smaller scales than drug companies, CDx deals are still very capital-intensive for the diagnostic partner.[137] The co-development process will require the diagnostic developer to submit a pre-market approval application to the FDA, increasing upfront costs dramatically, and adding risk associated with obtaining approval. While the diagnostic partner always has to account for the risk associated with being unable to develop a suitable CDx,[138] in the co-development world it must also account for the risk associated with the *drug* not being approved. The latter risk is magnitudes greater than the former.[139] For instance, Trusheim's statistical model found that delaying a drug launch by one year, for the purposes of developing a CDx, nearly doubles the diagnostic eNPV due to the decreased risk of cancellation of the drug development program.[140]

The diagnostic companies also face limited ability to gain a return on the more expensive R&D spent in co-development.[141] They often desire royalties from the pharmaceutical company on the sales of the drug or sales-based milestones to compensate for the risk that the drug won't be approved or will have lackluster sales.[142] But generally drug development partners have structured payments to test developers as a "fee for service."[143] This typically doesn't cover the full investment cost of the diagnostic developer,[144] so some degree of payer reimbursement to the diagnostic developer is necessary for them to recoup their full investment.[145]

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[137] Agarwal et al., *supra* note 17; Towse et al., *supra* note 30; Blair et al., *supra* note 23, at 259-60.

[138] Trusheim et al., *supra* note 31, at 827.

[139] Nicholas A. Meadows et al., *An Evaluation of Regulatory and Commercial Barriers to Stratified Medicine Development and Adoption*, 15 PHARMACOGENOMICS J. 6, 10 (2015).

[140] Trusheim et al., *supra* note 31, at 829.

[141] McCormack et al., *supra* note 32.

[142] Agarwal et al., *supra* note 17, at 105.

[143] *Id.*

[144] McCormack et al., *supra* note 32 (noting that some diagnostic companies sell tests at costs that reflect running the test and not overall investment of co-development or value CDx delivers to patient).

[145] Payer reimbursement for diagnostics has its own complications, however. Up until 2013, all payers billed *in-vtiro* diagnostic devices using the method of "non-specific coding/code stacking". Meckley & Neumann, *supra* note 27, at 97. This method describes the process associated with testing and therefore reimburses the cost of carrying out the individual

The costlier and higher-risk nature of co-development for a diagnostic company incentivizes those companies to gravitate towards CDx development for drugs already on the market.[146] These post-approval CDx's can be novel and commercial, like their co-developed counterparts. More often, however, they are LDT-CDx copies of previously co-developed commercial CDx's. This is largely achievable because of the weak intellectual property protection afforded to CDx test methods.[147] By generating LDT-CDx's, a diagnostic firm avoids the increased costs of applying for FDA pre-market approval. It can then amass more revenue in the short term to satisfy the investment community, at the expense of encouraging collaboration with drug companies, which only *might* lead to returns in the future for the diagnostic company. The large upfront investment and decreased certainty involved in developing a novel CDx through co-development consequently discourages competition between CDx developers until the first CDx reaches the market. The result is a dominance of late-stage over early-stage competition, facilitated by free-riding on first movers.[148] For example, after the FDA approved Roche's CDx, "Cobas 4800 BRAF Mutation Test" for the drug vemurafenib, at least nine laboratories began to offer their own LDT version of the test.[149] It has been estimated that as of 2013, at least 45% of BRAF testing is performed via LDT-CDx's.[150]

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components of a CDx test, *not* the value provided by the CDx. *Id*. Fortunately, some payers such as Medicare payers, have begun to move towards "value-based pricing" for diagnostics (the method always applied for drugs), which should help diagnostic companies to capture more value from their CDx's. *See* Meadows et al., *supra* note 139, at 9. But many authors still emphasize that there remains a lack of uniform standards for applying criteria across payers that makes coverage decisions unpredictable, and continues to make it difficult for diagnostic developers to obtain full reimbursement. *E.g.*, Real World Health Care, *Personalized Medicine & Companion Diagnostics: What You Need to Know*, HEALTH WELL FOUND. (Oct. 28, 2015), http://healthwellfoundation.org/news/2015/10/28/personalized-medicine-companion-diagnostics-speaking-with-dr-joshua-cohen-tufts-cent; Faulkner et al., *supra* note 42, at 1169.

[146] Luo et al., *supra* note 29, at 9; Agarwal et al., *supra* note 17, at 106-08.

[147] McCormack et al., *supra* note 32; Leeland Ekstrom et al., *Capturing Value for Dx in Personalized Medicines—Is There a Path?*, in Personalized Medicine, The Path Forward, 28 (McKinsey & Company, eds. 2013) (noting that lab services companies can provide substitutes for commercial CDx's without fear of patent challenges).

[148] *See infra* Part II.A.2.

[149] U.S. Food and Drug Administration, *The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies*, 29-30 (2015), http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM472777pdf.

[150] Ekstrom et al., *supra* note 147, at 36 (stressing that first mover advantage is limited because of significant competition from LDTs).

The success of other diagnostic developers in developing LDT-CDx's is attributable to the fact that many payer billing practices still don't allow the payer to discriminate between a commercial CDx and an LDT-CDx.[151] This allows labs who have spent less money on creating an LDT-CDx to be reimbursed the same amount as the more costly commercial, co-developed CDx. Fortunately, in November of last year, Medicare and Medicaid payers adopted a new reimbursement program known as "MolDx," which requires labs to use separate codes for commercial CDx's and LDT-CDx's.[152] The program will need to gain more momentum against payers before this issue is resolved.[153]

In theory, one might suspect that diagnostic companies are still better off pursuing co-development because co-development will lead to better evidence of clinical utility and a faster rate of payer reimbursement. But the reality is that the disparity in regulatory oversight between LDT-CDx's and commercial CDx's, coupled with remarkably weak IP protection for CDx biomarkers and methods, pulls diagnostic developers away from the world of co-development and pushes them towards late-stage, post-approval competition. [154] This is illustrated in the disparity in the number of co-developed versus post-approval CDx's, and the greater value of LDT-CDx's versus commercial CDx's in the market.[155]

Despite the misaligned incentives to engage in co-development detailed in this section, the number of deals between pharma and diagnostic companies has increased over recent years.[156] The deals are typically concentrated in a small number of companies with the appropriate financial stability, regulatory knowledge, technical expertise, and global reach for commercialization.[157] Deals are structured in four ways. The drug developer will develop companion diagnostics internally ("in house"), partner with a diagnostic company to develop the test, acquire the diagnostic company, or engage in a hybrid of those three

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[151] McCormack et al., *supra* note 32, at 1396.

[152] MOLDX, CLINICAL TEST EVALUATION PROCESS (CTEP) M00096, VERSION 5.0 (2015), http://www.palmettogba.com/Palmetto/Moldx.Nsf/files/MolDX_Clinical_Test_Evaluation_Process_(CTEP)_M00096.pdf/$File/MolDX_Clinical_Test_Evaluation_Process_(CTEP)_M00096.pdf.

[153] MolDx also adopts a set of standards and best practices for assessing clinical utility and cost-effectiveness but many have disavowed the clinical utility assessment criteria. Cohen & Felix, *supra* note 55, at 172.

[154] McCormack et al., *supra* note 32; Faulkner et al., *supra* note 42, at 1169.

[155] *See* Frost & Sullivan, *supra* note 61; *see also supra* note 113 and accompanying text.

[156] Agarwal et al., *supra* note 17, at 104-05.

[157] *Id.*

methods.[158] What these deals ultimately reflect are examples of successful risk-sharing between drug and diagnostic companies, underscoring the need for innovative risk-sharing models between the two types of companies, to drive co-development.[159]

Expediting CDx growth by incentivizing diagnostic companies to engage in co-development requires far more than innovative risk-sharing models, however. Before addressing the unique capabilities of stronger patent protection to solve many of the problems in this field, this part considers the possible ramifications of the FDA's recently proposed guidelines for increased regulatory oversight over all LDT-CDx's.

D. The FDA's Proposed Guidelines For Diagnostic Tests Could Exacerbate The Economic Challenges

In October 2014, the FDA formally issued draft guidance in the Federal Register to start regulating *all* LDTs in the future under a risk-based approach, rather than continuing to exercise its enforcement discretion.[160] The comment period ended in February of last year, but a final guidance document has yet to issue.[161] The guidelines describe the FDA's plan to take a "risk based approach" to oversight, by dividing all LDTs into three risk categories and subjecting each to different levels of increased regulation.[162] The FDA has made clear that CDx's will fall into the highest risk category and must therefore meet new registration, listing, adverse event reporting, and pre-market review requirements.[163]

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[158] *Id. See also* Leamon & Sherman, *supra* note 20 (illustrating the four deal types in a table and providing examples of companies that engage in each of the deal methods).

[159] Cohen et al., *supra* note 35, at 387 (noting a specific example of successful risk-sharing, the agreement between United Healthcare and Genomic Health for the Oncotype Dx test used in breast cancer treatment).

[160] *See* FDA Guidance for LDTs, *supra* note 59; Kenneth D. Levy et al., *FDA's Draft Guidance on Laboratory-Developed Tests Increases Clinical and Economic Risk of Adoption of Pharmacogenetic Testing*, 55 J. CLINICAL PHARMACOLOGY 725, 725–26 (2015).

[161] *See* Levy et al., *supra* note 160, at 726.

[162] FDA Guidance for LDTs, *supra* note 59, at 8, 11-15.

[163] The FDA will focus its enforcement efforts on the highest risk category, giving diagnostic labs twelve months from the date of final issuance to comply with the new regulations. *Id*. at 13–14. Pre-market review can be accomplished in one of two ways. The first route is for the diagnostic developer to conduct clinical studies and subsequently submit a pre-market approval application. If there is evidence providing a reasonable assurance that the test is safe and effective, the FDA will grant pre-market approval. The second and less expensive route is for the diagnostic developer to submit a 510(k) application proving that the test is substantially

From a public health and safety perspective, the proposal appears to be beneficial. A study conducted by the FDA of 20 LDTs, which included two LDT-CDx's, found that often manufacturer claims were unsupported, as evidenced by an overly large number of false positive and false negative results for some tests, risking harm to patients. This was attributed to the fact that LDTs are not subject to adverse event reporting, and that their safety and efficacy is undermined by a lack of agency review of performance data. LDT performance data is "informally" reviewed via the peer-review publication process, but the FDA maintains that this is insufficient to protect against patients and healthcare providers being misled.[164]

The chief concern for diagnostic developers is the prospect of bearing the burden of the costs of obtaining approval or clearance. The burden will fall most heavily on more modest diagnostic developers: academic research centers, labs based in hospitals, and other CLIA-certified labs that are typically not accustomed to complying with the regulatory requirements associated with conducting clinical studies, and that lack the expertise to do so.[165] In light of these increased hurdles, it is reasonable to suspect that these smaller diagnostic developers will be unable to continue to provide LDTs in general, absent federal funding agencies relieving this financial burden.[166]

But perhaps that would be a good thing. Consistent regulatory requirements across LDT-CDx's and commercial CDx's would level the playing field between commercial kit manufacturers and laboratories.[167] This could potentially mitigate the issue of LDT-CDx's proliferating after a commercial co-developed one reaches the market; the costs of obtaining FDA approval for LDT-CDx's would reduce the benefit associated with free-riding.[168] This could incentivize diagnostic companies to engage in earlier CDx co-development instead. Diagnostic developers with the resources to handle an additional pre-market approval, however, might still

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equivalent to one already FDA approved and on the market. If so the FDA will "clear" the test. *Id.* at 20, 23-24.

[164] *See* U.S. Food & Drug Administration, *supra* note 149, at 2, 4, 27.

[165] *Laboratory Developed Tests*, AM. CLINICAL LABORATORY ASS'N, http://www.acla.com/issues/laboratory-developed-tests/ (last visited Feb. 28, 2016).

[166] *Id.*

[167] The FDA has emphasized leveling this "uneven playing field" in supporting its recommendation. *See e.g.*, FDA, *supra* note 82, at 4.

[168] FDA pre-market approval for a commercial CDx can cost up to $75 million more to develop than a corresponding LDT-CDx. Doug Dolginow et al., *Mystery Solved! What is the Cost to Develop and Launch a Diagnostic?*, DIACEUTICS, INC., http://www.diaceutics.com/wp-content/uploads/2016/03/mystery-solved-what-is-the-cost-to-develop-and-launch-a-diagnostic.pdf (last visited Mar. 3, 2016).

develop LDT-CDx versions of co-developed CDx's because they would still save on the upfront R&D expenses. The potential impact of the regulations is therefore questionable.

III
RE-INVIGORATING PATENT PROTECTION FOR COMPANION DIAGNOSTICS IS THE MOST EFFICIENT WAY TO STIMULATE COMPANION DIAGNOSTIC MICROECONOMIC GROWTH

This Part addresses how patent protection for CDx tests can help resolve the misaligned incentive structure amongst the key stakeholders that continues to hamper CDx microeconomic growth.

A. Strengthening a Weak Business Case

Part II explained the difficulties diagnostic companies face in securing solid returns on R&D investment (what some have called the "weak business case" supporting CDx development).[169] On the one hand, partnering with drug companies helps diagnostic developers establish better evidence of clinical utility which can increase rates of payer reimbursement. On the other hand, however, the diagnostic company is burdened by the heightened risk associated with approval of the drug, and can spend less on upfront R&D expenses by developing an LDT-CDx version of a co-developed CDx already on the market. So even though avoiding the co-development process in favor of developing post-approval CDx's can increase the time it takes for payers to approve the test, the market is clear that diagnostic companies still prefer to develop LDT-CDx's. Stronger patent protection for CDx's can transform this "weak business case" supporting CDx development into a stronger one.

The function of patents as "signals" to investors that an invention possesses commercial potential is well-documented by scholars.[170] Particularly in the life sciences, patents increase prospects of obtaining earlier venture capital funding

[169] McCormack et al., *supra* note 32, at 1395-96.

[170] *See, e.g.*, Robert P. Merges, *A Transactional View of Property Rights*, 20 BERKELEY TECH. L.J. 1477, 1489–90 (2005); Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 653 (2002) (arguing that patents can be used to signal the quality of a startup to investors); Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1280–83 (2009); Ted Sichelman & Stuart J.H. Graham, *Patenting by Entrepreneurs: An Empirical Study*, 17 MICH. TELECOMM. & TECH. L. REV. 111, 159 (2010).

which facilitates commercialization.[171] This financial boost goes far for CDx developers. It can allow for greater expenditures on demonstrating clinical utility, thereby increasing rates of payer adoption and promoting greater patient access. It can help cover the cost of obtaining FDA approval. If the FDA's guidance becomes final, this will be particularly beneficial to smaller companies and research labs at universities and hospitals. These latter actors may not normally be as incentivized by the prospect of a patent as larger commercial ventures, but faced with the costs associated with obtaining FDA approval, the necessity of a patent is more compelling. Further, an increase in funding attracted by the patent can help in educating medical providers about the availability of the tests to encourage their adoption.

Then comes the most fundamental benefit of a patent: the right to exclude free-riders, or for our purposes, diagnostic developers who wait to develop LDT-CDx copies of commercial CDx's on the market, reducing the ability of the innovative CDx developers to recoup their investment.[172] Patents can therefore shift the abundance of late-stage competition between CDx developers into earlier-stage competition since the threat of liability for infringement will deter CDx developers from competing in LDT-CDx's that mimic the earlier, commercial one. This will force CDx developers to focus on the creation of *novel* CDx's. The FDA's proposed guidance might help to shift competition towards co-development, by increasing the costs of copying a commercial CDx with an LDT-CDx. But without the patent to attract investment upfront, and to spur collaboration with drug companies, as the next section argues, the costs to develop innovative, commercial CDx's will be prohibitive for all but the best-funded developers.

B. Patents Can Facilitate Co-Development

Greater patent protection eliminates many of the obstacles that stand in the way of CDx-drug development, and adds to the already existing benefits of co-development for diagnostic companies. For diagnostic companies, it reduces the risk that the increased costs associated with co-development will cause them to see a loss by increasing the diagnostic company's bargaining power against the drug company; the patent puts the diagnostic company on a less uneven playing field.[173] With patents in hand, diagnostic companies are in a stronger position to negotiate more favorable risk-sharing agreements: no longer can drug companies argue that

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[171] DAN L. BURK & MARK LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 4 (2009).

[172] *See infra* Part II.C.3.

[173] *See supra* note 166 and accompanying text.

the lack of IP protection on the CDx reduces its value such that royalty payments on sales of the drug are not feasible. And if the drug company doesn't budge, the diagnostic developer is now in a position to shop around for better co-development deals, without concern over potential appropriation of its data. This illustrates how when two parties bargaining at arm's length *each* have patents, Arrow's paradox disappears[174] – the security of the patent enables a sharing of information that might not otherwise occur when one party is concerned about keeping its proprietary information secret. Greater CDx patent protection for the diagnostic company would also provide a stronger incentive for drug companies to engage in CDx co-development: the exclusivity of a commercial CDx would reduce the amount pharmaceutical companies have to pay diagnostic developers to cover the costs associated with the reduction in the value of the CDx due to LDT-CDx competition.

Both drug and diagnostic companies could also stand to gain from considering joint or integrated patent strategies throughout the co-development process.[175] Coordinating patent filings and tailoring them to the specific CDx-drug pair could increase the commercial value of both products, and provide greater security of patent validity.[176] Patenting combinations of methods that apply both the drug and the CDx and vary the subject matter would increase the chances that at least some claims would withstand invalidity attacks.[177] If the relationship between the CDx and drug companies is a partnership, filing patents that overlap both company's products could create control problems. The drug company may want exclusive control so that competitors don't have access to the CDx, while the CDx may want exclusive control so it can do business with other drug companies. On balance, however, it is apparent that more secure patent protection for CDx developers would catalyze collaboration between stakeholders and drive CDx growth forward.

C. The Case Against Patents Does Not Apply To the CDx Niche

This Part briefly addresses some of the common counterarguments to extending patent protection in genetics-related research, and asserts that they don't

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[174] *See, e.g.*, Shyamkrishna Balganesh, *"Hot News": The Enduring Myth of Property in News*, 111 COLUM. L. REV. 419, 433 (2011) (describing "Arrow's information paradox" wherein "[a] potential licensee has no way of evaluating the information/intangible until it is disclosed to him; yet, upon such disclosure he has little reason to want to pay for it").

[175] *See* Ekstrom et al., *supra* note 58, at 22.

[176] Cynthia H. Zhang & Y. Philip Zhang, *Maximizing the Commercial Value of Personalized Therapeutics and Companion Diagnostics*, 31 NATURE BIOTECHNOLOGY 803, 803–04 (2013).

[177] *Id.*

apply in the unique context of the CDx industry. Critics of patent protection in the life sciences frequently point to the 2010 report written by the Secretary of Health and Human Services' Advisory Committee on Genetics, Health, and Society (the "SACGHS report").[178] The report found that patent rights were neither necessary nor sufficient conditions for the development of commercial diagnostic testing kits and LDTs.[179] This was because it determined that private funding was "supplemental to the significant federal government funding in this arena," and that most genetic research is conducted by academic researchers.[180]

These conclusions fail to differentiate between basic genetic research and the research involved in developing a CDx. Genetic research simply refers to the identification of genes associated with different conditions, and the case studies cited in the SACGHS report are circumscribed in this arena.[181] Developing a CDx, however, requires a more complicated understanding of how different variations in given genes correlate with the actions of a given drug.[182] CDx targets extend beyond genes themselves to other proteins, metabolites, and tracers that are all influenced by genetic variation and its downstream molecular processes.[183] Developing this research from scratch requires expensive, large-scale validation and replication studies, and is therefore more often funded by the private sector.[184]

Another concern is that greater patent protection in genetics-related research will interfere with research by academics and impede upstream experimental research.[185] Again, this may well be a valid concern for standard genetic research, but in the context of CDx development, it is not. The CDx industry is made up of many private firms because of the substantial costs associated with development and commercialization.[186] Empirical studies have also found that basic researchers follow a practice of ignoring patent infringement, while patent owners ignore

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[178] SEC'Y'S ADVISORY COMM. ON GENETICS, HEALTH, & SOC'Y, DEP'T OF HEALTH & HUMAN SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS (2010), *available at* http://osp.od.nih.gov/sites/default/files/SACGHS_patents_report_2010.pdf [http://perma.cc/RT2Y-7TYT].

[179] *Id.* at 20-36.

[180] *Id.* at 1, 9.

[181] *Id.*

[182] Drucker & Krapfenbauer, *supra* note 10, at 2-4.

[183] *See supra* note 118 and accompanying text.

[184] Frost & Sullivan, *supra* note 61.

[185] *See, e.g.*, Brief for American Medical Association et al. as Amici Curiae Supporting Petitioners at 13–16, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* 133 S. Ct. 2107 (2013) (No.12-398).

[186] *See* Cohen et al., *supra* note 35, at 387 (providing price ranges for various CDx's).

enforcement against basic researchers so long as no one is engaged in commercial endeavors associated with the patent.[187]

Fear that increased patent protection will promote monopoly pricing over CDx tests is another valid concern, especially where payer reimbursement is not increased to match the savings of the CDx, and costs are shifted onto the consumer. Given that the costs of CDx development pale in comparison to therapeutics, however, the concern is arguably less warranted. And while no one wants to have to pay more for diagnostic testing, the CDx tests, as explained in Part I, can save consumers far greater costs in the long-run by preventing them from using up their insurance policies on treatments that prove to be ineffective.

Of course, it would be myopic to assert that re-invigorating patent rights for CDx's is the *only* way to achieve an increase in CDx growth. There are other policy tools that could also be effective in different ways: non-patent exclusivities, government subsidies, prizes, and tax credits to name a few.[188] Evaluating the comparative merits of those proposals is beyond the scope of this note. But from a broad perspective, it is clear that the unique challenges facing the CDx industry embody all the most fundamental justifications for patent protection: significant upfront R&D expenses; significant risks associated with regulatory hurdles; uncertainty in the ability to recoup investments; cutting-edge, important science and technology; flagrant free-riding; and a need to share proprietary information with parties at arm's length.

D. Patent Law's Subject Matter Eligibility Doctrine Has Undermined the Prospects of Patenting Companion Diagnostic Tests

Patentability of diagnostic methods faced its first attack in the Supreme Court's decision in *Mayo Collaborative v. Prometheus Labs*.[189] There, the Court articulated a new two-part test for assessing the subject matter eligibility of inventions,[190] which was reiterated in the software case *Alice v. CLS Bank*.[191] It is now commonly referred to by the U.S. Patent & Trademark Office and the Federal Circuit as the *Mayo* or *Alice* "two-step."[192] Step one requires a court to determine

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[187] *See* Holman, *supra* note 2, at 305.

[188] *See* Trusheim, *supra* note 71, at 418 (discussing some of these policy proposals).

[189] *Mayo Collaborative Servs. v. Prometheus Labs*, 132 S. Ct. 1289, 1294 (2011).

[190] *Id.* at 1294, 1302.

[191] *Alice Corp. Pty. Ltd. v. CLS Bank Int'l et al.*, 134 S. Ct. 2347, 2355 (2014).

[192] *See, e.g.*, 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74618, 74619, 74622 (Dec. 16, 2014) (to be codified at 37 C.F.R. pt. 1); *Content Extraction & Transmission LLC v. Wells Fargo Bank, N.A.*, 776 F.3d 1343, 1346 (Fed. Cir. 2014) (noting that

whether the claims at issue are directed to a patent-ineligible concept (*i.e.*, an abstract idea, natural phenomenon or product of nature).[193] Step two asks the court to consider the elements of each claim individually, and as an ordered combination, to determine whether any additional elements transform the nature of the claim into a patent-eligible application (also known as the search for the "inventive concept").[194]

On its face, *Mayo* appears to be a flexible test: individual elements of all claims can be routine, conventional, and ordinary, but so long as the claims when considered *as an ordered combination* "transform" the naturally occurring phenomenon into a patent-eligible application, they are patent-eligible.[195] One might suspect that the debatable meaning of "as an ordered combination" and "patent-eligible application" would leave good room to distinguish the most innovative and meritorious applications of diagnostic methods from those that contain little more than the underlying unpatentable principles on which they rely. In practice, however, the Federal Circuit seems to have applied *Mayo* as a rule that diagnostic method patents are categorically unpatentable.[196] Only three cases involving diagnostic method claims have been decided since *Alice* so the sample size to evaluate how *Mayo* has affected the patentability of diagnostic methods is admittedly small.[197] But the fact that several diagnostic method claims have been invalidated across these cases, especially those in *Ariosa*[198] – included diagnostic method claims arising out of what scientists have lauded as one of the most remarkable discoveries of the century – suggests a bleak future for their survival.

Consequently, practitioners are undoubtedly reconsidering how to write diagnostic method claims to survive under the recent doctrine.[199] But while the patentability of diagnostic methods as a general matter has become dubious, the patentability of co-developed CDx's could be more promising if strategically

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"the two-step framework described in Mayo and Alice guides [the subject matter eligibility] analysis").

[193] *Alice*, 134 S. Ct. at 2355.

[194] *Id.*

[195] *Mayo*, 132 S. Ct. at 1298.

[196] Eisenberg, *supra* note 2, at 257.

[197] *See Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015) (reh'g *en banc* denied); *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 999 F.Supp. 2d 1377 (J.P.M.L. 2014); *Genetic Techs. Ltd. v. Lab. Corp. of Am. Holdings*, No. CV 12-1736-LPS-CJB, 2014 WL 4379587, at *13-14 (D. Del. Sept. 3, 2014).

[198] *Ariosa Diagnostics*, 778 F.3d at 1373 (laying out the key patent claims at issue).

[199] Rachel E. Sachs, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, 49 U.C. DAVIS L. REV. 1881, 1912 (2016).

tailored to the companion drug as well.[200] Even so, the heightened difficulties in obtaining patent protection for CDx's as a result of the doctrinal developments in subject-matter eligibility suggests that legislative or regulatory changes are necessary to enable economic growth in CDx development to catch up with its scientific growth – two unpredictable alternatives to a centuries-old system that was built to solve the very problems that plague this industry.

CONCLUSION

Furthering innovation in the development of all kinds of diagnostic tests is important to modern healthcare. But not all diagnostic tests should be viewed in the same light when debating innovation policy. As this note has illustrated, companion diagnostic tests possess unique economic challenges that stem from a complicated and misaligned incentive structure amongst the key industry stakeholders. Accordingly, CDx tests deserve their own innovation policy debate. Yet while literature in economics and pharmacology has addressed the unique circumstances surrounding the CDx industry and conducted insightful case studies, legal scholarship addressing innovation policy has yet to engage with these critical diagnostic tests as vigorously. In an effort to begin doing so, this note has imported many valuable insights from empirical case studies in other fields to argue that co-developing CDx tests with their companion drugs is the optimal pursuit for furthering economic growth in the CDx industry. It has further argued that increased patent protection in the narrow niche of CDx tests is the optimal policy choice for catalyzing the economic growth of CDx tests to enable them to one day match their rate of scientific growth. Unfortunately, strengthening patent protection in this niche seems a doubtful possibility in practice in light of the constraints that current subject-matter eligibility doctrine has created. Coupled with the potential for increased FDA regulation of companion diagnostic tests, the incentives to innovate in the CDx sector might become further eroded. In the meantime, the healthcare system that is predictive, preventive, personalized and participatory, where every patient receives the right drug, at the right dose, at the right time, will remain a fantasy. The science will have to remain patient.

[200] Zhang & Zhang, *supra* note 176, at 804.