Placebo Patents: Creating Stronger Intellectual Property Protection for Pharmaceuticals Approved by the U.S. Food & Drug Administration

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PLACEBO PATENTS: CREATING STRONGER INTELLECTUAL PROPERTY PROTECTION FOR PHARMACEUTICALS APPROVED BY THE U.S. FOOD & DRUG ADMINISTRATION

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I. INTRODUCTION

Desperate to end a lengthy cycle of chronic pain, seventy-nine-year-old Richard Smith decided to try the prescription medication Neurontin after multiple doctors recommended he use the drug "off-label" (in a way not approved by the U.S. Food & Drug Administration (FDA)). Two months later, Smith committed suicide. His widow blames the Neurontin and its manufacturer, Pfizer Inc., for promoting the drug for the treatment of neuropathic pain, an off-label use. She claims the medication changed his personality and led to his uncharacteristic decision to shoot himself.

Neurontin had not been approved by the FDA for neuropathic pain. But patent law frequently provides monopoly protection for pharmaceuticals that have not been approved by the FDA. However, a new and alarming trend has developed where patent law undermines the strength of patents for FDA-approved drugs for various reasons, including lack of utility. Thus, patent law appears to be operating contrary to public health and safety in its protection of pharmaceutical inventions.

One recent federal district court decision provides an example of unnecessary, expensive litigation over the patent of an FDA-approved drug. In *Eli Lilly v. Actavis Elizabeth LLC*, recently overturned by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), the U.S. District Court of New Jersey invalidated a patent for an FDA-approved drug for lack of data showing the utility of the drug at the time the patent was filed. Although the drug is currently approved and marketed for the use cited in the patent, the court found that the plaintiff had not adequately proven the usefulness of the drug when the patent was filed. The district court relied on precedent from the Federal Circuit, which had also invalidated a patent on the grounds of lack of utility in spite of FDA approval for the patented use. Overturning the lower court's decision, the Federal Circuit distinguished between the precedent and the new case, arguing the precedent was an example where utility was not

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2 Id.
3 Id.
7 Id. at *36.
8 Id.
9 In re '318 Patent Infringement Litig., 583 F.3d 1317, 1327 (Fed. Cir. 2009).
adequately demonstrated in the patent. The Federal Circuit sidestepped the key common factor, however: both cases involved challenges to patents covering an FDA-approved use of an FDA-approved drug.

These decisions threaten future research and development of pharmaceutical drugs. A drug manufacturer is not required to seek FDA approval in order to acquire patent protection of a drug. Rather, patent protection establishes a monopoly on which drug manufacturers rely while they develop a new drug and conduct the research necessary to acquire FDA approval.

Once a manufacturer acquires FDA approval for a certain indication, it frequently seeks to exploit that approval for the duration of the patent term through off-label marketing. Off-label marketing is illegal due to the safety risks involved with using drugs for an untested or unproven use. Such marketing is a common technique pharmaceutical companies employ to maximize profits during their patent terms. In recent years, federal officials have focused intensive efforts on reducing off-label marketing of pharmaceuticals. These efforts could potentially be bolstered by stronger patent protection of FDA-approved uses of drugs, but have instead been undermined by decisions invalidating patents for FDA-approved drugs.

In light of the prevalence of off-label marketing and the recent decisions creating disincentives for FDA approval, patent law needs reform in the area of pharmaceuticals. Specifically, patent law needs some mechanism to protect the rights of drug manufacturers that have invested in an FDA-approved drug.Trademark law offers one potential mechanism: the incontestability doctrine, which provides "conclusive evidence of the validity of the mark." For pharmaceutical products that have been proven safe and effective enough to achieve FDA approval for the use cited in the patent, this Note argues that an incontestable patent could similarly provide evidence of the validity of the

10 Eli Lilly, 2011 WL 3235718, at *8.
11 In re Brana, 51 F.3d 1560, 1568 (Fed. Cir. 1995) (citing Scott v. Finney, 34 F.3d 1058, 1063 (Fed. Cir. 1994)).
12 In re Krimmel, 292 F.2d 948, 954 (C.C.P.A. 1961).
13 Randall S. Stafford, Regulating Off-Label Drug Use — Rethinking the Role of the FDA, 358 NEW ENG. J. MED. 1427 (2008).
15 Stafford, supra note 13, at 1428.
To understand why pharmaceutical patents are so susceptible to validity challenges, Part II examines the legal landscape that created the breeding ground for the *Eli Lilly* decision and analyzes both the lower court decision and the Federal Circuit decision overturning it. Part II subsequently reviews the exploitation of patent monopolies through off-label uses to explain why decisions undermining incentives for FDA approval are so dangerous, and how federal legislation has distorted the incentives in pharmaceutical research. Part III begins with an economic analysis of pharmaceutical drug protection under current patent law. Finally, considering all factors, Part III concludes with an argument for reform to begin correcting the skewed world of pharmaceutical patent law. Such reform should be done with stronger guidance from the Federal Circuit and with an incontestability standard to protect the most valuable patents.

II. BACKGROUND

A. NUTS AND BOLTS OF SEEKING PATENT PROTECTION AND THE VALUE OF FDA APPROVAL

Economic incentives drive decisions to patent new pharmaceutical compounds, as well as decisions to pursue FDA approval for various potential uses of a compound.

It is rational economic behavior for a patent holder to seek to protect its patent: the patent has economic value and represents a very real barrier to entry that is enforceable by the holder: the patent holder can sue to stop infringement. Indeed, under the Hatch-Waxman Act, a pharmaceutical patent-holder can delay regulatory approval of a generic drug by simply alleging a patent infringement.

The same can be said as to any company which has spent millions of dollars to follow the law in securing FDA approval for a drug or a device.18

The function of patent law is to provide an incentive for innovation in the form of a limited monopoly.19 The exchange of monopoly for invention is

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19 *See U.S. CONST.* art. I, § 8, cl. 8.
commonly described as the quid pro quo of patent law.\textsuperscript{20} In the context of pharmaceuticals, the innovations most valuable to the public good are useful medications, which have established "the ultimate utility — prevention, alleviation, or cure of a disease in the human body."\textsuperscript{21} Patent protection of FDA-approved drugs is a key driver of innovation in the pharmaceutical and biotech industries.\textsuperscript{22}

Both patent law and FDA regulations create and enhance the value of a new pharmaceutical product. Patent law grants a monopoly that can be exploited once a product has received FDA approval for sale.\textsuperscript{23} In spite of this cooperation, patent protection and FDA approval are surprisingly divergent.\textsuperscript{24} Patent protection is based on an exclusively scientific inquiry that ignores the related issue of FDA approval necessary for a pharmaceutical manufacturer to fully use its patent.\textsuperscript{25}

Recognizing the huge financial investments in clinical research of potentially useful medications, the U.S. Patent and Trademark Office (USPTO) typically awards drug patents before any usefulness in humans has been ascertained.\textsuperscript{26} Because most pharmaceutical patents are filed and issued before the product receives FDA approval, the regulatory status of the product is mostly irrelevant to the patent prosecution.\textsuperscript{27} The lengthy, complex, and expensive process to achieve FDA approval has ultimately become a justification for a lower standard of utility in pharmaceutical patents, discussed below.\textsuperscript{28} A pharmaceutical manufacturer typically applies for a patent early in the

\textsuperscript{20} 60 AM. JUR. 2D PATENTS § 135 (2011).
\textsuperscript{21} In re Kimmel, 292 F.2d 948, 954 (C.C.P.A. 1961).
\textsuperscript{23} Rebecca S. Eisenberg, The Role of the FDA in Innovation Policy, 13 MICH. TELECOMM. & TECH. L. REV. 345, 355 (2007).
\textsuperscript{26} See In re Kimmel, 292 F.2d 948, 954 (C.C.P.A. 1961) (stating that nothing in the patent statute requires "an applicant to prove that compounds or other materials which he is claiming, and which he has stated are useful for 'pharmaceutical applications,' are safe, effective, and reliable for use with humans").
\textsuperscript{28} See, e.g., In re Malachowski, 530 F.2d 1402 (C.C.P.A. 1976) (finding utility based on animal studies without evidence of efficacy in humans); Chiron Corp. v. Genentech, Inc., 268 F. Supp. 2d 1148 (E.D. Cal. 2002) (finding utility where only partial aspects of the invention were useful).
development of a new product, before any testing in humans has been conducted. The scientific data used to support such a patent would not be adequate to support FDA approval of a drug; rather, it could potentially be used to support a request for permission to test the drug in human research subjects, as in the *Eli Lilly* case. Thus, this approach has posed serious problems in identifying a sufficiently enabled pharmaceutical patent.

Acquiring FDA approval is much more complex and expensive than securing patent protection. The process, from the initial discovery stage (during which a patent may be filed) to FDA approval, can cost from $800 million to $1.7 billion and take as long as fifteen years for one new medication. Because a patent is filed so early in this process, federal law has been adapted to account for the lengthy regulatory process. The Hatch-Waxman Act allows for a patent term extension of up to five years for prescription and over-the-counter drugs and other products regulated by the Federal Food, Drug and Cosmetic Act.

The process for FDA approval begins with in vitro (performed in a test tube or controlled environment rather than on a live object) and animal research, which may lead to a drug manufacturer filing an Investigational New Drug Application (IND) with the FDA. The IND enables transport of drugs (and other products that have not achieved regulatory approval) across state lines. The FDA requires that an IND include animal research, manufacturing details, and proposed human subjects research plans. After thirty days, barring an

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30 *Eli Lilly*, 731 F. Supp. 2d at 379.

31 See Kaye Scholer, *Section 101: Redefining Patentable Subject Matter and Utility and the Impact on Pharmaceutical and Biotech Patents*, 1017 PLI/PAT 59, 66–67 (2010) (stating that patent filing early in the research process “has led to a body of case law delineating the boundary between the unduly speculative and therefore unpatentable, and that which is of sufficiently promising utility to be worthy of patent rights.”).


33 STEVEN A. BECKER, PAT. APPLICATIONS HANDBOOK § 5:8 (2010).

34 Id.


37 Id.
objection from the FDA, the drug manufacturer can begin clinical research in human subjects.\textsuperscript{38}

The clinical research process involves four phases, each designed to gather specific types of data.\textsuperscript{39} Phase I research examines the “safety, dosage tolerance, and other pharmacokinetic properties of the drug” and identifies side effects; Phase II research is conducted in “a limited patient population to gather information about efficacy, optimal dosage levels, adverse effects, and safety risks”; and “Phase III trials test the efficacy and safety of the drug in an expanded patient population at geographically dispersed trial sites.”\textsuperscript{40} The results of the Phase I-III research are presented to the FDA in a New Drug Application (NDA), which should “tell the drug’s whole story” and prove that the efficacy and safety outweigh any of the risks.\textsuperscript{41} Phase IV research is conducted post-approval.\textsuperscript{42}

Statistically, few pharmaceutical compounds achieve the high bar of FDA approval.\textsuperscript{43} The high failure rate of pharmaceutical inventions—only twenty of about 5,000 potential compounds examined are seriously considered for testing in humans, and of those compounds, only one in five receives FDA approval—places a significant burden on those drugs that do reach the market to recoup huge research and development costs.\textsuperscript{44} These factors create an intense desire among major drug developers to have strong intellectual property protection for those drugs that are marketable.\textsuperscript{45} The Biotechnology Industry Organization (BIO), a lobbying group for the biotechnology industry, has stated that protection of intellectual property is the primary factor driving advancement and economic development of the industry.\textsuperscript{46}

\textsuperscript{38} Id.
\textsuperscript{40} Nathenson v. Zonagen Inc., 267 F.3d 400, 404 (5th Cir. 2001).
\textsuperscript{44} Id.
\textsuperscript{45} See Bruce Lehman, The Pharmaceutical Industry and the Patent System, 7 (2003), http://www.earth.columbia.edu/cgsd/documents/lehman.pdf (“The pharmaceutical industry is one of three technology-based industries in which the patent virtually equals the product.”).  
\textsuperscript{46} Christopher M. Holman, Biotechnology’s Prescription for Patent Reform, 5 J. MARSHALL REV.
certainty that a research-based manufacturer can obtain, inform, defend and make full, legitimate use of intellectual property rights is essential to maintaining the cycle of innovation upon which the industry and public rely.\textsuperscript{47}

Protection of the intellectual property rights for a new prescription drug, in which a pharmaceutical company has invested millions or billions of dollars, is paramount.\textsuperscript{48} These rights frequently come into question when a generic manufacturer seeks entry in the market with a competing generic version before the patent term has expired.\textsuperscript{49} The Hatch-Waxman Act, in addition to providing the patent term extension above, contains provisions designed to facilitate generic drug development and entry into the market.\textsuperscript{50}

Prior to the Hatch-Waxman Act, pharmaceutical companies had dual protection of intellectual property in the form of trade secrets and patent protection.\textsuperscript{51} A manufacturer providing clinical research data to the FDA could expect this data to remain a trade secret, so that generic manufacturers could not access or rely on the research in developing a generic version of the drug, and would instead need to duplicate the research.\textsuperscript{52} However, the Hatch-Waxman Act changed that, allowing generic manufacturers to seek FDA approval by conducting studies proving only bioequivalence (same strength and availability within the body) of the generic to the original drug, a much lower bar than the rigorous safety and efficacy standards required to achieve initial FDA approval.\textsuperscript{53}

A generic manufacturer can do this by filing an Abbreviated New Drug Application (ANDA).\textsuperscript{54} In filing an ANDA, a generic manufacturer must prove that it is not infringing a current patent, and can do so through one of four ways: Paragraph I-IV certifications.\textsuperscript{55} A Paragraph I certification states that there are no patents listed, Paragraph II certification states that the listed patents have expired, and a Paragraph III certification states that the FDA should approve of the generic drug after the date the last patent expires.\textsuperscript{56}

\textsuperscript{47} Glover, supra note 43, at 10.
\textsuperscript{48} Williams, supra note 29, at 363.
\textsuperscript{49} See id. at 364.
\textsuperscript{50} Irwin M. Aisenberg, Modern Patent Law Precedent: Dictionary of Key Terms and Concepts, at H90 (8th ed. 2010).
\textsuperscript{51} Baker, supra note 39, at 305.
\textsuperscript{52} Id.
\textsuperscript{53} Id. at 305–06.
\textsuperscript{56} Id. § 355(j)(2)(A)(vii)(I)–(III).
Paragraph IV certification, which is most relevant to this Note, means the generic manufacturer is claiming the patent is either not infringed or is invalid. A generic manufacturer that files an ANDA and claims the drug patent is invalid is subject to a thirty-month "cooling off" period during which the patent is litigated. The patent holder is given forty-five days to file an infringement suit and then receives thirty months of guaranteed monopoly, unless the patent holder loses a final appeal before thirty months have passed.

B. PHARMACEUTICAL PATENT UTILITY STANDARD

Patentable subject matter must be novel, have utility, and be non-obvious. In the pharmaceutical context, the threshold for meeting the utility requirement is relatively low, although the Supreme Court articulated certain restrictions in Brenner v. Manson. In that case, the Supreme Court invalidated a patent for lack of utility when the patentee argued its invention was a discovery worth further researching. The Brenner Court stated the broad rule that the object of valuable research is not in and of itself patentable, without proof of its utility. "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Articulating its reasons for refusing to grant a patent without proof of utility and therefore enablement, the Brenner Court stated:

Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.
Although the Brenner Court appeared to set a high bar requiring completion of research, the standard has been interpreted to be much lower, allowing patents that do actually function, to some extent, as hunting licenses.\textsuperscript{66} The courts have skewed the standard based on the presumption that a drug company will not invest in the requisite research and development to bring a drug to market without first receiving its patent.\textsuperscript{67} If the court required Phase II research as evidence of utility, “the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.”\textsuperscript{68}

To accommodate the practicalities of pharmaceutical research, the courts have developed multiple methods of ascertaining utility. In a decision predating Brenner, the In re Krimmel court found that evidence of a drug’s actions in animals can suffice to prove utility.\textsuperscript{69} Overturning the USPTO’s decision to deny a patent for lack of utility on the grounds that the patent applicant had failed to prove the pharmaceutical’s efficacy in humans, the Krimmel court held that a patentee asserting utility of a novel pharmaceutical compound based on support from animal testing meets the utility requirement under patent law.\textsuperscript{70} The court based its holding on the belief that identifying the pharmaceutical quality of the drug in an animal is a “significant and useful contribution to the art, even though it may eventually appear that the compound is without value in the treatment of humans.”\textsuperscript{71} Thus, evidence from animal testing may be used to support utility of a pharmaceutical patent.

In addition to animal testing, in vitro research of a drug’s pharmacology (how it works) and sound logic asserting why this action will be useful for a particular human condition may also provide evidence of utility.\textsuperscript{72} The Brana court found that a pharmaceutical patent may prove utility by demonstrating a reasonable correlation between the pharmacological activity of the product and the asserted utility in humans, even when the pharmacological activity has not yet been observed in humans.\textsuperscript{73}

The USPTO now instructs examiners that any “reasonable correlation” between “pharmacological or other biological activity of a compound” and the

\textsuperscript{66} See, e.g., In re Brana, 51 F.3d 1560, 1568 (Fed. Cir. 1995) (explaining that the stage at which pharmaceutical inventing becomes useful and thus patentable is well before the pharmaceutical may be administered to humans).

\textsuperscript{67} See, e.g., id.

\textsuperscript{68} Id.

\textsuperscript{69} In re Krimmel, 292 F.2d 948, 953 (C.C.P.A. 1961).

\textsuperscript{70} Id.

\textsuperscript{71} Id.

\textsuperscript{72} In re Brana, 51 F.3d at 1568.

\textsuperscript{73} Id.
asserted utility will suffice to establish utility, describing clinical testing in humans as an "unnecessary burden" that patent examiners should not impose in the context of pharmaceutical patents. Thus, the current standard is that evidence of pharmacological activity in vitro or in animals will "almost invariably" prove utility so long as a reasonable correlation exists between the evidence and the drug's asserted utility. The Federal Circuit has even left open the possibility that utility may be proven through analytical reasoning alone.

C. ELI LILLY V. ACTAVIS AND ITS PROBLEMATIC PRECEDENT

Contrary to the approach recognizing the economic value of a patent and the million-dollar investment in securing FDA approval for a medication, the district court decision Eli Lilly and Co. v. Actavis Elizabeth LLC invalidated the patent for an FDA-approved drug on the grounds the patent lacked utility. Plaintiff Eli Lilly, alleging infringement by generic drug manufacturer Actavis, filed for a patent in 1995, when plans for clinical testing in human subjects had been approved by the Institutional Review Board (IRB) charged with reviewing the testing, but not yet conducted. The USPTO issued the patent in 1997. By that time, Eli Lilly had acquired substantial evidence through the clinical trials of the efficacy of tomodetoxine for the treatment of ADHD in children, the indication identified in the patent. The FDA approved tomodetoxine for the patented use in 2002. Invalidating the patent, Judge Dennis M. Cavanaugh pointed to the lack of test data at the time of filing, combined with a lack of evidence that a person having ordinary skills in the art "would have recognized the method of treatment's utility in view of the specification and prior art." Judge Cavanaugh made this decision in spite of the fact that the patentee had received IRB approval to conduct research in human subjects, because none of this research had been conducted at the time of filing the patent. At
the time of the suit for infringement, the research had proven the efficacy of the
drug for the indication asserted in the patent. However, Cavanaugh stated that
utility should have been proven at the time of filing.\textsuperscript{84} In response, the plaintiff
argued that IRB approval to conduct the research provided sufficient evidence
of utility at the time of filing.\textsuperscript{85} According to the USPTO guidelines, approval
to conduct research in human subjects is not only beyond minimum utility
requirements, but should also create a presumption by the examiner reviewing
the patent “that the applicant has established that the subject matter of that trial
is reasonably predictive of having the asserted therapeutic utility.”\textsuperscript{86}

Rather than weighing the insight of the IRB charged with determining the
merit of the proposed clinical research to test the efficacy of the drug,
Cavanaugh stated the IRB lacked any members skilled in the art and argued
their approval meant nothing with regard to the utility of the drug.\textsuperscript{87}
Cavanaugh disagreed with the plaintiff’s argument that strict federal regulations
governing human subjects research prove that IRB approval requires some
showing of a drug’s utility.\textsuperscript{88} “In arriving at its conclusion, the Court cannot
agree with Plaintiff that the relevant regulations require that efficacy be shown
prior to clinical trial approval.”\textsuperscript{89}

Contrary to Cavanaugh’s statements, patent examiners are instructed that
approval to conduct clinical research trials in human subjects is a strong
indicator of utility, one that examiners should be “extremely hesitant to
challenge.”\textsuperscript{90}

Before a drug can enter human clinical trials, the sponsor, often
the applicant, must provide a convincing rationale to those especially skilled in the art (e.g. the Food and Drug Administration)
that the investigation may be successful. Such a rationale would
provide a basis for the sponsor’s expectation that the
investigation may be successful. In order to determine a protocol
for phase I testing, the first phase of clinical investigation, some

\textsuperscript{84} Id. at 385. (“[T]he enablement/utility case law instructs that patent applicants must
demonstrate utility (as well as other enablement-related requirements) at the time of filing the
patent application.” (citation omitted)).
\textsuperscript{85} Id.
\textsuperscript{86} USPTO MANUAL, supra note 74, § 2107.03(IV).
\textsuperscript{87} Eli Lilly, 731 F. Supp. 2d, at 388.
\textsuperscript{88} Id.
\textsuperscript{89} Id. at 389.
\textsuperscript{90} USPTO MANUAL, supra note 74, § 2107.03(V).
credible rationale of how the drug might be effective or could be effective would be necessary.\textsuperscript{91}

The ultimate irony, of course, is that Actavis, the company alleging that Eli Lilly's patent was invalid due to lack of utility, sought to profit from the usefulness of Lilly's patented drug. This irony may have been lost on Cavanaugh, but other courts have noted that an infringement case asserting lack of utility as a defense is fundamentally flawed. "People rarely, if ever, appropriate useless inventions."\textsuperscript{92}

Cavanaugh's decision relied on two major Federal Circuit decisions as precedent.\textsuperscript{93} First, he referred to statements made by the Federal Circuit in \textit{Rasmusson v. Smithkline Beecham Corp.}, articulating a view similar to \textit{Brenner} with regard to the enablement requirement:

If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later prove[s] true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked.\textsuperscript{94}

Second, Cavanaugh relied on \textit{In re '318 Patent Infringement Litigation}, another example where a patent was invalidated in the context of an infringement suit due to lack of enablement at the time of filing.\textsuperscript{95} In that case, the inventor combined multiple studies from prior art to conclude that the drug galantamine could be used as a treatment for Alzheimer's disease.\textsuperscript{96} The prior art included animal testing of the drug's effects on short-term memory loss.\textsuperscript{97} The USPTO originally rejected the patent for obviousness in light of the fact that the patent relied entirely on prior art to show the utility of the drug.\textsuperscript{98} Ultimately, the patentee convinced the USPTO that the patent was not obvious,

\begin{footnotes}
\footnotetext[91]{Id.}
\footnotetext[92]{Raytheon Co. v. Roper Corp., 724 F.2d 951, 959 (Fed. Cir. 1983).}
\footnotetext[94]{Rasmusson v. Smithkline Beecham Corp., 413 F.3d 1318, 1325 (Fed. Cir. 2005).}
\footnotetext[95]{\textit{In re '318 Patent Infringement Litig.}, 583 F.3d 1317 (Fed. Cir. 2009).}
\footnotetext[96]{Id. at 1321.}
\footnotetext[97]{Id.}
\footnotetext[98]{Id. at 1322.}
\end{footnotes}
and the patent issued in 1987. Galantamine was approved by the FDA to treat Alzheimer’s disease in 2001.

In 2005, multiple generic drug manufacturers infringed the patent and defended their infringement by claiming the patent was invalid. Remarkably, the plaintiffs were forced to defend the patent on claims that the patent was both obvious and not enabled due to lack of utility. The Federal Circuit, in finding that the patent lacked utility at the time of filing, relied on the statements the patentee made to prove non-obviousness, including multiple comments explaining that the prior art did not indicate that the drug would be useful for Alzheimer’s disease. Clearly, being required to prove both the non-obviousness and utility of an invention relying entirely on prior art put the plaintiffs in a nearly untenable position.

However, the court appeared to have no problem relying on the non-obviousness defense to impeach the claim of utility. Instead, the Federal Circuit distinguished the case from Krimmel by articulating the differences in the types of animal testing that had been performed prior to the filing for their respective patents and referring to the Brenner standard that a patent is not a hunting license. The court made this ruling in spite of the drug’s ultimate success and use for the indication specified in the patent.

The court claimed that the animal testing was not sufficiently related to Alzheimer’s, as it did not involve “the use of galantamine to treat Alzheimer’s-like conditions,” but instead tested the drug’s effects on drug-induced memory loss. The court denied the plaintiff’s argument that utility had been established by analytical reasoning (the basic logic the patentee used to conclude galantamine would be useful for Alzheimer’s disease). However, the court left open the possibility that analytical reasoning could be adequate support for utility, but not in In re ’318 due to the lack of “insights” in the specification that the plaintiffs argued provided the analytical reasoning.

Overturning the district court’s finding that Eli Lilly’s patent was invalid for lack of utility, the Federal Circuit stated the Eli Lilly case was distinguishable from the precedent on which Cavanaugh relied. The Federal Circuit
distinguished *Rasmusson v. Smithkline Beecham Corp.* on the basis that *Rasmusson* involved a patent interference case, "where evidence of actual reduction to practice was required to establish a priority date..." In other words, the standard at issue in *Rasmusson* simply did not parallel the question in *Eli Lilly*.

In distinguishing *In re '318*, the Federal Circuit left open the possibility that many potential infringers may still rely on that case to challenge patents. The court stated that in *In re '318*, because animal tests were not completed at the time the patent was issued, the patentee had failed to show the requisite correlation between the drug's activity and its purported therapeutic use. In *Eli Lilly*, however, the Federal Circuit noted that "the norepinephrine relationship was known, safety for antidepressant activity had been established, the specification contained a full description of the utility, experimentation had been obtained before the patent was granted, and the examiner had not requested additional information." Because the results of human subjects research were available soon after the patent was filed and before it was issued, Eli Lilly had provided sufficient evidence of utility. Much of the information available, particularly the drug's norepinephrine action and safety, had been gathered through prior research into a different potential use.

D. EXPLOITATION THROUGH OFF-LABEL MARKETING

Given that FDA approval is required for pharmaceutical products to be sold, invalidating the patents for FDA-approved products does not, alone, entirely destroy the incentives for FDA approval. However, pharmaceutical companies frequently circumvent FDA approval of certain medications through off-label marketing. Off-label marketing involves representations by pharmaceutical manufacturers that a product may be prescribed for uses for which it has not received FDA approval. Such marketing eliminates the burden of clinical research required to acquire FDA approval for a new indication. Federal

111 Id.
112 Id.
113 Id.
116 Edward P. Lansdale, "Used As Directed? How Prosecutors Are Expanding the False Claims Act to Police Pharmaceutical Off-label Marketing," 41 New Eng. L. Rev. 159, 163–64 (2006) (stating "[a]s noted by the United States District Court for the District of Columbia, 'a physician may prescribe an approved drug for any medical condition, irrespective of whether FDA has determined that the drug is safe and effective with respect to that illness.'").
investigators and the FDA have recently focused on prosecuting pharmaceutical companies engaged in off-label marketing of pharmaceuticals.\textsuperscript{117}

In a recent report, eight of the top ten False Claims Act settlements in the fiscal year of 2010 were shown to be related to off-label marketing of pharmaceuticals.\textsuperscript{118} Major settlements between the United States Department of Justice (DOJ) and pharmaceutical companies for alleged marketing of unapproved uses of their products have involved pharmaceutical giants such as Pfizer, Novartis, GlaxoSmithKline, Allergan, and AstraZeneca (among others).\textsuperscript{119} Eli Lilly and Company recently paid out $1.415 billion for its marketing of a drug approved for schizophrenia and bipolar disorder, Zyprexa.\textsuperscript{120} The company illegally marketed the drug for treatment of sleep disorders and dementia, according to the DOJ.\textsuperscript{121} The settlement was described at the time as “the largest amount paid by a single defendant in the history of the” DOJ.\textsuperscript{122}

The FDA has cited two primary goals of regulating off-label marketing: “(1) ensuring that physicians receive accurate and unbiased information so that they may make informed prescription choices; and (2) providing manufacturers with ample incentive to get previously unapproved uses ‘on label’ by testing them and submitting them to the FDA for approval.”\textsuperscript{123} Off-label use of a drug may be desirable in cases where a certain class of drug has been shown to have positive effects on a related or milder indications, or where a drug is prescribed for a population in which it has not been approved for use (such as children) or for a condition sharing symptoms with the condition for which a drug is approved.\textsuperscript{124}

Recently, pharmaceutical giant Pfizer paid a huge settlement for claims related to off-label marketing of its anti-epileptic drug Neurontin

\begin{footnotesize}
\textsuperscript{121} Id.
\textsuperscript{122} Id.
\textsuperscript{123} Eisenberg, \textit{supra} note 23, at 379.
\textsuperscript{124} Stafford, \textit{supra} note 13, at 1427.
\end{footnotesize}
(gabapentin),\textsuperscript{125} which Pfizer and its predecessors marketed off-label for neuropathic and other types of chronic pain.\textsuperscript{126} Pfizer acquired a patent for multiple off-label uses (one patent, the '479 patent, covers "neurogenerative diseases," defining these as Alzheimer's, Huntington's, Parkinson's diseases, stroke and ALS).\textsuperscript{127} Pfizer's assignee then used the '479 patent to prevent another drug manufacturer from manufacturing and marketing the drug for its FDA-approved use as adjunctive therapy for seizures.\textsuperscript{128} The crevasse between pharmaceutical patent issuance and FDA approval is wide, but Pfizer, according to Thomas Greene, never intended to make the leap in its patented uses of Neurontin, choosing instead to maximize profits through off-label marketing.\textsuperscript{129}

Pfizer is just one example. Multiple major pharmaceutical companies have recently paid large sums in settlements for their off-label marketing of medications.\textsuperscript{130} Because there is no mandatory correlation between a patented use and an FDA-approved use, off-label marketing provides ample opportunity for drug companies to exploit their patents.\textsuperscript{131} A drug company may patent and market a use (in spite of the fact that off-label marketing is illegal) without ever

\textsuperscript{125} Pfizer, Medication Guide: Neurontin, FOOD & DRUG ADMIN., http://www.fda.gov/downloads/Drugs/DrugSafety/UCM229208.pdf ("NEURONTIN is a prescription medicine used to treat: Pain from damaged nerves (postherpetic pain) that follows healing of shingles (a painful rash that comes after a herpes zoster infection) in adults. Partial seizures when taken together with other medicines in adults and children 3 years of age and older.").


\textsuperscript{129} Greene, supra note 126.

\textsuperscript{130} See, e.g., California Drug Firm Settles Fraud Case, Will Pay Nearly $37M, 22 No. 10 ANDREWS PHARM. LITIG. REP. 4 (Nov. 20, 2005); Seattle Drug Firm Settles Medicare Suit, Will Pay $10.5 Million, 23 No. 5 ANDREWS PHARM. LITIG. REP. 14 (June 21, 2007); Astrazeneca Settles "Off-Label" Servquel Action for $520 Million, 26 No. 04 WESTLAW J. PHARM. 1 (May 17, 2010); Arizona Drug Firm Settles Fraud Suit for $9.8 Million, 23 No. 5 ANDREWS PHARM. LITIG. REP. 5 (June 21, 2007).

\textsuperscript{131} Stafford, supra note 13, at 1428.
bothering with clinical research trials or FDA approval for that use.\textsuperscript{132} Not only does this potentially pose a danger to consumers, it also blocks legitimate research that competitors might actually conduct for alternative uses of a drug.\textsuperscript{133} The '479 patent is an example of using the patent to block legitimate uses of the pharmaceutical.\textsuperscript{134}

A pharmaceutical patent can protect not only the patented use, but also other uses of a product. This may occur through the theory of inducement, which allows for liability even when the generic product is intended to be used for a purpose other than the patented use.\textsuperscript{135} Thus, this monopoly on information poses risks to consumers and challenges to regulators who seek accurate information for patients.\textsuperscript{136}

E. EFFECTS OF THE HATCH-WAXMAN ACT

Typical defenses to patent infringement include asserting that all or part of the patent is invalid.\textsuperscript{137} It is not surprising, then, that such an assertion has been codified in the Hatch-Waxman Act. However, one outcome of the Hatch-Waxman's procedural provisions has been extensive litigation over patent infringement. As stated by one author, "[a]n issued patent can easily become the epicenter of a legal battle between drug manufacturers by virtue of its status as the most valuable component of the drug development process, because it is this exclusive property right, and figurative security blanket, which allows its owner the ability to exclude..."\textsuperscript{138}

Such litigation has ultimately led to numerous settlement agreements in which generic drug makers agree to delay entry into the market.\textsuperscript{139} These agreements cost consumers billions of dollars and undermine the Hatch-

\textsuperscript{132} Id. at 1427.
\textsuperscript{133} Id. at 1427–28.
\textsuperscript{135} 94 AM. JUR. 3D Proof of Facts § 179 (2010).
\textsuperscript{136} Eisenberg, supra note 23, at 347 ("Pharmaceutical firms sell drugs rather than selling information as such, and they face powerful incentives to cheat in developing and selectively disclosing information about their products in order to improve sales. Inducing firms to provide high quality information about the effects of drugs in patients is thus a major challenge for regulators.").
\textsuperscript{137} 60 AM. JUR. 2D Patents § 892 (2010).
Waxman Act’s goal of increasing generic options,\textsuperscript{140} and have in turn spurred anti-trust actions by the Federal Trade Commission.\textsuperscript{141} Rather than helping to identify valid challenges to patents, or expediting the arrival of generic drugs, the Hatch-Waxman Act has encouraged cooperation between the patentees and generic manufacturers to delay generic entry until the patent expires.\textsuperscript{142} This routine procedure imposes extra costs on the patentee, but fails to benefit the public with the generic’s entry prior to patent expiration.\textsuperscript{143} These settlements can add to the expense of a patent without any countervailing benefit.\textsuperscript{144}

F. INCONTESTABILITY DOCTRINE IN TRADEMARK

A trademark becomes incontestable after five years of trademark registration and creates a presumption of the validity of the trademark. In other words, “the registration is conclusive evidence of the validity of the registered mark and of the registration of the mark, of the registrant’s ownership of the mark, and of the registrant’s exclusive right to use the registered mark in commerce.”\textsuperscript{145} In trademark law, incontestability significantly reduces the burden of proof on the plaintiff whose trademark is being infringed.\textsuperscript{146} Incontestability strengthens a trademark and creates additional incentives to register a trademark.\textsuperscript{147}

\textsuperscript{140} FTC Chairman Heralds Opposition to ‘Pay for Delay’ Drug-Making Agreements, 26 No. 7 WESTLAW J. PHARM. 10, 10 (2010).


\textsuperscript{142} Jeff Bliss & Susan Decker, Ending the Silence of Generic Drugmakers, BLOOMBERG BUSINESSWEEK, June 24, 2010, http://www.businessweek.com/magazine/content/10_27/b4185020593221.htm.

\textsuperscript{143} Dickey et al., supra note 27, at 390 (stating that some types of settlements impose costs on consumers).


\textsuperscript{145} 74 AM. JUR. 2D Trademarks & Tradenames § 69 (2010) (“An incontestable trademark thus cannot be challenged for mere descriptiveness, or on the basis that the mark lacks secondary meaning. Nonetheless, such conclusive evidence of the right to use the registered mark is subject to proof of infringement as well as certain other specified defenses or defects.”).

\textsuperscript{146} 15 U.S.C. § 1115(b) (2006) (“To the extent that the right to use a mark has become incontestable, … the registration shall be conclusive evidence of the validity of the registered mark and of the registration of the mark, of the registrant’s ownership of the mark, and of the registrant’s exclusive right to use the registered mark in commerce … on or in connection with the goods or services specified in [the registration] subject to any conditions or limitations [stated therein].”).

Trademark law offers an exception to incontestability, allowing challenges to the trademark when it violates the functionality doctrine. The functionality doctrine prevents use of a trademark that has a functional purpose other than identifying the source of the goods. This doctrine helps to separate trademark and patent law and to ensure that a trademark does not offer a competitive edge or prevent competitors from using a functional material or characteristic of the product. The policy concerns that prohibit the use of a trademark that has functional characteristics simply outweigh incontestability.

The concept of an incontestable patent has been suggested in the context of sweeping patent reform by authors L. James Harris and Regan Fay. Their proposal would track the trademark incontestability doctrine by making any seventeen-year patent incontestable after five years (the proposal also called for shorter, seven-year patents that become incontestable after one year). Their arguments in favor of incontestable patents are: that the Constitution directs Congress to secure a limited monopoly for inventors, and an incontestable patent reflects that goal; that this security would encourage an entrepreneur to invest in his invention and “bring it to the marketplace”; and that incontestability would efficiently eliminate wasteful litigation resources. They also suggest that all potential infringers or challengers to the patent would have notice of and utilize the time frame in which they can challenge a patent: the five years prior to it becoming incontestable.

### III. Analysis

#### A. Economics and the disincentive created by Eli Lilly

In examining the broad patent incentive structure, Judge Richard Posner has identified certain economic problems with patents, which are relevant to any discussion of reform of pharmaceutical patenting. Namely, that patents “bias investment toward types of inventive activity that yield patents”; discourage or prevent similar research; and drive customers to “less efficient substitutes.”

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150 Id. at 164 (“It is the province of patent law, not trademark law, to encourage invention by granting inventors a monopoly over new product designs or functions for a limited time.”).
151 See L. James Harris & Regan Fay, Certain Incontestable Patents Are Warranted, 60 J. PAT. OFF. SOC’Y 27 (1978) (arguing for sweeping patent reform through the establishment of a Validity Court, a dual patent program offering short- and long-term patents, and incontestability).
152 Id.
153 Id. at 30–31.
154 Id.
Applying Posner's economic critique of patent law to the pharmaceutical industry, the concern that patents bias research investments is the area in which both the district court and Federal Circuit Eli Lilly decisions are so critical. The district court's holding sent the message to pharmaceutical companies that research supporting a drug patent involves not the clinical research that leads to FDA approval, but rather the research that yields in vitro results that meets the utility standard. The problem here is that pharmaceutical patents are already skewed by the low threshold for utility, and, in a case where a company was actually conducting research that contributed to the body of FDA-approved uses of a pharmaceutical product at the time of filing for the patent, the patent was temporarily invalidated.

The Federal Circuit decision, unfortunately, missed an opportunity to redirect the incentive structure. By turning its holding on the fact that the patentee knew a great deal of information about the drug based on previous research into the drug's potential use for another indication, the court's decision encourages pharmaceutical manufacturers to invest in research of well-known drugs. While this research obviously yields useful results in some instances, it may not always do so. The decision also encourages drug manufacturers to patent multiple uses of a particular pharmaceutical product once a sufficient base of knowledge about the drug has been established. In this way, the holding further encourages off-label marketing.

Clearly, patent law is directing pharmaceutical research away from its safest end use. From an economic standpoint, this can be problematic generally because of the forgone research. From a practical standpoint, and the viewpoint of federal officials attempting to limit off-label marketing of drugs, this incentive structure paints a bleak picture. The prevalence of off-label marketing suggests that the incentives for FDA approval are more complex than the practical need to acquire FDA approval to sell a drug. Because drug companies know how to circumvent FDA approval, and because they frequently do so in spite of eventually paying hefty criminal and civil fines for this action, any decision affecting the incentives for FDA approval has broad implications.

The fact that patents can "impede competing inventive activity" is particularly relevant in the context of off-label uses of drugs. If the patentee is not conducting the research into additional potential uses of a drug, it is highly unlikely that other manufacturers are. Generic manufacturers simply cannot recover the costs of extensive clinical trials. This means that the critical
information a clinical trial could yield in regard to a proposed off-label use may never be discovered. Not only is this problematic due to the possibility that some potentially valuable off-label uses may be undiscovered or unused, it is also a problem because of the excess costs that many consumers may invest into a purportedly helpful off-label use that has not been properly tested. The settlement with Novartis included a $1.8 million reimbursement to Connecticut's Medicaid fund for off-label uses of Neurontin, which Medicaid does not cover.\textsuperscript{159} An off-label use without additional research takes the pharmaceutical company off the hook for claims about efficacy, and that company can continue to profit from such claims without ever having to face cold hard facts in the context of clinical research. Without competitors who can observe and challenge the claims, or conduct the research to find out what off-label indications a drug is actually useful for, the monopoly granted in a pharmaceutical patent is not only a monopoly on the market, but a monopoly on information. Such monopolies have created "patent thickets" in which information is so limited that the industry suffers from a "tragedy of the anti-commons," where an abundance of property rights constricts available information and limit research.\textsuperscript{160} Universities have begun to use patents as leverage to negotiate with pharmaceutical companies.\textsuperscript{161} As a result, many scholarly articles argue that patent protection is too broad in the pharmaceutical industry.\textsuperscript{162} However, the problem may also be that the wrong types of patents are incentivized under current patent law.

B. OVERTURNING ELI LILLY

The Federal Circuit missed a significant opportunity for reform in overturning the \textit{Eli Lilly} decision. Rather than simply following the plaintiff's arguments distinguishing \textit{Eli Lilly} from the precedent on which the lower court relied, the Federal Circuit should have instead adopted a broad rule that no patent for an FDA-approved drug should be invalidated for lack of utility, thereby overturning the problematic \textit{In re '318} decision. A rule that FDA-approved drug patents cannot be invalidated for lack of utility would serve dual purposes: it would help to prepare for the incontestability standard suggested


\textsuperscript{161} Eisenberg, supra note 23, at 354–56.

\textsuperscript{162} See, e.g., \textit{id}; Morgan, supra note 22.
below, and it would end the recent trend of absurd patent challenges on utility grounds for drugs with obvious utility.

The Federal Circuit decision upholding Eli Lilly’s patent provided multiple facts on which to base its finding that the patentee had fulfilled its burden of proving utility.\(^{163}\) The Federal Circuit decision ultimately lists a set of facts for future litigants to use in challenging or supporting the validity of a patent. Whether the precise set of facts is matched, or the patentee makes a compelling argument that its particular facts are analogous, is far less relevant than the end product the patent protects. If the patent ultimately confers a monopoly onto a drug that is safe and effective according to FDA standards, this fact ought to be determinative, rather than the facts used in any precedent to determine validity of a patent.

As biotechnology advances, the nature of the corresponding patents will continually evolve. The current utility standard may eventually prove to be too high of a bar as researchers learn more about the human body, pharmacology, and medicine. Patent law traditionally leaves open the possibility of change. The Supreme Court in *Bilski v. Kappos* refused to limit patentability to subject matter that passes the machine or transformation test;\(^{164}\) the Federal Circuit similarly stated analytical reasoning alone could potentially suffice as proof of utility.\(^{165}\)

These areas do not reflect merely a reticence to create a blanket rule; they acknowledge that patent law will continually govern what we cannot yet foresee. With regard to pharmaceutical research and invention, technical rules that are too strict regarding the data available when a patent is filed may potentially limit the medications available to the general public and drug companies’ willingness to invest in research. As the industry garners knowledge about the human body, analytical reasoning alone may eventually be an accurate forecast of the usefulness of a drug. Patent law needs to be on the cutting edge of this evolution.

Patents are available to pharmaceutical inventors from a very early stage in order to encourage continuous investment in the newly discovered product.\(^{166}\) The traditional patent law quid pro quo is different with regard to pharmaceuticals, and for good reason. A pharmaceutical inventor who believes he has found the next wonder drug is not likely to abandon this invention upon receiving a patent; rather, the inventor will strive to quickly seek FDA approval of the drug. Thus, the understanding is that a patent is issued in exchange for

\(^{163}\) See supra notes 112–13 and accompanying text.


\(^{165}\) *In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1326 (Fed. Cir. 2009).

\(^{166}\) See supra note 68 and accompanying text.
additional research in the pharmaceutical industry. This tradeoff is made possible by the additional incentive to seek FDA approval—to create a safe, useful, and effective drug.

Obviously, some patents will be issued prior to the acquisition of extensive data on the medication. These patents, however, should only concern the courts and Congress when they are not followed to the end of FDA approval. Abandoning a patent or cutting off research in a subject area with a patent lacking utility is entirely different than pursuing, in good faith, regulatory approval of a new invention and filing for a patent while in the process of seeking that approval.

The Federal Circuit should, when faced with another challenge to the patent of an FDA-approved drug, narrow litigation over the utility to those patents that do not offer the benefit of a useful drug. Much debate over the Hatch-Waxman Act, healthcare, and pharmaceutical legal reform involves the desire to reduce costs through a variety of mechanisms. The most straightforward mechanism, however, would be to eliminate frivolous litigation when a patent has been used to confer a public benefit in the form of a new drug on the market.

C. CREATING AN INCONTESTABILITY STANDARD IN PATENT LAW

Given the preliminary nature of a pharmaceutical patent and the relatively low percentage of pharmaceutical patents that actually lead to an FDA-approved drug, it is obvious that the patent for an FDA-approved drug is the most precious and valuable patent available in the pharmaceutical industry. Such patents merit the highest level of protection available in patent law and should not be susceptible to challenges of validity after the extensive investment in developing the drug has already occurred. Allowing generic manufacturers to attack the drug patent after the patentee has made a drug marketable creates uncertainty about the value of a patent. This will ultimately reduce investment in research and development of new drugs.

Although there is an obvious interplay between patent protection and FDA approval, \(^\text{167}\) patent law does not take FDA approval into account in assessing the validity of a drug patent. This oversight ought to be remedied with strong

\(^{167}\) See Eisenberg, *supra* note 23, at 359 ("The FDA is pervasively called upon to track patents in administering its system of drug approvals, although without ever making substantive judgments about patent validity and infringement. At the same time, the PTO is called upon to track the FDA approval process in timing the expiration of patents. The two systems operate in tandem to confer exclusivity in markets for new products and to determine when that exclusivity should end, blurring the line between concerns about health and safety and efforts to reward innovation.").
patent protection rewarding the efforts of drug manufacturers that acquire FDA approval of their patented medications. This could begin to close the great divide between a patentable pharmaceutical and a marketable pharmaceutical.

Looking to other forms of intellectual property protection, trademark law offers a potential remedy: incontestability. Just as trademark law offers incentives to register a trademark, offering incontestability of a patented drug or use of a drug once it receives FDA approval could create an incentive—likely much stronger than that in trademark—for pharmaceutical manufacturers to seek FDA approval for any patented uses of their inventions. Specifically, Congress should create an incontestable patent for those patents protecting FDA-approved uses of a pharmaceutical. Incontestability for FDA-approved uses would provide an incentive to strengthen the patent for an off-label use, rather than an incentive to exploit that patent without seeking FDA approval.

Most importantly, an incontestable patent based on FDA approval must eliminate infringement defenses that challenge the validity of a patent. Because patent law presumes the validity of a patent and places the burden of proving invalidity on an infringer, an incontestable patent must present conclusive evidence that the patent is novel (or non-obvious) and fully enabled in order to offer additional protection. The incontestability need only last as long as the patent term, but could be used to avoid frivolous defenses to infringement, such as the lack of utility defense raised in the Eli Lilly case.

Substituting the FDA's judgment for an assessment of the patentability of a drug is not really as significant of a logical leap as it may initially appear. The FDA monitors patents as part of the Hatch-Waxman Act, and FDA approval ultimately determines the value of the patent at issue.

FDA approval, for obvious reasons, certainly provides extensive evidence that a new drug is useful. Pharmaceutical inventors must demonstrate safety and efficacy in order to show the FDA that the drug merits approval. Even assuming a patent lacked utility at the time of filing, acquiring FDA approval is a lengthy process, demonstrating significant investment in the product and likely a good faith belief in the utility of the product at the time the patent was filed. Given that the patent term is actually tied to the regulatory approval process, offering an inventor additional time to demonstrate utility after filing for the patent seems a logical extension.

FDA approval also addresses obviousness. In order to support an IND and justification for clinical research, a drug maker must present cogent arguments articulating the scientific need for and value of the new drugs, which may

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170 See FDA, New Drug Application, supra note 41.
include an explanation of why a new drug is potentially superior to currently marketed drugs. Moreover, obviousness in the pharmaceutical context carries different policy concerns than it does in other contexts. Viewed broadly in patent law, obviousness protects against patents for meaningless inventions lacking any originality. In the pharmaceutical industry, however, a useful drug that may have been obvious at the time the patent was filed based on the prior art still requires extensive investment and development in order for consumers to use it. In other words, obviousness should not outweigh the incentive to bring a new drug to the market, even if the inventor created the compound primarily from the prior art. The modified quid pro quo in pharmaceutical patent law allows for offering a patent for an invention that may be viewed as legally obvious in exchange for the development of a safe and useful new drug based on the prior art.

Harris and Fay's proposed patent reform, discussed above, also helps to address the possible loophole with regard to obviousness by allowing potential infringers to challenge the patent prior to it becoming incontestable. Potential challengers questioning the obviousness of a patent would not be prevented from raising that challenge; rather, they would need to do so before the drug receives FDA approval. Given that Hatch-Waxman offers up to a five-year extension, depending on the amount of time until regulatory approval, potential patent challengers could have several years before the drug is approved and the patent becomes incontestable. After approval, potential infringers would have notice that they could no longer challenge the validity of the patent.

The largest obstacle to an incontestable patent based on FDA approval is the Congressional decision to make generic drugs more available through the Hatch-Waxman Act. However, those aspects of the Hatch-Waxman Act that did make generic entry easier, particularly the creation of the ANDA to reduce research required for generic drugs, would still be available and relevant. An incontestable patent would not eliminate generic manufacturers' ability to rely on the patentee's clinical research information. It would merely demand that when a generic manufacturer files an ANDA the manufacturer knows it is not infringing, or presents a stronger challenge to validity than the basic arguments of inequitable conduct, obviousness, and lack of utility.

Just as trademark law offers an exception to incontestability when a trademark is functional, patent law's incontestability could incorporate certain limitations that would still enable some challenges to the patent. In the same

171 See IND Content and Format, 21 C.F.R. § 312.23 (2011).
172 Harris & Fay, supra note 151, at 37–38.
way that trademark is concerned with a competitive edge under functionality, the primary policy concern with an incontestable patent is that it could be used to prevent competitors from research and development in the same arena. For this reason, in patent law, the exception to incontestability should be for enablement arguments on the basis of undue experimentation. Such an argument is based on the claim that the alleged infringer's product was not enabled by the patentee's patent because the infringer had to conduct undue experimentation in order to create its product. The classic example is Thomas Edison's light bulb, which technically fell within the claims of an earlier light bulb patent. The earlier patent called for "fibrous materials" to be used as the filament for the light bulb. Edison, in creating his light bulb, experimented with a wide array of plant and fibrous materials in order to create his light bulb, ultimately selecting bamboo as the filament. The Court stated that a holding allowing the original patentee to block off the entire world of plant and fibrous materials "would be an unwarranted extension of his monopoly, and operate rather to discourage than to promote invention."

These arguments are not entirely addressed by FDA approval, which should not be used to support an overly broad patent that restricts scientific advancement. Certainly, the average generic manufacturer presenting a bioequivalent drug would have difficulty arguing that the patentee had not enabled the generic drug. However, when a patentee has filed an overly broad patent, and within the scope of that patent has created a useful new drug, the scope of the patent should still be susceptible to legal challenge when another drug manufacturer has created a drug that falls within the scope of the patent but is not enabled by that patent. Some leeway needs to exist for new drug development to continue.

Allowing the exception for lack of enablement when a patent requires undue experimentation can balance some concerns about eliminating the utility argument. Although undue experimentation and utility are components of enablement, an argument on the basis of utility borders on the absurd when applied to a useful new drug. However, the undue experimentation argument is still useful in certain cases where a patentee has simply claimed more than he or she was entitled to.

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174 See, e.g., Consol. Elec. Light Co. v. McKeensport Light Co., 159 U.S. 465 (1895); 35 U.S.C. § 112 (2006) ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.").
176 Id.
177 Id. at 472–73.
178 Id. at 476.
she has earned. Those cases where a patent literally cuts off relevant research that leads to new drugs should be the only patents of concern in the pharmaceutical industry. These instances can properly be addressed through undue experimentation.\textsuperscript{179}

IV. CONCLUSION

Reforming the pharmaceutical industry is no small task. Many brilliant legal minds have sought, through a variety of mechanisms, to reduce healthcare costs while maintaining incentives for innovation. However, innovation in the pharmaceutical industry comes at high costs to the inventors and to consumers. Those inventors who create a useful new drug need to recover the cost of their investments, particularly when a company has invested billions of dollars in developing a drug from initial research all the way through regulatory approval. Sometimes, these inventors seek to expand their profits through off-label marketing of their new drugs. Although federal officials have worked diligently for years to curb off-label marketing, federal courts have recently begun to undermine those efforts through patent law. A federal court decision to invalidate a drug patent for an FDA-approved drug erodes the value of the patent and eliminates the incentive to seek FDA approval for the patented use.

Patent law need not, however, conflict with federal pharmaceutical regulatory goals. Reviewing recent court decisions, much needless litigation and uncertainty with regard to the security of a pharmaceutical patent could be remedied through new rules acknowledging the role the FDA plays in pharmaceutical development. The Federal Circuit should create a rule that no FDA-approved drug patent will be invalidated for lack of utility. Furthermore, Congress, in an effort to better coordinate the link between patent law and FDA approval, should create an incontestable patent for those patents covering FDA-approved drugs and FDA-approved uses.

Despite efforts to promote generic entry into the market, Congress has also created a more litigious atmosphere in the pharmaceutical industry. Rather than making access easier, one byproduct of the Hatch-Waxman Act has been litigation and settlement agreements to keep generics off the market until the patent expires. These settlement agreements impose dead-weight costs on the original drug manufacturers and on consumers that ultimately increase the prices of the patented product.

Acknowledging the realities at work within the system, in particular the notion that generic drug entry will always be particularly litigious and therefore

somewhat more expensive than desirable, adopting simple rules to modify the issues that can be litigated could significantly reduce needless costs in the pharmaceutical industry.