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The Need to Reform in Pharmaceutical Protection: The Inapplicability of the Patent System to the Pharmaceutical Industry and the Recommendation of a Shift Towards Regulatory Exclusivities

Amanda Fachler
Fordham University School of Law

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Cover Page Footnote

J.D., 2014, Fordham University School of Law; B.S., 2011, University of Maryland. I extend endless gratitude to Mom, Dad, and Adam for believing in me and loving me unconditionally. I would also like to especially thank Professor Deborah Denno for her guidance with this Note, her unwavering support, and for inspiring to push the limits of my capabilities.

The Need for Reform in Pharmaceutical Protection: The Inapplicability of the Patent System to the Pharmaceutical Industry and the Recommendation of a Shift Towards Regulatory Exclusivities

Amanda Fachler^{*}

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INTRODUCTION

Millions of lives are saved each year thanks to the production and distribution of increasingly innovative pharmaceuticals. These technological advances are not created without cost, however; the pharmaceutical industry is one of the most heavily regulated and must expend substantial time and money researching and developing products that will be safe and effective for public consumption.¹ As a result, the pharmaceutical industry relies more than any other on the patent system as a means of ensuring returns for its substantial investments.² While pharmaceutical companies

¹ See Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really \$802 Million?*, 25 HEALTH AFF. 420, 420 (2006); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 151 (2003).

² See Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 721 (2005); Adam Lewin, *Medical Device Innovation in America:*

are incentivized to innovate through market exclusivity in patent protection, the enormous public benefits they provide demand effective and meaningful protection for the innovators in this industry.

However, the pharmaceutical industry faces many obstacles: the United States is suffering one of the largest drug shortages in history; research and development costs for pharmaceutical companies are rising; the number of new drugs entering the market is declining; and pharmaceutical innovation is stifled.³ Many of these setbacks appear directly linked to the difficulties drug companies face when entering a new product into the market, as they are challenged by the interplay of the patent system and federal approval from the Food and Drug Administration (“FDA”).⁴ The ever-increasing cost—in both time and money—of successfully receiving patent protection and FDA approval of a new drug excessively burdens drug companies and suppresses their incentive for innovation.⁵ Although critics have characterized the patent system as the road to profit and the FDA regulations as a speed-bump on that road, it is actually the conflict created by the combination of the two systems—systems that can only be constructive if they can effectively work in tandem—that hinder the market-entry process.⁶ Significantly, the timeline of market entry renders it impossible for these companies to receive the total benefit of their patented market-exclusivity because of the stringent standards that govern the process.⁷ Pharmaceutical companies must decide whether to pursue innovation despite the

Tensions Between Food and Drug Law and Patent Law, 26 HARV. J.L. & TECH. 403, 404 (2012).

³ See Matthew Herper, *The Cost of Creating a New Drug Now \$5 Billion, Pushing Big Pharma to Change*, FORBES, Aug. 11, 2013, <http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine>.

⁴ See Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 351–52 (2007).

⁵ See *id.*

⁶ See generally Lewin, *supra* note 2, at 403 (discussing the conflicts created by the interplay of the FDA approval process and the patent system, and noting their effect on market entry).

⁷ See Ronald L. Desrosiers, *The Drug Patent Term: Longtime Battleground in the Control of Health Care Costs*, 24 NEW ENG. L. REV. 115, 120–21 (1989).

certainty they will not receive maximum rewards, limit their medical advances to products that they are positive will receive patentability and likely gain federal approval, or simply leave the industry and invest elsewhere. Worse, these companies may be tempted to enter into the newly-regulated compounding pharmaceutical market, one that is notoriously less stable but may guarantee a better turnaround for their investments. Consequently, it is ultimately consumers who suffer, because they are denied innovative medical discoveries, required to pay larger sums to get their hands on the available drugs in an increasingly scarce market, or are forced to obtain drugs from a less reliable industry. Though patent reform and FDA regulatory review are topics that have been proposed numerous times, never has a proposal for change been so urgent as it is now.

Part I of this Note will provide background information on market entry, discussing both the patent system as well as the FDA approval requirements. Part I will also analyze the difficulties that pharmaceutical companies face when attempting market entry of a new drug because of the intricate challenges inherent in FDA approval and the patent application process. Further, this Part will provide a brief background on the current state of the pharmaceutical industry, which would benefit from more fluidity.

Part II of this Note will address the conflicts engendered by both the requirements for patentability and the problems with the effective patent protection afforded once a patent application is approved. This Part will separately address each of the three requirements for patentability, and discuss the problems they create as applied to pharmaceuticals. Last, this Part will discuss the conflict arising from the length of the patent term as it relates to the pharmaceutical industry due to the timeline of creating a successful drug product.

Finally, Part III of this Note will argue that pharmaceutical protections should be revisited to render them more able to serve the interests of drug companies and consumers alike. This Part will also recommend ways to reform the FDA regulatory process to generate a more efficient system for the pharmaceutical industry with respect to both market entry and market exclusivity while preserving the incentive to innovate.

I. A BACKGROUND ON MARKET ENTRY IN THE PHARMACEUTICAL INDUSTRY: THE PATENT PROCESS, REGULATORY DRUG APPROVAL, AND THE CURRENT STATE OF THE INDUSTRY

Pharmaceuticals in the United States constitute a multi-billion dollar industry, which provides value to the public through innovative technologies and essential drugs. In order to appreciate the discussion of pharmaceutical protection, one must understand how pharmaceuticals enter the market and the steps each drug must undergo to achieve market entry. These steps include both the patent process as well as approval from the FDA. Additionally, in order to understand the necessity of revisiting the protections surrounding the pharmaceutical industry—and, specifically, the incentives in place to fuel pharmaceutical innovation—one must have a greater understanding of the current state of the industry and certain prominent trends therein.

A. *The Federally Regulated Pharmaceutical Industry*

The commercial drug industry enhances the public good by providing health services. While the Food and Drug Administration was created with intent to regulate medicines and vaccines in the early 1900s, it was not until the 1930s that the FDA as it is now known took effect.⁸ In 1938, the Food, Drug, and Cosmetic Act was created to mandate the safety of pharmaceuticals and laid out the requirements for pre-marketing approval and proof of clinical testing with respect to the pharmaceutical industry.⁹ Subsequent drug regulations continued to follow, including laws that separated over-the-counter drugs from prescription drugs,¹⁰ mandated that large-scale manufacturers abide by registration requirements and stricter safety and efficacy

⁸ See Hasumati Rahalkar, *Historical Overview of Pharmaceutical Industry and Drug Regulatory Affairs*, S11 PHARMACEUTICAL REG. AFF. 002, 3 (2012), available at <http://www.omicsgroup.org/journals/historical-overview-of-pharmaceutical-industry-and-drug-regulatory-affairs-2167-7689.S11-002.pdf>.

⁹ Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399f (2012)).

¹⁰ Durham–Humphrey Amendment, Pub. L. No. 82-215, 65 Stat. 648 (1951) (current version at 21 U.S.C. §353).

standards,¹¹ and endeavored to incentivize pharmaceutical innovators by means of patent protections.¹² Due to these regulations, drug companies must make substantial investments to produce and develop a new drug for market entry, a process that results in famously high costs to consumers.¹³ Although the pharmaceutical industry must necessarily rely on the government to grant the market approval it needs to make its drugs commercially available, it has also notoriously relied heavily on patent protection to ensure a high rate of profit to make up for development costs.¹⁴ For years, patents, which have traditionally been viewed as a “fundamental incentive to innovative activities in pharmaceuticals and biotechnology,”¹⁵ have acted in tandem with the federal regulatory approval process to shape the pharmaceutical industry as it exists today.

1. Market Entry Overview

Pharmaceutical companies that wish to bring a new drug to the market must engage in a multistep process that includes both receiving a patent and gaining approval from the FDA. While patent approval affords protection to pharmaceuticals that are new and useful—thereby enabling a competitive advantage and market exclusivity—the FDA grants approval only to those drugs that are safe and effective.

All processes combined, the market-entry process is notoriously costly and timely.¹⁶ A 2013 *Forbes* report tracked

¹¹ U.S. Kefauver Harris Amendment, Pub. L. No. 87-781 76 Stat. 780 (1962) (current version at 21 U.S.C. §§ 301-92).

¹² Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 35 U.S.C. §271(e) (2012)).

¹³ See Paul D. Jorgensen, *Pharmaceuticals, Political Money, and Public Policy: A Theoretical and Empirical Agenda*, 41 J.L. MED. & ETHICS 561, 563 (2013).

¹⁴ See M.J. Murray, *The Pharmaceutical Industry: A Study in Corporate Power*, 4 INT’L J. HEALTH SERVICES 625, 637 (1974).

¹⁵ F. Pammoli et al., *Global Competitiveness in Pharmaceuticals: A European Perspective*, prepared for the Directorate General Enterprise of the European Commission, November 2000, available at http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/comprep_nov2000_en.pdf.

¹⁶ See Vincent J. Roth, *Will FDA Data Exclusivity Make Biologic Patents Passé?*, 29 SANTA CLARA COMPUTER & HIGH TECH. L.J. 249, 251 (2013).

ninety-eight publicly traded biotechnology and drug companies over the past decade with data from the Innothink Center for Research in Biomedical Innovation and found that the average cost-per-drug for a pharmaceutical company to introduce between eight and thirteen drugs into the market was \$5.3 billion.¹⁷ A different study from researchers at Tufts University revealed that the average cost-per-drug for new-drug development is roughly \$802 million.¹⁸ Though initially challenged, the Tufts study was later confirmed by further estimates, which revealed even higher calculated averages for companies introducing one drug into the market.¹⁹ Furthermore, the time spent on patent approval combined with the time spent conducting clinical trials to satisfy FDA approval can result in a market-entry process that lasts as long as fourteen years.²⁰

a) The Patent System: The General Process and the Patent Term

Patent law has been described as the “classic legal embodiment of innovation.”²¹ Few industries, if any, rely as heavily on the patent system and the protection afforded thereunder as the

¹⁷ See Herper, *supra* note 3 (explaining that the high costs pharmaceutical companies spend per drug must also account for encountered failures during the R&D process).

¹⁸ See DiMasi et al., *supra* note 1, at 166.

¹⁹ See Adams & Brantner, *supra* note 1, at 420 (estimating an average R&D cost per drug of \$868 million); Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 *MANAGERIAL & DECISION ECON.* 469, 469, 475 (2007) (estimating an R&D cost per drug of \$1.24 billion for large-molecule biopharmaceuticals); see also Jim Gilbert et al., *Rebuilding Big Pharma's Business Model*, 21 *IN VIVO: BUS. & MED. REP.* 10, (2003), available at http://www.bain.com/bainweb/PDFs/cms/Marketing/rebuilding_big_pharma.pdf (adding that these costs notably include not only successful drug products and clinical trial outcomes, but also failed drug products and all failed attempts).

²⁰ See Dennis Fernandez, James Huie & Justin Hsu, *The Interface of Patents with the Regulatory Drug Approval Process and How Resulting Interplay Can Affect Market Entry*, in *INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES* 969 (A. Krattiger et al. eds., 2007) [hereinafter *Interface of Patents with Regulatory Approval*], available at www.ipHandbook.org (noting that the FDA approval process typically takes between ten and twelve years, and the patent approval process takes an average of three years).

²¹ See Lewin, *supra* note 2, at 412.

pharmaceutical industry.²² The invention of pharmaceuticals is driven by the security that patent protection provides in ensuring that the company is both compensated for its investments in research and development (“R&D”) and made profitable by its competitive advantage in the form of exclusivity. This protection for innovation has significant social value because the security granted to pharmaceutical companies is meant to fuel innovation and thereby provides health benefits for the public.

With respect to the pharmaceutical industry, patents provide legal protection for the new medicines discovered by research-based pharmaceutical companies. Patents give their owners the right to use and exclude others from using an invention or discovery for a limited period of time,²³ which in turn enables the pharmaceutical innovator the ability to recoup her investment. Pharmaceutical patents are granted to “compositions of matter” that are “new and useful,”²⁴ and are subject to the conditions that the invention or discovery is both novel²⁵ and non-obvious.²⁶ Importantly, patent-holders must fully disclose the research and science underlying their discoveries,²⁷ which makes such information available to the public at large. The average patent pendency—the time between when an application is filed and when the patent is either approved or denied—is about two and a half years.²⁸ Approved patented products receive market exclusivity for 20 years from the date that the application of the patent was filed.²⁹ However, patents are issued very early on in a product’s development; for pharmaceutical innovations, they are

²² See Eisenberg, *supra* note 2, at 721; Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 507 (2009); Robert Weissman, *A Long, Strange Trips: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT’L ECON. L. 1069, 1075–85 (1996).

²³ See *Patents*, USPTO, <http://www.uspto.gov/patents/index.jsp> (last visited Apr. 15, 2014).

²⁴ 35 U.S.C. § 101 (2012).

²⁵ *Id.* § 102.

²⁶ *Id.* § 103.

²⁷ *See id.*

²⁸ See U.S. PAT. & TRADEMARK OFF., PERFORMANCE AND ACCOUNTABILITY REP. FISCAL YEAR 2013 (2013).

²⁹ See 35 U.S.C. § 154.

issued before the clinical trial testing required for FDA approval has occurred.³⁰ As a result, the effective market-exclusivity term for pharmaceutical companies is considered a more limited monopoly, typically spanning 14 years of its exclusive term,³¹ and possibly none of its term at all.³²

Pharmaceutical companies invest hundreds of millions—and in some cases even billions—of dollars into R&D for new drugs, while generic companies do not need to spend as much for their market entry because they can rely on the clinical trial results and satisfied approval requirements submitted by the patented pharmaceutical company.³³ Without patent protection, it is unlikely that pharmaceutical companies would make the costly investments necessary to provide this social benefit because they would never be able to recover these investments.³⁴ It is for this reason that the patent system is typically acknowledged as a successful and necessary component of pharmaceutical development; despite the higher cost to consumers who purchase patented drugs, the drugs might not exist but for patent protection.³⁵

i. Patent Term Extensions Through Regulatory Exclusivities

There are a number of opportunities afforded to pharmaceutical patents to supplement the term provided by the Patent Act. These

³⁰ See Eisenberg, *supra* note 4, at 348.

³¹ See Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 *MANAGERIAL & DECISION ECON.* 491, 492 (2007) (noting that the “maximum effective patent life” is fourteen years).

³² See Eisenberg, *supra* note 4, at 348 (“Much (or even all) of the term of these initial patents may have expired by the time the products are brought to market.”).

³³ See 21 U.S.C. § 355(j) (2012) (listing the FDA generic drug application requirements).

³⁴ See Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 *YALE L.J.* 1900, 1908 (2013) (“Conventional economic actors will only produce a good when they can appropriate sufficient returns to recoup the capitalized costs of providing the good.”); see also Roin, *supra* note 22, at 508 (highlighting the basic economic concept of corporate hesitation to invest in ideas without a chance of substantial returns).

³⁵ See Roin, *supra* note 22, at 508.

extensions have been referred to as regulatory exclusivities³⁶ or “pseudo-patents.”³⁷ The Orphan Drug Act of 1983³⁸ and the Hatch–Waxman Act of 1984³⁹ were the first of these exclusivities to have an impact on the patent system with respect to pharmaceuticals. The Orphan Drug Act provides a financial incentive to pharmaceutical companies that create drugs to treat rare diseases and conditions⁴⁰ by providing extended market exclusivity, among other financial aids like grants and tax exemptions.⁴¹ The Hatch–Waxman Act of 1984 increased the effective exclusivity period for new brand-name drugs and also provided drug innovators with market exclusivity for making changes to a previously approved drug product.⁴² Thus, this Act grants drug innovators the ability to temporarily prevent generic companies from relying on their updated R&D information to create a generic drug.⁴³ The act also seeks to lower drug prices through competition, and still enables generic companies to file for FDA approval by relying on the brand-name drug’s approval application for a previously approved drug.⁴⁴ Several years after the passage of these Acts, The Food and Drug Administration Modernization Act of 1997 (FDAMA) created an additional

³⁶ See John R. Thomas, *Into a Silver Age: U.S. Patent Law 1992–2012*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 525, 541 (2013).

³⁷ See Eisenberg, *supra* note 4, at 359.

³⁸ Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended in 21 U.S.C. §§ 360aa–360ee).

³⁹ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 35 U.S.C. § 271(e) (2012)).

⁴⁰ 21 U.S.C. § 360bb (defining “rare” as “any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug”).

⁴¹ *Id.* § 360cc–ee. Though not stated in the Act, drugs that treat rare diseases are “commonly referred to as orphan drugs because, prior to the Act, few drug companies were willing to ‘adopt’ products to treat these diseases.” M. ANGELES VILLARREAL, CONG. RESEARCH SERV., RS20971, ORPHAN DRUG ACT: BACKGROUND AND PROPOSED LEGISLATION IN THE 107TH CONGRESS (2001).

⁴² Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch–Waxman Act), Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (codified at 35 U.S.C. § 271(e)).

⁴³ *Id.*

⁴⁴ *Id.*

incentive in the form of an exclusivity term extension for drugs with applications to pediatric medicine.⁴⁵

b) An Overview of the FDA Regulatory Approval Process and Its Role in the Pharmaceutical Industry

After receiving patent approval but before entering the market, a pharmaceutical product must receive FDA approval, which assures that the new product is both safe and effective enough to be made commercially available.⁴⁶ While the patent process is viewed as the key to success for pharmaceutical innovators, the FDA approval process is traditionally perceived as both an economic and time-consuming setback.⁴⁷ With a patent term already running, drug companies wish to expedite any further approval requirements as quickly and inexpensively as they can to gain maximum profitability with their limited market-exclusivity.⁴⁸ However, pharmaceutical companies can spend up to several billion dollars per new drug to gain entry into the market.⁴⁹ About half of the money that companies spend on R&D is spent performing clinical trials in order to satisfy the FDA regulations governing market approval.⁵⁰ Furthermore, the FDA approval process can take as long as ten to twelve years.⁵¹ Importantly, the cost to pharmaceutical companies does not stop after approval; the final phase of safety and quality assessments that occur during the

⁴⁵ Food and Drug Administration Modernization Act of 1997, 111 Stat. 2296 (1997) (codified as amended at 21 U.S.C. § 301).

⁴⁶ 21 U.S.C. § 355.

⁴⁷ See Eisenberg, *supra* note 4, at 349; Rebecca S. Eisenberg, *The Shifting Functional Balance of Patents and Drug Regulation*, 20 HEALTH AFF. 119, 132 (2001).

⁴⁸ See Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When Is It the Best Incentive System?*, in 2 INNOVATION POLICY AND THE ECONOMY 51, 70 (Adam B. Jaffe et al. eds., 2001) (noting that a running patent causes drug firms to make every effort to accelerate progress because their reward is conditional on the success of the drug as well as the amount of time they are competitively valuable).

⁴⁹ See Herper, *supra* note 3.

⁵⁰ See DiMasi et al., *supra* note 1 (estimating clinical-period costs of \$467 million per drug).

⁵¹ See *Interface of Patents with Regulatory Approval*, *supra* note 20, at 966.

post-marketing period can cost pharmaceutical companies between twenty and thirty million dollars.⁵²

The requirements that must be met for approval of a newly patented drug are extensive, and the FDA has the authority to deny market approval to any drug that does not meet its standards.⁵³ Most importantly, these requirements include investigatory reports of clinical trials, which demonstrate the drug's safety and efficacy.⁵⁴ They also require chemical-ingredient lists accompanied by a statement of the drug's composition; a detailed report containing how and where the drug was manufactured, processed and packaged; samples of the drug or its components at the request of the Secretary; samples of the proposed drug label; and any supplemental documentation as deemed necessary by the Secretary or with respect to the drug's pending approval.⁵⁵ The application for FDA approval typically also requires the inclusion of the respective patent for which drug the applicant seeks approval.⁵⁶ Though FDA approval is still required for generic drugs, the standards that generic drug companies must meet are far less exacting than those governing new drugs.⁵⁷

In total, the FDA approval process requires successfully completing twelve steps from the preclinical through post-marketing periods.⁵⁸ These steps include animal testing and an outline for proposed human testing in the preclinical period, three phases of human testing and studies in the clinical period, meeting time, application submission, application review, research review, labeling review, and facility review in the New Drug Application

⁵² See Charles Steenburg, *The Food and Drug Administration's Use of Postmarketing (Phase IV) Study Requirements: Exception to the Rule?*, 61 FOOD & DRUG L.J. 295, 370 (2006).

⁵³ 21 U.S.C. § 355(b) (2012).

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ Compare *id.* (approval requirements for newly developed products), with § 355(j) (approval requirements for generic products).

⁵⁸ *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA, <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm> (last visited May 22, 2014).

review period, and then a final decision from the FDA.⁵⁹ Furthermore, there is also a fourth phase of safety monitoring and risk assessment that occurs during the post-marketing period, because it is presumably impossible to determine all of the effects of any given drug in the clinical trial phases alone.⁶⁰

B. Current Industry Trends: Compounding Pharmacies and Nationwide Drug Shortage

In order to understand why it has become so necessary to review the protections surrounding the pharmaceutical industry and move towards reform, it is important to be made aware of the current state of the entire pharmaceutical industry as well as certain relevant trends. Both the recent unprecedented federal regulation of compounding pharmacies, as well as the ongoing nationwide drug shortage, play a role in ensuring that pharmaceutical innovation is at its highest and that the incentives provided to innovators are both reliable and effective.

1. The Non-Federally Regulated Pharmaceutical Market:
Compounded Drugs

In addition to the federally regulated pharmaceutical industry, there is also another large but traditionally unregulated sector of pharmaceutical manufacturers in the United States—compounding pharmacies. According to a *Forbes* article from September 2013, a “2012 article in *Nature Reviews Drug Discovery* says the number of drugs invented per billion dollars of R&D invested has been cut in half every nine years for half a century.”⁶¹ Furthermore, with the costs of R&D steadily increasing and the rate of success steadily declining, small companies stand almost no chance of competing in the industry, becoming swallowed by the pharmaceutical giants who have greater resources to invest in a drug that might potentially succeed.⁶² This leaves a smaller company with two basic options: (1) become an exclusively

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ See Herper, *supra* note 3.

⁶² See *id.*

generic drug company; or (2) adopt drugs that were abandoned by large companies, forfeiting the opportunity to patent its own drugs and potentially costing enormous amounts of money to purchase a patent license.⁶³ However, soon there may be another option available to such companies, as the traditionally unregulated compounding pharmacies have recently become targeted by regulators.

Compounding drug pharmacies began in the 1800s, and used to be the only source of prescription medication.⁶⁴ Traditionally, compounding pharmacies filled special orders placed by doctors for individual patients.⁶⁵ The purpose of compounding pharmacies was to address these individual patient needs on a small scale by customizing prescription medications in small batches on a case-by-case basis. Today, there are currently over 50,000 compounding pharmacies in the United States.⁶⁶

Until very recently, state pharmacy boards—and not the FDA—oversaw compounding pharmacies. This is unlike the commercial drug manufacturing process discussed above, whose products are subject to intensive oversight.⁶⁷ In 1997, the FDA crafted the first piece of legislation to address compounding pharmacies, the FDAMA.⁶⁸ Under the FDAMA, true compounding pharmacies were exempt from various FDA regulations: the Act exempted compounded drugs from FDA approval and registry and compounding pharmacies from compliance with any “Good Manufacturing Practices” or safety

⁶³ *See id.*

⁶⁴ *See* DAVID L. COWEN & WILLIAM H. HELFAND, PHARMACY: AN ILLUSTRATED HISTORY 100–01 (1990).

⁶⁵ *See Ohio: Ohio Weighs Changes in Execution Methods with Focus on Obtaining New Sources of Lethal Drugs*, U.S. OFFICIAL NEWS, at 2 (Feb. 16, 2013).

⁶⁶ *See* Kara Net Hinkley, *Compounding Pharmacies: Compounding Interest*, 06.2013 NAT'L CONF. ST. LEGIS. MAG. 22, 23 (2013).

⁶⁷ *See* STAFF OF DEL. EDWARD J. MARKEY, STATE OF DISARRAY: HOW STATES' INABILITY TO OVERSEE COMPOUNDING PHARMACIES PUTS PUBLIC HEALTH AT RISK 6 (2013) [hereinafter STATE OF DISARRAY] (a report written by the staff of then Congressman, now Senator Edward J. Markey (D–MA) using the responses to an investigation which examined the state oversight of compounding pharmacies).

⁶⁸ Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105–115, § 127, 111 Stat. 2296, 2328 (1997).

and efficacy standards.⁶⁹ The theory behind these seemingly permissive regulations is that “public health concerns are minor when mass production is not involved,” and it is not until mass manufacturing occurs that safety and effectiveness become a greater risk.⁷⁰ Compounding pharmacies have the ability to perform quality control with ease because of the small quantities produced at a time, so deferring to state authorities for regulation was deemed reasonable.⁷¹

Regulations governing these pharmacies remained untouched until October 2012, when a contaminated steroid produced by the New England Compounding Center (NECC) in Massachusetts killed or injured hundreds.⁷² The NECC was allegedly one of the many compounding pharmacies that operated more like a large drug manufacturer than a small-scale compounding pharmacy.⁷³ The FDA took direct action to find the root of the safety issues plaguing the NECC by inspecting several compounding pharmacies, and the results of their inquiry proved disturbing.⁷⁴

⁶⁹ See Jessica Dye, *U.S. Senate Committee Advances Drug Compounding Bill*, REUTERS (May 22, 2013), <http://www.reuters.com/article/2013/05/22/us-fda-drugs-legislation-idUSBRE94L1AU20130522>; see also STATE OF DISARRAY, *supra* note 67, at 6.

⁷⁰ See Jesse M. Boodoo, *Compounding Problems and Compounding Confusion: Federal Regulation of Compounded Drug Products and the FDAMA Circuit Split*, 36 AM. J.L. & MED. 220, 232–34 (2010).

⁷¹ See *id.*

⁷² See CTRS. FOR DISEASE CONTROL & PREVENTION, MULTI-STATE OUTBREAK OF FUNGAL MENINGITIS AND OTHER INFECTIONS—CASE COUNT (2013), available at http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html#casecount_table. For more information on the meningitis outbreak and the continually developing outcomes, see Scott Gottlieb, *Compounding a Crisis at FDA*, FORBES, May 24, 2013, <http://www.forbes.com/sites/scottgottlieb/2013/05/24/compounding-a-crisis-at-fda>.

⁷³ See STAFF OF DEL. EDWARD J. MARKEY, COMPOUNDING PHARMACIES COMPOUNDING RISK 10 (2012) [hereinafter COMPOUNDING RISK] (a report written by the staff of then Congressman, now Senator Edward J. Markey (D-MA)).

⁷⁴ See U.S. FOOD & DRUG ADMIN., SUMMARY: 2013 FDA PHARMACY INSPECTION ASSIGNMENT 10 (2012), available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm347722.htm>. Faulty pharmacy conditions included “unidentified black particles floating in vials of supposedly sterile medicine; rust and mold in ‘clean rooms’ where sterile injectable medications were produced; technicians handling supposedly sterile products with bare hands; and employees wearing non-sterile lab coats.” Margaret A. Hamburg, *Proactive Inspections Further Highlight Need for New Authorities for Pharmacy Compounding*, FDA VOICE

After attempts to initiate regulatory changes to the compounding pharmacy market, a final piece of proposed legislation was signed into law in November of 2013.⁷⁵ This regulatory law, entitled the “Drug Quality and Security Act,”⁷⁶ clarifies current federal law about pharmacy compounding in an effort to create a uniform, nationwide standard applicable to compounding pharmacies.⁷⁷ The Act separates regulation over traditional small-scale compounding pharmacies from large-scale compounders that operate more like pharmaceutical manufacturers, and creates a category for these types of pharmacies called “outsourcing facilities.”⁷⁸ It also provides voluntary federal registration for outsourcing facilities, set to begin in 2015.⁷⁹ These facilities will be permitted to compound bulk quantities of drugs on the FDA’s drug shortage list, in addition to other drugs that are on a “‘clinical need’ list to be established by the FDA, without a prescription, as well as distribute these formulations out of state without limitation.”⁸⁰ Registered outsourcing facilities will be subject to FDA oversight similar to the oversight to which regular commercial pharmaceutical manufacturers in the United States are subjected.⁸¹ The FDA will also have the authority to conduct risk-based inspections.⁸² Further, certain drugs will be listed as prohibited from being compounded at these facilities.⁸³

(Apr. 11, 2013), <http://blogs.fda.gov/fdavoices/index.php/2013/04/proactive-inspections-further-highlight-need-for-new-authorities-for-pharmacy-compounding> (Dr. Margaret A. Hamburg is the Commissioner of the Food and Drug Administration). In her post, Dr. Hamburg linked to SUMMARY: 2013 FDA PHARMACY INSPECTION ASSIGNMENT, *supra* note 74, to reference the inspections conducted.

⁷⁵ See, e.g., Sabrina Tavernise, *Bill on Drug Compounding Clears Congress a Year After a Meningitis Outbreak*, N.Y. TIMES, Nov. 19, 2013, at A15.

⁷⁶ Drug Quality and Security Act of 2013, Pub. L. No. 113-54, 127 Stat. 587 (2013).

⁷⁷ *Id.* § 503B.

⁷⁸ *Id.*

⁷⁹ *Id.* § 744K.

⁸⁰ See Press Release, Imprimis Pharmaceuticals, Imprimis Optimistic After Congressional Passage of the Drug Quality and Security Act (Nov. 19, 2013), available at <http://online.wsj.com/article/PR-CO-20131119-905263.html?dsk=y>.

⁸¹ Drug Quality and Security Act of 2013, Pub. L. No. 113-54, 127 Stat. 587 (2013).

⁸² *Id.* § 503B(b)(4).

⁸³ *Id.* § 503B(a)(5)–(6).

2. Nationwide Drug Shortage

An ongoing nationwide drug shortage also bears upon the reform of the pharmaceutical industry as it currently exists. The nationwide drug shortage in the United States has persisted for several years; hundreds of drugs appear on a federal notice shortage list including cancer drugs, anesthetics for surgery, drugs for emergency medicine, and electrolytes for intravenous feeding.⁸⁴ Manufacturing problems, production disruption, approval oversight, need for recall, increased demand, and a shift towards compounding pharmacies are all included in the ongoing list of reasons for the unprecedented shortage.⁸⁵ More often than not, manufacturing problems occur as a result of quality-control problems with the product or the facility in which the product is created—areas the FDA regulatory approval process is designed to monitor before market entry occurs.⁸⁶ Drug shortages are a unique feature of the pharmaceutical industry because the supply and demand of necessary drugs operates differently than supply and demand in other markets given that prices cannot fix the need for essential medications.⁸⁷ Also, the shelf life of drugs is an

⁸⁴ See Katie Thomas, *Drug Shortages Persist in U.S., Harming Care*, N.Y. TIMES, Nov. 16, 2012, at A1; *Current Drug Shortages Index*, FDA, <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm> (last visited June 6, 2014).

⁸⁵ See U.S. FOOD & DRUG ADMIN., STRATEGIC PLAN FOR PREVENTING AND MITIGATING DRUG SHORTAGES 11 (2013) [hereinafter STRATEGIC PLAN FOR DRUG SHORTAGES], available at <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf> (explaining that “[o]nce a manufacturer experiences a discontinuance or interruption in manufacturing, a shortage will occur if there is no other manufacturer to step in to fill the gap in supply, or if other manufacturers cannot increase production quickly enough to make up the loss” (citing J. Woodcock and M. Wosinska, *Economic and Technological Drivers of Generic Sterile Injectable Drug Shortages*, 93:2 CLINICAL PHARMACOLOGY & THERAPEUTICS 170, 174–75 (2013))); see also KEVIN HANINGER, AMBER JESSUP & KATHLEEN KOEHLER, ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, OFF. OF SCI. & DATA POL’Y, ISSUE BRIEF: ECONOMIC ANALYSIS OF THE CAUSES OF DRUG SHORTAGES 1 (2011) [hereinafter ECONOMIC ANALYSIS], available at <http://aspe.hhs.gov/sp/reports/2011/DrugShortages/ib.shtml>.

⁸⁶ See STRATEGIC PLAN FOR DRUG SHORTAGES, *supra* note 85, at 1 (including issues “such as roof leakage; mold in manufacturing areas; or unsterilized vials or containers to hold the product”). Quality issues are those that pose a serious risk to the health and safety of patients, and often include problems related to contamination or sterility of the product and facility. *Id.*

⁸⁷ ECONOMIC ANALYSIS, *supra* note 85, at 1.

important consideration because of how dangerous the consumption of expired pharmaceutical products may be.⁸⁸

Drug shortages directly affect consumers because of the necessity for access to a particular drug.⁸⁹ In fact, in direct response to the pleas from desperate patients in 2011, President Obama was effectively forced into issuing an executive order providing that drug makers must notify the FDA when a shortage appeared imminent.⁹⁰ Most importantly, however, the drug shortage has also caused the FDA to loosen its grip on drug importation procedures as well as on drug approvals for manufacturers.⁹¹ In fact, part of the FDA's strategic plan to address these drug shortages is to expedite the review of drug products that are facing a shortage, and to use its discretion in enforcing approval of drugs that are considered medically necessary.⁹² The impact of a drug shortage on drug companies is that hasty drug approval, for example, may force a company that is in the process of developing a new drug product to regress and redirect its focus on a product that has already entered the market. The reasons for drug shortages and the additional post-market approval and review subsequently required may cut into effective patent terms and add to the costs of R&D. Accordingly, the frequency of drug shortages may provide insight into a revisiting of patent protection, specifically with respect to the term.

⁸⁸ See STRATEGIC PLAN FOR DRUG SHORTAGES, *supra* note 85, at 4.

⁸⁹ See Thomas, *supra* note 84, at A1.

⁹⁰ Press Release, White House Office of the Press Secretary, We Can't Wait: Obama Administration Takes Action to Reduce Prescription Drug Shortages, Fight Price Gouging: President Issues Executive Order, Backs Legislation to Require Drug Companies to Report Shortages (Oct. 31, 2011), <http://www.whitehouse.gov/the-press-office/2011/10/31/we-can-t-wait-obama-administration-takes-action-reduce-prescription-drug>.

⁹¹ U.S. FOOD & DRUG ADMIN. CTR. FOR DRUG EVALUATION AND RES., MANUAL OF POLICIES AND PROCEDURES, MAPP 6003.1: DRUG SHORTAGE MANAGEMENT 4 (2012), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/ucm079936.pdf>.

⁹² See U.S. FOOD & DRUG ADMIN., STRATEGIC PLAN FOR PREVENTING AND MITIGATING DRUG SHORTAGES 13–14 (2013), available at <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf>.

II. THE INHERENT CONFLICT BETWEEN THE PATENT SYSTEM AND THE PHARMACEUTICAL INDUSTRY

The patent system operates effectively with respect to industries that would suffer from unfair market disadvantages if they were barred from developing a superior version of a product that is not original enough to warrant overarching monopolistic protection. However, the patent system is often viewed as a poor fit as it is applied to the pharmaceutical industry.⁹³ Although inventions in other markets may still be created even if they cannot receive patent protection, the same does not hold true in the case of pharmaceuticals. There are few other industries, if any, in which participants must spend as much money to gain market entry, and the pharmaceutical industry is burdened by this cost not only because of the complexities involved in making a drug, but also because of the regulatory barrier created by the FDA in order to ensure that drugs on the market are safe and effective.

A. *The Difficulty with Applying the Patent Requirements to the Pharmaceutical Industry*

All three patent requirements engender conflict when they are applied to the pharmaceutical industry. The useful, novel, and non-obvious⁹⁴ requirements are seen as a shortcoming in Patent law with respect to advancing the interests of the pharmaceutical industry. The utility requirement serves as an inappropriate standard for pharmaceuticals because of how early in the R&D process drug patents are filed. Further, the novel and non-obvious requirements of Patent law “operate to prevent valuable drugs from being patented before they have been developed for public use.”⁹⁵ The patent system offers no reward for investing in clinical trials if one of these standards is not met.⁹⁶

⁹³ See Eisenberg, *supra* note 4, at 364–65.

⁹⁴ 35 U.S.C. §§ 101–103 (2012).

⁹⁵ Roin, *supra* note 22, at 516 (noting that these requirements fail to ultimately consider that the significance of a patent stems directly from the social value that the public receives from a product, not simply from knowledge of the information underlying that product).

⁹⁶ See *id.*

1. The Utility Requirement

The utility requirement of Patent law conflicts with the nature of pharmaceutical law. The Supreme Court specifically articulated that the useful requirement of patent law is not a “hunting license,” meaning that patent law exists to reward the conclusions rather than the search.⁹⁷ This requirement is sufficient for most products, whose creators can easily establish the utility they provide upon application. In the context of pharmaceuticals, the reasonableness of this requirement is clear: Patent law seeks to protect valuable inventions, and a drug only has value so long as it is useful.⁹⁸ However, the nature of the pharmaceutical industry effectively requires the utility standard to be lowered because the actual usefulness of a drug cannot possibly be proved at the onset of patent application.⁹⁹ Instead, a drug company must invest significant amounts of time and money into R&D, as explained above, in order to meet the FDA clinical requirements that will eventually determine whether or not the drug is actually useful to the extent that it was set out to be in its patent.¹⁰⁰ Courts have recognized the cyclical nature of this problem; indeed, a drug company needs guaranteed intellectual property protection over the information disclosed in its patent and will not invest time or money into pharmaceutical innovation without that protection.¹⁰¹ As a result, the USPTO has adjusted the current standard for utility for pharmaceutical patents to any “reasonable correlation” between a drug’s pharmacological activities, or how the drug works, and how or why that product will work in humans as it is asserted in the patent application.¹⁰² The USPTO even instructs patent examiners that proof of clinical testing in humans for patent approval is an “unnecessary burden” for pharmaceutical patents.¹⁰³ This is certainly a departure from the utility standard that almost

⁹⁷ See *Brenner v. Manson*, 383 U.S. 519, 536 (1966).

⁹⁸ See Eisenberg, *supra* note 2, at 720.

⁹⁹ See *id.* (“Patent protection on drugs typically begins and ends too early to permit firms to capture the full value of subsequently developed information about drug effects.”).

¹⁰⁰ See Herper, *supra* note 3.

¹⁰¹ See *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995).

¹⁰² MPEP § 2107.03 (9th ed. Mar. 2014).

¹⁰³ *Id.*

all other kinds of patent applications require, as well as a departure from the high bar that the *Brenner* Court established for proof of utility for a patent.¹⁰⁴ It also serves as an acknowledgement that the utility standard is not appropriate on its face with respect to pharmaceuticals.¹⁰⁵

2. The Novelty Requirement

Oversight of the pharmaceutical industry is also part and parcel of the novelty requirement. Once a claimed invention has been made available to the public before its effective filing date, it is generally considered no longer novel, and therefore not patent eligible.¹⁰⁶ An exception exists for inventors or joint inventors who have disclosed their invention or idea within one year of the effective filing date.¹⁰⁷ Such publications are not considered prior art,¹⁰⁸ thus encouraging the early application of patentable creations. The patent system is designed to reward inventions that the public could not receive if not for the incentives gained from protection. Of course, there is no reason to protect information once it is publicly available in order to obtain its value because it is freely accessible.¹⁰⁹ It is for this reason that the novelty requirement is perceived as a sensible and central bar to patent approval, no matter the invention seeking protection.¹¹⁰ However,

¹⁰⁴ *Brenner v. Manson*, 383 U.S. 519, 534–35 (1966).

¹⁰⁵ See Eisenberg, *supra* note 2, at 724.

¹⁰⁶ The novelty doctrine bars the patent approval for any innovation that was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or “the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.” 35 U.S.C. § 102(a) (2012).

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* § 102(b). The specific language of this statute includes exceptions for “(1) disclosures made 1 year or less before the effective filing date of the claimed invention; and (2) disclosures appearing in applications and patents.” *Id.*

¹⁰⁹ See *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186 (1933) (explaining the purpose of rewarding inventors who “give something of value to the community by adding to the sum of human knowledge”).

¹¹⁰ See Roin, *supra* note 22, at 519 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 5–6 (1966) (quoting U.S. CONST. art. I, § 8, cl. 8)) (noting the Supreme Court’s reverence of the novelty requirement as the key to promoting the constitutional purpose for patents).

this broad application of the novelty doctrine overlooks the needed incentive for protecting the actual pharmaceutical development of patented invention, a concept that plays a crucial role in this industry.¹¹¹

The nature of the pharmaceutical industry—and, in particular, the FDA approval requirement—conflicts with the novelty requirement in a unique way. Patents are awarded in return for the disclosure of an invention but without any regard for the development of that idea.¹¹² This concept threatens the pharmaceutical industry in several ways. A considerably small percentage of proposed drugs ever even make it through all of the required phases of FDA approval,¹¹³ so the public never actually gains access to the patented drug but, rather, to the drug information. Furthermore, it is common for scientific journals and academic publications to disclose drugs in such a way that those publications therefore stand as a bar to patentability.¹¹⁴ Often, courts make matters worse by “invalidating drug patents on the basis of seemingly trivial disclosures often made before anyone recognized the value of the drug or knew enough about it to file a patent.”¹¹⁵ However, because the information has been disclosed, it is no longer considered novel and therefore can no longer be patented for use in a drug that passes FDA approval in the future.¹¹⁶ Accordingly, this requirement creates a paradox with respect to patent protection for pharmaceuticals “wherein a new

¹¹¹ See Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919, 924–26 (2011). Note that while this argument utilizes pre-AIA patent law, the analysis regarding novelty remains the same for the post-AIA patent law with respect to the pharmaceutical industry.

¹¹² See *id.* at 924–25.

¹¹³ For example, a study conducted from 2004 through 2010 found only 7% of traditional small molecule chemical drugs that entered human clinical trials obtained FDA marketing approval. See Bill Berkrot, *Success Rates for Experimental Drugs Falls: Study*, REUTERS (Feb. 14, 2011), <http://uk.reuters.com/article/2011/02/14/health-us-pharmaceuticals-success-idUKTRE71D2U920110214>.

¹¹⁴ See Roin, *supra* note 22, at 517.

¹¹⁵ *Id.*

¹¹⁶ See Seymore, *supra* note 111, at 948–49.

drug can become unpatentable before it has been tested in clinical trials.”¹¹⁷

This problem arises frequently because it is quite common for information in the pharmaceutical industry to be disclosed, either intentionally or accidentally.¹¹⁸ The patent system, with respect to such disclosure, places researchers who are simultaneously working in the same area in a difficult position insofar as the novelty requirement serves as a barrier to pharmaceutical patents.¹¹⁹ Patent applications for pharmaceuticals typically include a broad range of all of the drugs in consideration for compounding because the application process occurs so early in R&D.¹²⁰ It is difficult to know at that time which drugs will actually be compounded to create the final developed drug product, so the application becomes a type of catchall to ensure protection for the patent owner.¹²¹ However, some of the disclosed drugs are eventually discarded, mistakenly or otherwise, and as a result are not able to be patented for use in subsequent drug development even if they could prove valuable in the future.¹²² Thus, innovators may be forced to give up their patent and consequently forfeit their

¹¹⁷ Roin, *supra* note 22, at 520. “In the pharmaceutical industry, this rule means that a drug cannot be patented if the idea for it was previously disclosed to the public; no exception is made for when the disclosed drug has not yet been tested in clinical trials and thus has not been approved by the FDA.” *Id.* at 517. “As a result, the novelty requirement makes it easy for valuable drugs to become unpatentable before they have been developed for public use.” *Id.* While not the main issue of the case, an illustration of this problem occurred in the facts underlying a case in 2007 when the Federal Circuit heard an issue relating to a drug that was invented based on the idea of combining two older drugs to create an even more beneficial effect. *See* Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1322–23 (Fed. Cir. 2007). Although the company was unaware that the other drug information was previously publicly disclosed, its patent on the combination drug became unenforceable once the previous publication was realized, despite the fact that the tangible value received by the combination was unknown to the public before the idea was patented and FDA approved.

¹¹⁸ *See* Roin, *supra* note 22, at 522.

¹¹⁹ *See* Stephen T. Schreiner & Patrick A. Doody, *Patent Continuation Applications: How the PTO’s Proposed New Rules Undermine an Important Part of the U.S. Patent System with Hundreds of Years of History*, 88 J. PAT. & TRADEMARK OFF. SOC’Y 556, 557 (2006).

¹²⁰ *See id.*

¹²¹ *See id.*

¹²² *See* Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521, 1542–43 (2005).

research for what could have developed into a vital and valuable drug product.¹²³ Those abandoned applications that inventors are forced to give up can then be considered as prior art for future applications.¹²⁴ Moreover, it is also possible that lost within this broad range of information is the disclosure of a new drug that a researcher does not even realize he has disclosed.¹²⁵ Further, the doctrine of inherent anticipation dictates that a drug is not considered novel if it has been unknowingly disclosed, even if the researchers do not realize their own discovery.¹²⁶ Accordingly, this doctrine interacts with the novelty requirement in a way that precludes patent approval for drugs that may have provided the public with a large social benefit but whose value can never be realized because certain information was disclosed in an unrecognizable way. While support for this doctrine may be reasonable for certain inventions,¹²⁷ it overlooks and suppresses innovation for others, namely pharmaceuticals. For other products whose development does not require the same level of complexity as pharmaceuticals do, knowledge of those inventions may reasonably preclude patentability because the public can already benefit from disclosure of that knowledge.¹²⁸ However, without the subsequent R&D of drugs, the costs of which drug companies rely on patent protection to cover, the public will never benefit from a pharmaceutical simply because its underlying information was disclosed,¹²⁹ because the drug will never make its way to

¹²³ See Roin, *supra* note 22, at 528; see also Moore, *supra* note 122, at 1542–43.

¹²⁴ See MPEP § 901.02 (9th ed. 2014).

¹²⁵ See Maria Souleau, *Legal Aspects of Product Protection—What a Medicinal Chemist Should Know About Patent Protection*, in *THE PRACTICE OF MEDICINAL CHEMISTRY* 707, 721 (Camille Georges Wermuth ed., 2d ed. 2003), available at <http://www.sciencedirect.com/science/book/9780127444819>.

¹²⁶ See Roin, *supra* note 22, at 526 (“Consequently, whenever a drug is unknowingly disclosed to the public, it can cease to be novel before anyone knows about it, and the patent system will no longer reward any efforts to discover it or establish its therapeutic value.”).

¹²⁷ See Dan L. Burk & Mark A. Lemley, *Inherency*, 47 *WM. & MARY L. REV.* 371, 383–84 (2005).

¹²⁸ See *id.*

¹²⁹ See Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 *HIGH TECH. L.J.* 1, 55, 65–69 (1992) (discussing the disclosure theory and noting how sometimes, the disclosure of technical information alone may benefit the public).

gaining FDA approval and entry into the market. The complexity inherent in to the actual invention of a pharmaceutical product demonstrates that a drug only has value so long as it is developed and tested by creators who understand those complexities. Because of the necessity for FDA approval in order to enter the market, the value of a drug is heavily dependent on product development and production of information about whether a drug is safe and effective, and not simply the information alone.¹³⁰

Lastly, the ability to obtain patents in the pharmaceutical industry is often undercut by the novelty requirement because of the nature of the development and research that is required in order to invent a beneficial drug. University and private-sector researchers are often pressured to publish their findings for new drug discoveries given the nature of their work.¹³¹ However, the weight given to academic publishing makes it difficult to keep certain elements of research confidential as information may be published before its value is realized,¹³² and it is not always clear which portions of the research must remain secretive in order to ensure patentability.¹³³ This problem is clearly evidenced by the large number of universities that were unable to patent their “life-science” discoveries because of published research.¹³⁴ Moreover, the idea that the novelty requirement conflicts in its application to

¹³⁰ See JERRY AVORN, POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS 39–68 (2004) (examining the extensive clinical trial procedures that are necessary in order to adequately identify drugs that hold significant value).

¹³¹ See Joshua A. Newberg & Richard L. Dunn, *Keeping Secrets in the Campus Lab: Law, Values and Rules of Engagement for Industry-University R&D Partnerships*, 39 AM. BUS. L.J. 187, 208 (2002) (discussing the pressure academic researchers encounter to publish their findings early, because of its influence on hiring and job security as well as preference for research grants, and academic awards).

¹³² See *Nichols Inst. Diagnostics, Inc. v. Scantibodies Clinical Lab., Inc.*, 195 F. App'x 947, 952 (Fed. Cir. 2006) (finding that a patent on certain antibodies was anticipated by the inventors' own abstract, in which they had inadvertently disclosed the patented antibodies, even though the “significance of the claimed antibody was not known until after the abstract was submitted”).

¹³³ See Roin, *supra* note 22, at 527.

¹³⁴ See Eric G. Campbell & Eran Bendavid, *Data-Sharing and Data-Withholding in Genetics and the Life Sciences: Results of a National Survey of Technology Transfer Officers*, 6 J. HEALTH CARE L. & POL'Y 241, 252 (2003) (finding that 82% of universities with large medical-research programs were unable to patent at least one of these inventions because of research publications).

the pharmaceutical industry is well supported by the numerous drugs that have been denied patents for lack of novelty.¹³⁵

3. Non-Obvious Requirement

The final requirement for patent approval, the non-obviousness standard, also clashes with pharmaceutical innovation. Described as the “the most important of the basic patent requirements,”¹³⁶ this requirement helps uphold the true purpose of patent law in “promot[ing] the Progress of . . . useful Arts.”¹³⁷ The non-obviousness requirement ensures that only the results of true innovation discovered through risks and effort are rewarded, and not the “results of ordinary innovation[.]”¹³⁸ The non-obviousness requirement precludes patent approval for subject matter that is obvious, before the effective filing date of the invention, to a person who has an “ordinary skill in the art” which the invention pertains to.¹³⁹ In the context of pharmaceuticals, patents are not awarded to drug discoveries that are the results of “routine procedures” that produce expected results,¹⁴⁰ where a skilled drug researcher or chemist would have to do no more than simply verify

¹³⁵ See, e.g., *Ex parte* Ames, No. 2007-1138, 2007 WL 1033514, at *3–4 (B.P.A.I. Mar. 28, 2007); *Ex parte* Sander-Struckmeier, No. 2005-1150, 2005 WL 4773290, at *3–5 (B.P.A.I. Aug. 25, 2005); *Ex parte* Williams, No. 2005-0902, 2005 WL 4773220, at *4 (B.P.A.I. June 22, 2005); *Ex parte* Bhagwat, No. 2003-1424, 2004 WL 366282, at *4 (B.P.A.I. Jan. 6, 2004); *Ex parte* Bennett, No. 2003-1678, 2004 WL 318775, *4–5 (B.P.A.I. Jan. 1, 2004); *Gilbert v. Levin*, No. 2004-1391, 2004 WL 1697793, at *2 (B.P.A.I. Jan. 1, 2004); *Ex parte* Feldmann, No. 2002-0253, 2003 WL 25281968, at *2–4 (B.P.A.I. Mar. 21, 2003); *Ex parte* D’Antonio, No. 1998-1987, 2001 WL 35825743, at *6–10 (B.P.A.I. July 24, 2001); *Ex parte* Hofmann, No. 1996-0729, 1999 WL 33548892, at *4–5 (B.P.A.I. Sept. 14, 1999) (rejecting the claims on a compound proposed as a treatment for HIV, but allowing the method-of-use claims to issue); *Ex parte* Saito, No. 94-4009, 1999 WL 33230062, at *5–6 (B.P.A.I. June 9, 1999); *Ex parte* Murrer, No. 95-2603, 1995 WL 1696811, at *5 (B.P.A.I. Jan. 1, 1995); *Ex parte* Picard, No. 95-2879, 1995 WL 1696846, at *4 (B.P.A.I. Jan. 1, 1995).

¹³⁶ ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 611 (4d ed. 2007).

¹³⁷ U.S. CONST. art. I, § 8, cl. 8.

¹³⁸ See *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007).

¹³⁹ 35 U.S.C. § 103(a) (2012); see also *In re* Dow Chemical Co. 837 F.2d 469, 473 (Fed. Cir. 1988) (stating that patents are not awarded where “the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in light of the prior art”).

¹⁴⁰ *Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 809 (Fed. Cir. 1989).

the successful results of those reasonable expectations.¹⁴¹ However, like the novel requirement, this standard for patent approval overlooks the unique nature of pharmaceutical development.

The practical application of this standard is what makes it inappropriate for pharmaceutical inventions. Alarming, in application, the non-obviousness standard denies patent protection to an idea or concept for a new drug that is expected to produce successful results—*drugs that are expected to benefit the public are facially denied patent protection*.¹⁴² Therefore, the general rule is that “the more likely it appears that a new drug will be successful, the less likely it is to be patentable under the non-obviousness requirement.”¹⁴³ The outcome of this rule as an effect of the non-obviousness standard creates a paradoxical result for the pharmaceutical industry, because drugs that seem to hold significant value early in their development may almost certainly be denied patent protection.¹⁴⁴

Furthermore, the non-obviousness standard denies patent protection for a potentially obvious idea without considering the substantial investment necessary to give that idea value. The public gains no benefit from an idea or concept, no matter how obvious, until an investment is made into that idea’s development.¹⁴⁵ A major criticism of the non-obviousness requirement is that it does not take the cost of development into account¹⁴⁶ and, therefore, fails to consider the possibility that

¹⁴¹ See *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1367 (Fed. Cir. 2007).

¹⁴² See *id.* at 1371 (“[A]ny superior property must be unexpected to be considered as evidence of non-obviousness.” (citing *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987))). For example, when a pain reliever was characterized as having a “substantially greater analgesic effectiveness than one of the most, if not the most, active analgesic compound of the art,” its patent application was rejected because these superior drug properties were deemed predictable based on its chemical structure. *In re Carabateas*, 345 F.2d 1013, 1017–18 (C.C.P.A. 1965).

¹⁴³ See Roin, *supra* note 22, at 537 (citing *Ex parte Childers*, No. 2003-0890, 2003 WL 25277879, at *4 (B.P.A.I. Dec. 22, 2003)).

¹⁴⁴ See *id.*

¹⁴⁵ See WILLIAM J. BAUMOL, *THE FREE-MARKET INNOVATION MACHINE: ANALYZING THE GROWTH MIRACLE OF CAPITALISM* 10 (Princeton Univ. Press 2002).

¹⁴⁶ Compare Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1678 (2003) (“If patents are to drive innovation in biotechnology, rather than

although an idea may be obvious, its development into an invention that reaches the public may never occur “without a patent to motivate its development.”¹⁴⁷ Incorrectly, this standard assumes that, once the concept for any invention is “accessible to the public through its obviousness, the invention itself will also be available.”¹⁴⁸ While a non-obvious standard forms a reasonable barrier to patentability for inventions in other industries that can be easily developed once underlying information is disclosed or easily obtained, the cost of R&D provides a disincentive to drug companies to invest in a new product absent patent protection.¹⁴⁹ “The non[-]obviousness standard is therefore based on the dubious assumption that obvious inventions do not have significant development costs, or that firms will always be willing to incur those costs without having patents on the inventions.”¹⁵⁰

Perhaps the most alarming conflict of the non-obviousness standard with the pharmaceutical industry is that it creates a paradoxical result for the medical community because scientific advances in pharmaceutical technology serve to exacerbate the issue of non-obviousness.¹⁵¹ As researchers and scientists work to make the process of drug discovery and development more predictable, and subsequently more efficient, the non-obviousness standard becomes more of a barrier, by denying patent protection for products that rely on that predictability.¹⁵²

merely invention . . . courts must take account of the cost and uncertainty of post-invention testing and development.”), with MERGES & DUFFY, *supra* note 136, at 34 (arguing against awarding patents on the basis of commercialized and developmental costs).

¹⁴⁷ Roin, *supra* note 22, at 535.

¹⁴⁸ *Id.* at 522 (citing Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 69 (1992)).

¹⁴⁹ See Eisenberg, *supra* note 4, at 350.

¹⁵⁰ Roin, *supra* note 22, at 533.

¹⁵¹ See *id.* at 542 (“[T]he non[-]obviousness requirement, almost by definition, turns progress in the pharmaceutical sciences against itself; that is, it denies patent protection to new drugs based on the very advances in science that led to their discovery.”); *id.* (“Through their successes, medicinal chemists are beginning to get better at predicting the pharmacological properties of compounds based on their structure.”).

¹⁵² See *id.*

B. Conflict with the Patent Term

An additional conflict that exists between the patent system and the pharmaceutical industry is the timeline of the patent term. Pharmaceutical innovators rely on the market exclusivity granted through patent protection to make returns on their investments in their products.¹⁵³ This market exclusivity serves as an incentive to invest and take risks, as well as security for profitability.¹⁵⁴ Unlike most other products, however, pharmaceuticals require extensive FDA testing and approval before their product ever gains entry into the market.¹⁵⁵ In recent years, the FDA has implemented even more requirements and has created higher standards that must be met.¹⁵⁶ As discussed above, these clinical trial periods can last as long as ten to twelve years, and therefore cut into the twenty-year exclusivity term in a significant and detrimental way.¹⁵⁷ Indeed, regardless of the amount of time the clinical trials take, the FDA approval process guarantees the impossibility for a pharmaceutical company to enjoy the market exclusivity benefits of its full patent term.¹⁵⁸ The largest conflict here, from the position of pharmaceutical innovators, is that patents should be meaningful for as long as they are set to be, and “what Congress grants should not be taken away by regulatory agencies.”¹⁵⁹ Furthermore, the unpredictability of the patent system with respect to its application

¹⁵³ See Christopher M. Holman, *Unpredictability in Patent Law and Its Effect on Pharmaceutical Innovation*, 76 MO. L. REV. 645, 650 (2011).

¹⁵⁴ See *id.* (classifying the process of developing, testing, and marketing a drug as a “notoriously expensive and high risk gamble”); see also Roin, *supra* note 22, at 503.

¹⁵⁵ See Grabowski & Kyle, *supra* note 31, at 493.

¹⁵⁶ See Bill Berkrot, *Success Rates for Experimental Drugs Falls: Study*, REUTERS (Feb. 14, 2011), <http://uk.reuters.com/article/2011/02/14/health-us-pharmaceuticals-success-idUKTRE71D2U920110214>.

¹⁵⁷ See *Interface of Patents with Regulatory Approval*, *supra* note 20, and accompanying text.

¹⁵⁸ See Desrosiers, *supra* note 7, at 120–21 (1989) (“Since many FDA pre-market testing requirements are yet to be performed after the point most patents are obtained, a manufacturer is unable to market the drug for the full . . . patent term.”).

¹⁵⁹ *Id.* at 124 (citing *Patent Term Extension and Pharmaceutical Innovation: Hearing Before the Subcomm. on Investigations and Oversight of the Comm. on Sci. and Tech.*, 97th Cong. 18 (1982)) [hereinafter *Patent Hearings*] (statement of Robert S. Walker, U.S. Rep., Pa.) (citing *The Half-Life Patents*, N.Y. TIMES, May 23, 1981, <http://www.nytimes.com/1981/05/23/opinion/the-half-life-patents.html>).

to pharmaceuticals has also had a deteriorating impact on the effective market exclusivity term that innovators actually enjoy for their patented products.¹⁶⁰

III. A PROPOSED SHIFT TOWARDS REWARDS-BASED INCENTIVES OR REGULATORY EXCLUSIVITIES INSTEAD OF PATENT-BASED PROTECTION FOR THE PHARMACEUTICAL INDUSTRY

In return for the benefits afforded to pharmaceutical companies under patent protection, the companies provide health benefits to the public. This relationship serves as a particularly strong incentive for the provision of adequate protection to pharmaceutical innovators. Until recently, the patent system was not perceived as a barrier to innovation.¹⁶¹ Recently, however, industry critiques of the patent system as it currently exists have explained how the system is a problem for many companies, in that it is no longer feasible to predict how long a company's patent exclusivity term will actually last.¹⁶² Without such predictability, the patent system becomes useless for pharmaceutical innovators and investors.

Despite their need to work in tandem, the patent system and the FDA regulatory approval process have been known to lack the cooperation necessary to operate effectively with respect to the pharmaceutical industry; “[p]atent protection is based on an

¹⁶⁰ See Holman, *supra* note 152, at 648 (citing Robert Armitage, A Fresh Start on Limiting Patent Eligibility: Barring Patents Where Information or the Exercise of Human Intellect is an Element of a Purported Invention, U. Ill. C. L. (Sept. 22, 2010), www.law.uiuc.edu/facultyadmin/chakrabarty/videos/armitage.html). Law suits from either generic drug companies or other innovators challenging patent validity, inconsistent judicial application of patent law and standards, post-market entry clinical testing, and product recall are just a few of the many setbacks in pharmaceutical industry that make the effective patent term unpredictable. *Id.* at 648–51.

¹⁶¹ Compare WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 316 (2003) (“The strongest case for patents in something like their present form is said to be found in a subset of the drug industry.”), with Kapczynski & Syed, *supra* note 34, at 1951 (“[Proposed incentive] approaches fill in a gap left by patents’ failure to incent valuable but highly nonexcludable innovations, and they counter the tendency of patents to exacerbate the problem by drawing resources away from such innovations.”).

¹⁶² See Holman, *supra* note 153, at 648–51.

exclusively scientific inquiry that ignores the related issue of FDA approval necessary for a pharmaceutical manufacturer to fully use its patent.”¹⁶³ Additionally, for the pharmaceutical industry, the current patent system does not achieve its intended goal in advancing innovation. Rather, the current patent system inhibits innovation due to its overbroad requirements and a far too limited term period that do not cooperate with FDA approval, deeming patent protection meaningless. “The current unpredictable environment, wherein the investment backed expectations of investors are given short shrift, disincentivizes investment and thereby hampers innovation.”¹⁶⁴

For the patent system to work, it must actually enhance innovation, a goal that is not being met with respect to pharmaceuticals.¹⁶⁵ Economists and scholars have approached the difficulties presented by the current U.S. patent system in several different ways, debating whether there are better schemes than patent protection to incentivize pharmaceutical innovation.¹⁶⁶ The exploration of alternative strategies has increased in recent years, but no substantial reform has been made with respect to the pharmaceutical industry and the patent system.¹⁶⁷ Alternative approaches need to be implemented in order to ensure the continuance of innovative, effective, and beneficial health products in a federally regulated and safe pharmaceutical market. These approaches include a proposed rewards-based incentive program for pharmaceutical innovators and shifting the limited monopoly

¹⁶³ Sarah Renée Craig, *Placebo Patents: Creating Stronger Intellectual Property Protection for Pharmaceuticals Approved by the U.S. Food & Drug Administration*, 19 J. INTELL. PROP. L. 143, 147 (2011) (citing *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 731 F. Supp. 2d 348, 348–50 (D.N.J. 2010), *aff'd in part, rev'd in part*, 435 F. App'x 917 (Fed. Cir. 2011)).

¹⁶⁴ Holman, *supra* note 153, at 650–51.

¹⁶⁵ See Jorgensen, *supra* note 13, at 563.

¹⁶⁶ See, e.g., Gallini & Scotchmer, *supra* note 48, at 51; Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 AM. ECON. REV. 691 (1983).

¹⁶⁷ See Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1045 (2005).

ensured by the patent system to a regulatory market-exclusivity that will become part of the FDA market entry drug process.

Before these proposed alternatives are addressed, it is necessary to acknowledge how the patent system should be reformed in a way that better accommodates pharmaceuticals. The long development cycles, approval cycles, and heavy regulations on patented pharmaceuticals distinguish them from other types of products with shorter development cycles or that are subject to less regulation. In fact, the “one size fits all” approach adopted by many intellectual property laws, and patent laws in particular, has been met with strong criticism.¹⁶⁸ Integrating Patent law more harmoniously with the pharmaceutical industry may prove to be an inconvenient and time-consuming undertaking¹⁶⁹ that is not as efficient as other proposed alternatives. Moreover, reforming Patent law so that it better serves the pharmaceutical industry may be unfair to other industries and, more pressingly, violates the WTO TRIPS agreement that ensures that patent protection is enforced in a way that is nondiscriminatory with respect to “the place of invention, the field of technology and whether products are imported or locally produced.”¹⁷⁰ Furthermore, creating a patent that is specific to the pharmaceutical industry—thereby rendering such patents similar to design patents—is an undertaking that would likely take years of reform, thus providing no immediate benefit to the pharmaceutical industry. This naturally presents a problem in light of the time-sensitive nature of the need for, and social benefit provided by, pharmaceuticals. Instead, a different incentive program or set of FDA regulations would better resolve the conflicts presented by the patent system as it currently relates to the pharmaceutical industry.

¹⁶⁸ See Gallini & Scotchmer, *supra* note 48, at 71 (“Each IP regime should cover subject matter with similar needs for protection, especially if heterogeneous needs cannot be remedied by courts. Many controversies arise because of heterogeneity within IP regimes.”); see also Eisenberg, *supra* note 4, at 364 (“But the needs of these fields for patent protection differ greatly, making it difficult to fine-tune the patent laws to meet the needs of the pharmaceutical industry without upsetting the balance of protection and competition in other industries.”).

¹⁶⁹ See Thomas, *supra* note 36, at 542.

¹⁷⁰ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, 33 I.L.M. 1197 (1994).

A. Rewards-Based Incentives

For over thirty years, it has been recognized that patents are not necessarily the best incentive for innovation.¹⁷¹ There has been significant debate over the benefit that the exclusivity incentives of patents truly provide, suggesting that perhaps rewards-based incentive programs are better suited for sparking innovation in the pharmaceutical industry.¹⁷² As discussed in Part II, the requirements of patent protection do not allow for free and full innovation because such requirements effectively bar the use of certain drugs due to their patent ineligibility, even including those that may prove to be the most likely to succeed. Accordingly, it is important to invest in an incentive program that allows total usage of all drugs, rewarding those that provide heightened social value instead of those that are simply novel and non-obvious.

In response to an urge to make use of “technology inducement prizes”¹⁷³ as well as Congress’s clear grant of authority to offer prizes,¹⁷⁴ various government agencies have awarded millions of dollars in prizes to reward and incentivize innovation.¹⁷⁵ Rewards systems pay innovators directly, thus incentivizing innovation

¹⁷¹ See Wright, *supra* note 166, at 69.

¹⁷² See Gallini & Scotchmer, *supra* note 48; Kapeczynski & Syed, *supra* note 34, at 1951; Kapeczynski et al., *supra* note 167, at 1045 (“Economists have long debated whether direct government funding or prize systems would have better welfare effects than patents.”); Aidan Hollis, An Efficient Reward System for Pharmaceutical Innovation 4–9 (Jan. 17, 2005) (unpublished manuscript), available at <http://www.who.int/intellectualproperty/news/Submission-Hollis6-Oct.pdf> (“Because pharmaceutical markets function poorly, the patent system does not effectively stimulate drug research and development. Instead, it induces large amounts of research into drugs with relatively little incremental therapeutic value, while providing inadequate incentives to innovate in some areas of great therapeutic value.”).

¹⁷³ See NAT’L ACAD. OF ENG’G, CONCERNING FEDERALLY SPONSORED INDUCEMENT PRIZES IN ENGINEERING AND SCIENCE, app. A, at 1–2 (1999) (defining each term).

¹⁷⁴ See America COMPETES Reauthorization Act of 2010, H.R. 5116, 111th Cong. (2d Sess. 2011) (codified at 15 U.S.C. § 3719 (2012)) (granting agencies the authority to “carry out a program to award prizes competitively to stimulate innovation that has the potential to advance the mission of [each] respective agency”). President Obama has also recently urged agencies to make use of their ability to offer rewards as an incentive for innovation. See NAT’L ECON. COUNCIL ET AL., A STRATEGY FOR AMERICAN INNOVATION: SECURING OUR ECONOMIC GROWTH AND PROSPERITY 12 (2011).

¹⁷⁵ See Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303, 308 (2013).

without providing a monopolistic advantage.¹⁷⁶ Instead of providing an exclusivity period to make up for the money expended during R&D and clinical testing, grants awarded to innovative drugs could support those costs on the front end, while prizes awarded could reward and supplement that costly development process post-market entry.¹⁷⁷ Furthermore, reward systems redistribute the source of the money provided to the innovator from the consumer, who benefits from the product (through purchase), to the government.¹⁷⁸ Under a rewards system, the government and interested agencies could incentivize innovation in a number of different ways.¹⁷⁹ One reward includes offering a prize for the first creator of a certain kind of drug. Another reward is a grant to decrease the costs of R&D for drugs that target certain illnesses or demonstrate a high likelihood of success. A third such reward is a tax credit on the costs of R&D. The timing of a reward system varies and thus differs from the patent system in a meaningful way. Although the benefit of such rewards, like patents, are reaped after R&D because they are granted to innovators who actually prove successful, grants and tax incentives depart from this condition of Patent law because they are typically awarded before R&D occurs (and not as a retroactive reimbursement).¹⁸⁰

¹⁷⁶ See Steven Shavell et al., *Rewards Versus Intellectual Property Rights*, 44 J.L. & ECON. 525, 525 (2001).

¹⁷⁷ See Jorgensen, *supra* note 13, at 563 (citing Marc A. Rodwin, *Independent Clinical Trials to Test Drugs: The Neglected Reform*, 6 ST. LOUIS U. J. HEALTH L. & POL'Y 113 (2012)).

¹⁷⁸ See Hemel & Ouellette, *supra* note 175, at 308. Importantly, some of the funding for rewards may come from independent agencies or private donors, while in the case of government grants, for example, this really just means the wealth distribution comes from taxpayers. *See id.* at 345.

¹⁷⁹ For a detailed discussion and monetary breakdown of an example of what each of the many suggestions for a rewards-incentive program looks like, see Hemel & Ouellette, *supra* note 175, at 311–12. This discussion also reveals a cost-benefit analysis of each of these rewards, acknowledging what each has that the others may be lacking. *See id.* Further, the article suggests how to assess the amount of money for each reward based on the likelihood of success or demand for the drug. *Id.* This Note acknowledges the difficulty involved in assessing a monetary reward amount. *See, e.g.,* Shavell et al., *supra* note 176 (although specific considerations that should be taken into account to price each reward are outside the scope of this Note).

¹⁸⁰ See Hemel & Ouellette, *supra* note 175, at 333.

One concern for a rewards system is the difficulty involved in calculating the amount of money to be offered in each reward. Although this challenge is more difficult with prize rewards than tax credits or grants, the government simply does not have enough information at the early stage of R&D—that is, when rewards would be offered—to devise an appropriate reward.¹⁸¹ This component of a rewards-based system makes patents seem more favorable, because the benefit of patents directly correlates to the success of the product once it is on the market.¹⁸² Notably, however, a rewards-based system could simply be made “to value a project’s inputs rather than its outputs,”¹⁸³ relying on the profits the pharmaceutical product brings its creator due to its market success to reflect the value of the outputs.¹⁸⁴

Another concern is that completely replacing the patent system with a rewards-based system hurts pharmaceutical innovators, because issuing a set reward and denying all market exclusivity leaves no room for unexpected additional profits. However, being the first to create a pharmaceutical product still provides a creator with a competitive advantage.¹⁸⁵ Even if generic companies can figure out how to copy the pharmaceutical product through reverse engineering or otherwise, the original creators may still enjoy a high level of profitability simply because those creators are the brand-name makers of that product.¹⁸⁶ Accordingly, a rewards-based program can be used to incentivize pharmaceutical innovation while still preserving the profits generated by being the first and the best in the market.

¹⁸¹ See Shavell et al., *supra* note 175, at 526.

¹⁸² See Gallini & Scotchmer, *supra* note 48, at 70.

¹⁸³ See Hemel & Ouellette, *supra* note 175, at 314.

¹⁸⁴ In an ideal world, social value could be calculated in a way that the prize could easily reflect its worth. See Gallini & Scotchmer, *supra* note 48, at 70 (“Prizes could serve the same purposes if the size of the prize could be linked to the social value but without the deadweight loss of monopoly pricing.”).

¹⁸⁵ See Hemel & Ouellette, *supra* note 175, at 310.

¹⁸⁶ See Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & ECON. 331, 340 (1992) (discussing that findings revealed that, despite the fact that brand-name drug prices triple generic drug prices, brand-name drugs still retain approximately fifty percent of their market share two years after generic entry).

B. Regulatory Exclusivities

With respect to the pharmaceutical industry, the patent system and the FDA regulatory approval process are in disharmony. The patent process does not sufficiently account for the elements of the FDA approval process and their impact on the pharmaceutical industry in a way that makes the effective patent term worthwhile. Because there are already other regulatory exclusivities,¹⁸⁷ it is conceivable that the FDA can simply extend its control over the pharmaceutical industry in a way that includes the incentives for innovation currently received through the intellectual property component. Furthermore, it is the FDA's current regulatory approval process that shortens the patent term and makes the opportunity for excludability without a patent less likely due to the substantial information disclosure requirements. Accordingly, it is within the FDA's authority to regulate market excludability for pharmaceuticals due to the inevitable influence of the FDA on the industry.¹⁸⁸

Regulatory exclusivities administered by the FDA can be used in a way that enhances innovation in the pharmaceutical industry.¹⁸⁹ Like patent protection, regulatory exclusivities can be designed to grant pharmaceutical innovators periods of exclusivity in the market, as well as over their information in general. If their scope is broadened and their effects are heightened, regulatory exclusivities can serve as the protection and security—analogueous to the patent protection on which the pharmaceutical industry currently relies—to ensure returned investments and offer promise for sufficient profitability.

The pharmaceutical industry already enjoys certain kinds of regulatory exclusivities administered by the FDA.¹⁹⁰ For example,

¹⁸⁷ See Eisenberg, *supra* note 4, at 360–61 (discussing the role that the FDA already plays in issuing patent extensions by the use of its regulatory authority, and terming these regulatory exclusivities “pseudo patents”).

¹⁸⁸ The pharmaceutical industry has long argued that the period of time spent performing clinical testing for FDA approval should be returned to them in the form of additional market exclusivity. See *Patent Hearings*, *supra* note 159.

¹⁸⁹ See Eisenberg, *supra* note 4, at 348.

¹⁹⁰ See *supra* Part I.A.1.

the FDCA grants drug innovators five years of data exclusivity.¹⁹¹ Data exclusivities prevent generic drug companies from relying on the clinical trial data and drug information produced by the original drug maker to obtain FDA approval once the original patent has expired. The FDA also administers market exclusivities, which bear an even stronger relation to the limited monopoly granted by patent protection.¹⁹² Regulatory market exclusivities like these appear in the Orphan Drug Act¹⁹³ and the pediatric provision in the FDAMA.¹⁹⁴ Naturally, market exclusivities grant stronger protection for the innovator because they bar other companies from entering into the market at all, whereas data exclusivity still enables market entry to drug companies who invest in their own clinical trials and drug testing.¹⁹⁵

Regulatory market exclusivities are a better approach than patent protections, because they fill the gaps left by patent law and allow for necessary “fine tuning” to the pharmaceutical industry without disrupting other patentable markets.¹⁹⁶ Importantly, regulatory market exclusivities include protection for the products that are left behind and rendered unpatentable due to the problems that lie within the useful, novel, and non-obviousness requirements addressed in Part III. As noted, the patent requirements are not appropriate when applied to the pharmaceutical industry because they do not account for the social value that is provided by a drug deemed unpatentable by these strict standards. Consequently, they force pharmaceutical innovators to tip-toe around the rigidity of patentability standards, often foregoing what would be the more socially beneficial approach to safeguard the possibility that their innovations will receive the protection they need to be worth the

¹⁹¹ See 21 U.S.C. § 355 (2012). However, the actual effective period of market exclusivity afforded by this data exclusivity regulation is not generally viewed as long enough to sufficiently incentivize innovation and investment into drug development. See Henry Grabowski, *Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition*, 7 NATURE REVS. DRUG DISCOVERY 479, 487 (2008).

¹⁹² See Eisenberg, *supra* note 47, at 123.

¹⁹³ See Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended in 21 U.S.C. § 360aa–ee).

¹⁹⁴ See Pub. L. No. 105-115, § 127, 111 Stat. 2296, 2328 (1997).

¹⁹⁵ See Eisenberg, *supra* note 4, at 348.

¹⁹⁶ See *id.* at 364.

investment. In practice, innovators often must avoid using any drugs that might be deemed unpatentable,¹⁹⁷ even if the possibility exists that the avoided drug is the best-known option. Furthermore, patentability standards also discourage innovators from disclosing experimental failures for fear that such disclosure might damage their chances of patenting certain drugs in the future due to lack of novelty. This is problematic because such drug information is helpful in promoting efficiency¹⁹⁸ and fostering innovation.¹⁹⁹ In addressing this concern, FDA regulatory market exclusivities could replace patent protection in a way that would close this gap. Instead of affording protection to products for meeting standards that ignore the reason pharmaceutical innovation is so important to this country, regulatory exclusivities are designed to protect products that are socially valuable.²⁰⁰

Regulatory market exclusivities are also more appropriate in light of the pharmaceutical development process.²⁰¹ Because the time and cost of the stringent FDA standards for approval for market entry often cut into the effective patent term,²⁰² it seems

¹⁹⁷ See Roin, *supra* note 22, at 503 (“The novelty and non[-]obviousness requirements make no concession for the development costs of inventions and thus cause patents to be withheld from drugs that are unlikely to reach the public without that protection.”).

¹⁹⁸ See Seymore, *supra* note 111, at 955–56 (“At minimum, the disclosure saves time and money by preventing the repetition of dead-end experiments.”).

¹⁹⁹ See *id.* (“There is indeed hope that reading the details of the failed experiment will induce innovative thinking to solve that specific problem or others.”).

²⁰⁰ See Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049; Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585; Pediatric Exclusivity Incentive in the Food and Drug Administration Modernization Act of 1997, PL 105–115, Nov. 21, 1997, 111 Stat 2296, §505(A), for marked examples of regulatory exclusivity extensions for drugs that are valuable or needed; see also STRATEGIC PLAN FOR DRUG SHORTAGES, *supra* note 85 (strategic Plan to expedite approval of drugs on drug shortage list); America COMPETES Reauthorization Act of 2010, Pub. L. No. 111-358, §105, 124 Stat. 3982, 3989-93 (codified at 15 U.S.C. § 3719) (granting agencies the authority to “carry out a program to award prizes competitively to stimulate innovation that has the potential to advance the mission of [each] respective agency”); see also *supra* note 174 (providing examples of regulatory incentives awarded to drugs that are valuable or needed).

²⁰¹ See Eisenberg, *supra* note 4, at 351–53.

²⁰² Although the Hatch–Waxman Act seeks to address this conflict by giving pharmaceutical patents term extensions for up to five years due to delays in the regulatory approval process, the approval process often compromises much longer than five years of the patent term, and regulatory approval delays are not the only factors that cut into the

more sensible for the FDA to administer the term for market exclusivity. The interplay between the length of the FDA approval process and the patent term creates a paradoxical situation for pharmaceutical innovators who are forced to choose between a drug that may have a greater benefit to the public but guarantee a longer clinical testing period, and drugs that are more likely to have a shorter clinical trial period but may not be as socially valuable.²⁰³ In response, regulatory exclusivities are more suitable than patents because regulatory exclusivity periods “typically do not begin until a product is on the market,”²⁰⁴ in contrast with a patent term that begins at the time the patent application is filed.²⁰⁵ Furthermore, the period of market exclusivity provided to drug companies is uniform under a regulatory regime, rewarding pharmaceutical innovators in the same way for investing in effective health products that serve to benefit the public.²⁰⁶

An example of this type of regulatory market exclusivity appears in the Modernizing Our Drug & Diagnostics Evaluation and Regulatory Network Cures Act of 2013 (“MODDERN Cures Act of 2013”),²⁰⁷ which was introduced on September 17, 2013, and promotes using regulatory exclusivities over patent law. The bill specifically acknowledged findings that the lack of development of potentially valuable drugs is due to “insufficiencies” in the patent-protection system and, therefore, seeks to remedy that problem by supplementing—and perhaps

patent term. See *Interface of Patents with Regulatory Approval*, *supra* note 20; see also Andrew A. Caffrey, III & Jonathan M. Rotter, *Consumer Protection, Patents and Procedure: Generic Drug Market Entry and the Need to Reform the Hatch-Waxman Act*, 9 VA. J.L. & TECH. 1, 26–76 (2004).

²⁰³ See Maxwell R. Morgan, *Regulation of Innovation Under Follow-on Biologics Legislation: FDA Exclusivity As an Efficient Incentive Mechanism*, 11 COLUM. SCI. & TECH. L. REV. 93, 106 (2010); see also LANDES & POSNER, *supra* note 161, at 300 (discussing that, despite the correlation between the costs of R&D and the degree of patent protection needed to adequately incentivize development, the patent system does not tailor patent protection to the costs of R&D).

²⁰⁴ Thomas, *supra* note 36, at 542.

²⁰⁵ 35 U.S.C. § 154 (2012).

²⁰⁶ See Morgan, *supra* note 203, at 105–06 (suggesting a uniform approach, and noting that most ideally, exclusivity time periods would be tailored to the time and costs of clinical research and development).

²⁰⁷ H.R. 3116, 113th Cong. (1st Sess. 2013).

replacing—patent protection with regulatory exclusivities.²⁰⁸ For example, one component of the proposed legislation includes extending the exclusivity period for drugs that address unmet medical needs (“dormant therapies”), giving such drugs an additional fifteen years of data exclusivity.²⁰⁹ Furthermore, the bill provides the opportunity to extend the patents on approved drugs that qualify as dormant therapies.²¹⁰ The MODDERN Cures Act of 2013 also provides for an extension of the exclusivity of drugs that demonstrate—through diagnostic testing—applicability to a certain patient population.²¹¹ Lastly, the bill directs the Secretary to engage with appropriate authorities in an analysis of current intellectual property protection laws governing pharmaceuticals to determine the best way to shape those laws to enhance necessary development.²¹² Importantly, the bill is broader than the kinds of regulatory exclusivities that would be needed to completely overcome patent law, the details of which are outside the scope of this Note. Furthermore, it is also in an early stage and may stand to face a great deal of opposition. Nonetheless, the MODDERN Cures Act of 2013 represents a significant shift in the area of pharmaceutical protection and innovation, and remains a relevant example of the direction the pharmaceutical industry may take over years to come.

CONCLUSION

A review and reform of the way that the pharmaceutical industry is protected and pharmaceutical innovation is incentivized is long overdue. Innovation in this industry is essential, and it is necessary that the incentives designed to fuel innovation take into account the way the industry functions. In this regard, the patent system fails to serve its intended purpose. Any reforms that are implemented should account for the cost and time inherent in the R&D process as well as the social value of pharmaceutical

²⁰⁸ *Id.*

²⁰⁹ *Id.*

²¹⁰ *Id.*

²¹¹ *Id.*

²¹² *Id.*

innovation to the public. Ultimately, such reforms would enable the development of desirable and effective pharmaceutical products while providing room for creative and inventive research that is not restricted or restrained by the stringent standards of the patent system.