Extinguishing Exclusive Marketing Rights: Interpreting the Medical Innovation Prize Fund Act of 2011

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$2.5 trillion.\(^1\) That was the amount spent in the United States on health care in 2009.\(^2\) For that year, this spending translated into 17.6 percent of gross domestic product, even though it was the slowest annual increase in spending seen in decades.\(^3\) $249.9 billion, approximately 10 percent of the total, was spent on prescription drugs.\(^4\) As with overall health spending, the amount spent on prescription drugs actually decreased, and has been decreasing since the implementation of Medicare Part D,\(^5\) dropping from 18 percent growth in 1999 to 3 percent growth in 2008.\(^6\) Despite the recent slow-down in spending, attributable partially to the recession of 2008,\(^7\) forecasts for health expenditures are projected to increase to $4.6 trillion by the year 2020.\(^8\) The impact of high prescription prices is readily observed, be it the consumer who cannot afford needed medications, or the employer who avoids hiring workers with pre-existing medical needs.\(^9\)
So why are health care costs so high in the United States? Compared to other developed countries, the U.S. health care consumer spends considerably more. Experts attribute this to an increased role of non-US governments in negotiating drug prices or imposing other measures of price controls. For example, in Canada, the government requires compulsory licensing of all patented drugs to generic manufactures, thus allowing for drastically reduced prescription drug costs. Germany utilizes a different strategy: the government acts as a monopoly insurer, dictating the maximum amount of reimbursement. The United Kingdom relies on the “quality-adjusted life year” (QALY) to determine whether a new drug provides value in addition to efficacy. To implement QALY, the cost of a treatment is divided by the QALY score, which is then used as the price ceiling.

In the United States, while the government does play a role in negotiating prices, it leaves much of the pricing structure to the free market. Because of the current system of exclusivities granted by both the patent system and the FDA, pricing for patented drugs is not necessarily based on competitive market prices, but on monopoly pricing power. In effect, because governments in other countries limit prices but not in the United

11. Id. at 116.
12. Id.
13. Id.
15. Id.
16. See Channick, supra note 5, at 253-54. The government does reimburse drug suppliers through Medicare and Medicaid insurance plans and controls pricing to some degree. Id. The Center for Medicare & Medicaid Services determines the price for covered drugs, and reimburses suppliers based on those determinations under Medicare parts A and B. Id. However, in Medicare Part D prescription plans, the preferred providers directly negotiate prices with the pharmaceutical suppliers, rather than having government set prices. Id.
States, companies are able to charge higher prices in the United States to offset those limits—a form of price discrimination.\(^{18}\)

In order to address these problems, Senator Sanders offers a potential solution: The Medical Innovation Prize Fund Act of 2011.\(^{19}\) In the Bill, Senator Sanders proposes implementing a prize-based system of incentives, with the first company receiving FDA-approval for a drug collecting a substantial financial prize in lieu of market exclusivity.\(^{20}\) Simply stated, the incentive mechanism would be prize-based rather than exclusivity-based, with prize awards replacing post-FDA approval exclusivities.\(^{21}\) Thus, the primary goal of the Bill is to de-couple R&D costs from the final price of a prescription drug, with the prize serving as the mechanism to cover R&D costs, rather than the patient paying supra-competitive prices.\(^{22}\)

However, as written, the Bill makes concessions to the current patent- and FDA-granted exclusivities.\(^{23}\) These concessions weaken its impact considerably, and muddle its practical implementation. Additionally, the Bill fails to specify whether it would be a voluntary or non-voluntary system.\(^{24}\) That is, would the Bill compel a company to forego post-FDA approval exclusivity, or could the company opt for the prize instead of exclusive rights? Of course, either route creates its own problems. If the Bill were mandatory, then how would a company be compelled to freely share its invention? If the Bill were voluntary, then why would a company opt for the prize when monopoly pricing could generate potentially higher profits? To be truly


\(^{20}\) \textit{Id.} \S 9.

\(^{21}\) \textit{See id.} \S\S 2, 5, 6.

\(^{22}\) \textit{Id.} \S 2.

\(^{23}\) \textit{Id.} \S 5.

\(^{24}\) \textit{See id.} \S\S 5, 9 (neither section describes if a company \textit{must} compete for a prize, or if it \textit{may} compete if desired).
effective, the Bill needs to clearly define how it would operate in light of its exceptions to patent and FDA-granted exclusivity. Further, the Bill needs to clarify whether the prize system is mandatory or voluntary.

Part II of this note will begin by exploring the traditional rationales for the patent system as a means of inducing innovation, as well as the practical manifestation of those underlying rationales. Part II will also introduce the basic rationale behind the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman") and its relation to the proposed Bill. Part III addresses the Bill itself, describing the content of the proposed legislation, as well as an initial assessment of its usefulness. Part IV provides an analysis of the Bill’s substantive proposals. Specifically, the analysis will first focus on the proponents and opponents of the Bill. Next, the analysis will focus on the theoretical impact of a prize system of incentives, and the limitations of theory when it comes to reality. Part IV ends with suggestions for improving the Bill, including recommendations on how to effectively implement the Bill’s provisions. Part V concludes this note.

II. BACKGROUND

A. Overview of the Patent System

The patent system is supposed to promote progress and stimulate innovation, with its underlying rationale enshrined in the Constitution itself: "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries . . . ."25 As the rationale goes, by affording an inventor the right to exclude others from practicing his invention (i.e. effectively a monopoly), the inventor is able to reap the financial rewards of his invention without worrying about possibly better positioned competitors.26 The

25. U.S. Const. art. 1, 8, cl. 8.
prospect of a monopoly serves as a powerful incentive to innovate in the first place.\textsuperscript{27} If an inventor knew his product could readily be co-opted by a competitor, then the inventor would have little financial incentive to spend the time and money necessary to develop any truly ground-breaking inventions.\textsuperscript{28} With exclusivity in place, however, the inventor now has a financial incentive to engage in such expensive and time-consuming research and development.\textsuperscript{29}

Moreover, in exchange for the limited period of exclusivity, patent laws provide a mechanism to ensure that society also benefits: the requirement of disclosure.\textsuperscript{30} The quid pro quo is the inventor gets exclusive rights for a period of time. In exchange, the inventor must also disclose exactly what the invention is, and how to use the invention, information which then enters the public domain when the patent expires.\textsuperscript{31} Thus, both the inventor and the public benefit, with the inventor profiting from his creativity, and the public eventually improving on the invention, and continuing the cycle of innovation and progress.\textsuperscript{32}

Apart from the traditional notions of promoting innovation and discovery through the lure of monopoly, there is also the prospect theory of patents.\textsuperscript{33} "Prospect" patents are broad patents issued in the very early stages of technical development. Because these products are not yet fully developed, traditional patent justifications dictate that these products do not receive protection.\textsuperscript{34} However, granting patents on these products is still socially beneficial because the patent provides "an incentive to make

\textsuperscript{28} Cotropia & Gibson, \textit{supra} note 26, at 922.
\textsuperscript{29} Lee, \textit{supra} note 27, at 661; Cotropia & Gibson, \textit{supra} note 26, at 926-27.
\textsuperscript{31} Id.
\textsuperscript{32} Lee, \textit{supra} note 27, at 670.
investments to maximize the value of the patent without fear that the fruits of the investment will produce unpatentable information appropriable by competitors.35 Thus, under the prospect theory, the function of the patent system is to encourage investment in a technological prospect after the property right has been granted, akin to the granting of prospective mineral rights.36 In terms of pharmaceuticals and biotechnology products, this incentive to continue developing medical treatments is critical owing to the high costs of developing these treatments from start to finish.37

Industry groups report that it costs roughly $800 million to develop a new drug.38 A follow-up study suggests that development costs are roughly $1.2 billion.39 Under the pharmaceutical industry’s rationale, it is these costs that justify the high prices seen in prescription drugs.40 The final price reflects not only the R&D costs of the drug itself, but also the costs of all other failed drugs.41 Considering that only approximately 8 percent of possible drug candidates actually receive FDA approval and reach the market, the costs of developing drugs that ultimately fail can

35. Kitch, supra note 33, at 276.
36. Dan L. Burk & Mark A. Lemley, Policy Levers in Patent Law, 89 VA. L. REV. 1575, 1600-03 (2003). In granting mineral rights, the minerals have not been discovered yet—there is merely the prospect of finding them. Thus, giving exclusive ownership rights provides an incentive to invest in the hunt since the owner knows a competitor cannot claim ownership once the minerals have been found. See id. Additionally, because it is an investment, there is a built-in incentive to allocate resources in the most efficient manner possible. See id.
37. Id. at 1616.
40. Id. at 131.
reach staggering numbers. Due to the high initial investment and failure costs involved in drug development, there would be little to no incentive to develop drugs at all if the patent-granted exclusivity ceased to exist. Further, because other countries limit the price of drugs, pharmaceutical companies must be able to charge higher prices somewhere to recoup development costs. Because the United States allows for monopoly pricing, these companies can charge those higher prices, recoup R&D costs, and ultimately continue investigations into innovative new products.

Additional support for the patent system to promote innovation comes from the relative ease of reproducing the patented product. In the field of small molecular entities (e.g. common pharmaceuticals like aspirin), competitors can relatively easily duplicate a drug once it is publicly available after the patent has expired. Indeed, the number of generics entering the market once a drug loses patent protection, and the speed with which they enter, bolsters this notion: competition begins to appear in as little as one to two months post-patent expiration. Moreover, because the generics need not go through the same lengthy review process required by the FDA, nor engage in the initial R&D, the final costs for producing the generic equivalent are quite low. In the absence of patent protection, and faced with low-cost generic competition, a pioneer company would have a difficult time capturing the market share needed to recoup costs if it could only

43. See Cotropia & Gibson, supra note 26, at 922.
44. See Ingram, supra note 10, at 116; Knocke, supra note 14, at 182-83.
45. See Adams & Brantner, supra note 39, at 131.
47. Id. See Chester G. Moore, Generic Biologic Drugs What’s in A Name?, 5 ABA SciTech Law. 16, 16 (2008) (noting that small molecule drugs are structurally simple, making synthesis simpler).
charge competitive prices.\textsuperscript{50} The result: little incentive to design new drugs without some form of exclusivity protection.\textsuperscript{51}

\textbf{B. Critiquing the Patent System}

Ideally, exclusivity serves as the primary economic driving force behind innovation in many commercial sectors.\textsuperscript{52} For biotechnology and pharmaceutical companies, patents and FDA-granted exclusivity provide assurances that these companies can charge the prices necessary to recover research and development (R&D) costs.\textsuperscript{53}

Yet, there are numerous downsides associated with exclusivity, particularly in the field of pharmaceuticals and biotechnology.\textsuperscript{54} From a purely economic standpoint, monopolies are inefficient. A monopoly skews the pure competitive supply and demand dynamic, allowing a company to charge higher prices than the market would normally support.\textsuperscript{55} Because of this higher pricing, there will inevitably be a portion of the population that needs the product but simply cannot afford it, or is unwilling to pay such a high price.\textsuperscript{56} Thus, both the consumer loses out on a needed good, and the producer loses potential sales. In economic terms, this is known as deadweight loss.\textsuperscript{57} While price discrimination is one way of mitigating such deadweight loss, in practice, discrimination is typically inefficient and results in an inexact allocation of

\textsuperscript{50} By pioneer, the author means companies making brand new, first-of-its-kind products.

\textsuperscript{51} Cotropia & Gibson, supra note 26, at 926-27.

\textsuperscript{52} See Lee, supra note 27, at 670.

\textsuperscript{53} See Overview of the Patent System, supra Section II(A); Cotropia & Gibson, supra note 26, at 926-27.

\textsuperscript{54} See generally Gifford, supra note 18; Love & Hubbard, supra note 9; Love & Hubbard, supra note 17; Cotropia & Gibson, supra note 26; Lee, supra note 27; Burk & Lemley, supra note 36.

\textsuperscript{55} Cotropia & Gibson, supra note 26, at 928.

\textsuperscript{56} Id. at 928-29.

costs. As a result, pharmaceutical companies in the United States continue to charge monopoly prices to both consumers who can afford such prices and consumers who cannot.

A phenomenon closely tied to economic inefficiency is the incentive to develop, and patent, minimally improved versions of pre-existing products. This essentially extends the life of the pre-existing product, but offers only a minimal benefit to the end-user while having the same high cost. Because demand for pharmaceutical and biotechnology products typically are necessities, a company providing such products can continue to develop minimally improved versions and offer it at the same price. Provided the consumer perceives that there is still ample benefit from the new version, the consumer will still purchase it at that price.

Some of the additional criticisms are more conceptually straightforward. One of the problems the Bill seeks to address is the lack of R&D targeting neglected diseases, such as those afflicting predominantly the poor, or afflicting smaller numbers of people. This lack of development arises simply because the costs of developing and manufacturing a treatment are far higher than potential revenue. If a company cannot recover its costs, let

58. Love & Hubbard, supra note 17, at 1548-49. See Gifford, supra note 18, at 112-113.
59. Love & Hubbard, supra note 17, at 1548-49.
61. Love & Hubbard, supra note 17, at 1523.
62. Id.
64. See Cotropia & Gibson, supra note 26, at 922.
alone turn a profit, then there is little incentive to pursue that market. 65

Lastly, there is the issue of the “anticommons.” 66 When there are too many patents in a particular field, these patents will potentially disrupt or even prevent further innovation. 67 This is particularly important in the biotechnology industry, where there is a great deal of basic scientific research utilized in developing a medical product. 68 If there are too many patents on “upstream” research tools, then “downstream” innovation can be hampered. 69

Senator Sanders’ proposed Bill offers a potentially simple solution to many of these systemic weaknesses, and will be discussed in more detail in Part IV. 70

C. Hatch-Waxman: Generic Competition and Impact on Pricing

Even in the 1980s, law-makers were aware of the seemingly relentless increase in the cost of prescription drugs. 71 The passage of the Drug Price Competition and Patent Term Restoration Act of 1984 emerged as a compromise between the pioneer drug companies and the generic manufacturers. 72 As noted by the Court of Appeals for the Federal Circuit, Hatch-Waxman had to balance

65. Id.
68. See Heller & Eisenberg, supra note 67, at 699.
69. Lee, supra note 27, at 674. “Upstream” refers to basic research tools and products which are used to develop the actual finished, or “downstream,” products. See Heller & Eisenberg, supra note 67, at 698.
71. Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1326 (Fed. Cir. 2001) (quoting Abbott Labs. v. Young, 920 F.2d 984, 991 (D.D.C. 1990)).
two conflicting policy objectives: “to induce brand name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.” On one hand, the pioneer companies were complaining that the lengthy FDA approval process was eroding the effective life of their patents by upwards of five years. If there is insufficient time to sell a drug exclusively, then the cost of R&D cannot be recouped, resulting in a loss of incentive to actually develop such new compounds. On the other hand, FDA regulations required that generic drugs undergo the same lengthy safety and efficacy trials that the pioneer drugs had to endure, presenting a formidable barrier to entry owing to the added costs of such studies. Moreover, from the viewpoint of the generic manufacturers, the law effectively increased a pioneer’s patent by several years, as the generic had to wait until after the patent expired before even beginning investigations of generic versions.

Hatch-Waxman’s compromise involved two major provisions. The first provision allowed a patented drug to extend its term for up to five years, based on the length of time between filing an Investigational New Drug (IND) application and submission of a New Drug Application (NDA), provided that the applicant acted with due diligence prior to the patent’s expiration. In addition to patent term extensions, the bill also provided for a period of post-approval exclusivity. For New Chemical Entities (NCE), the holder of the approved NCE would be entitled to five years of

73. Mylan Pharms., 268 F.3d at 1326 (quoting Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. 1990)).
74. Nussbaum & Radice, supra note 60, at 233.
75. Id. at 233-34.
76. Nussbaum & Radice, supra note 60, at 233.
77. Id. at 234.
80. Weiswasser & Danzis, supra note 78, at 592.
market exclusivity, during which time no one can utilize its safety and efficacy data.\textsuperscript{81}

The second provision covered generic competition by providing an accelerated approval process, known as the Abbreviated New Drug Application (ANDA).\textsuperscript{82} Instead of going through independent clinical trials to show safety and efficacy, the generic drug need only show that it was the bioequivalent of the FDA-approved original, resulting in significantly reduced up-front investment costs.\textsuperscript{83} Upon this showing, the generic could then rely on the original product's safety and efficacy data.\textsuperscript{84} However, in order to gain market approval, the generic still could not infringe on a pioneer's patent: rather, the generic manufacturer had to certify that (1) no patent existed for the drug; (2) the relevant patent had expired; (3) the generic would wait for the relevant patent to expire; or (4) allege that the relevant patent is invalid or not infringed.\textsuperscript{85} While options one through three were relatively straightforward, option four ("Paragraph IV") was markedly more complicated.\textsuperscript{86} Upon Paragraph IV certification, the generic maker must notify the pioneer of the certification, after which the pioneer has forty-five days to bring an infringement suit against the generic maker.\textsuperscript{87} The FDA would then grant a thirty-month period during which the generic would not be approved once the pioneer


\textsuperscript{82} Weiswasser \& Danzis, \textit{supra} note 78, at 593.

\textsuperscript{83} \textit{Id.} at 594. For bioequivalence, the generic had to show that its bioavailability (e.g. rate of absorption into the blood stream) was the same as the pioneer. \textit{See} Hatch-Waxman § 101.

\textsuperscript{84} Weiswasser \& Danzis, \textit{supra} note 78, at 593; Hatch-Waxman § 101.

\textsuperscript{85} Hatch-Waxman § 101.

\textsuperscript{86} This Update will not address the issue of Paragraph IV certification, as the proposed legislation does not necessarily address these issues. The reader is directed to the relevant case law: \textit{In re Ciprofloxacin Hydrochloride Antitrust Litig.}, 544 F.3d 1323 (Fed. Cir. 2008); \textit{In re Tamoxifen Citrate Antitrust Litig.}, 466 F.3d 187 (2d Cir. 2006); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005); \textit{In re Cardizem CD Antitrust Litig.}, 332 F.3d 896 (6th Cir. 2003).

\textsuperscript{87} Hatch-Waxman § 101.
initiated an infringement suit. Considering the expense involved in infringement litigation, Hatch-Waxman also provided a 180-day exclusivity period to the generic manufacturer, during which time the FDA would not approve any competing versions provided the generic manufacturer prevailed. This served as an incentive for the generic maker to incur the costs of litigation.

Prior to passage of Hatch-Waxman in 1984, only 35 percent of top-selling drugs off-patent had generic versions available on the market. In 1998, nearly all off-patent drugs had at least one generic version on the market. Further, prior to passage, generic manufacturers accounted for only 13 percent of prescription drug sales, whereas a decade later, generics accounted for almost 60 percent of all drug sales.

For a specific example, take Zantac, the popular heartburn medication. GlaxoSmithKline first launched Zantac in 1983, and the first generic gained approval and market entry in 1997. After only one year, the number of generic versions of Zantac grew to thirteen, with the generic versions accounting for 75 percent of the market. Moreover, the average price of the generic versions were only 30 percent of the brand name price, contributing to the loss of market share experienced by the brand name drug. By most accounts, the implementation of Hatch-Waxman had the intended effect in terms of promoting generic drug development, and driving down the price of prescription drugs.

88. Id.
89. Weiswasser & Danzis, supra note 78, at 603 (as the authors note, this provision has created its own interpretation problems—e.g. when does the 180 day period begin? At the time of marketing? After a decision has been rendered?); Hatch-Waxman § 101.
90. Weiswasser & Danzis, supra note 78, at 603.
91. CBO REPORT, supra note 46, at 37.
92. Id.
93. CBO REPORT, supra note 46, at 37.
95. Id.
96. Id.
97. Id. at 17-18.
III. PROPOSED LEGISLATION

A. Medical Innovation Prize Act, House Bill 417 (2005), and Senate Bill 2210 (2007)

In 2005, then Representative Bernie Sanders introduced his first Medical Innovation Prize bill. In it, Sanders cited Congressional findings that (1) prescription drug prices were increasing at a rate of over 7 percent per year between 1993 and 2003; (2) uninsured persons were foregoing medications because of the high cost; (3) many new drugs approved by the FDA failed to offer significant improvements over existing drugs in terms of efficacy; and (4) many diseases remained neglected due to lack of financial incentives. Ultimately, the 2005 measure failed to reach the House floor for voting. As a Senator in 2007, Sanders introduced a similar measure in the Senate, Senate Bill 2210, which mirrored his earlier effort almost exactly, noting the high price of prescription drugs and the lack of incentives to develop truly innovative drugs. The 2007 version failed to reach the Senate floor for voting.

B. Medical Innovation Prize Fund Act of 2011, Senate Bill 1137

The current Medical Innovation Prize Fund Act of 2011, Senate Bill 1137, again mirrors the core elements of both previous failed versions, but emphasizes the reward mechanisms of the current system, including the legally granted market exclusivities of patents and FDA-approval. As of May 26, 2011, the Bill was read twice and referred to the Senate Committee on Health,
Education, Labor and Pensions. No further action has been taken.

Section Two of the Bill outlines the findings leading to the creation of the Bill, noting the flaws of the current system. In particular, this section notes that the current system of exclusivities is both expensive and inefficient. Additionally, Section Two stresses the need to “de-link” R&D costs from the final price of products, noting that such a process could result in substantial cost savings to the end consumer. Section Two also introduces the prize fund’s size as being 0.55 percent of gross domestic product (GDP) of the United States—a sum of approximately $80 billion in 2011. Lastly, this section emphasizes the importance of information sharing, noting that “[t]he development of new medicines benefits from greater sharing of knowledge, data, materials, and technologies.” In recognition of the importance of such sharing, the Bill would allocate 5 percent of the prize fund “to those who provide open access” to critical information and materials.

Section Three defines the Bill’s purpose, and is closely related to the findings made in Section Two:

It is the purpose of this Act to provide incentives to encourage entities to invest in research and development of new medicines and to share knowledge, data, materials, and technology, through the establishment of a Medical Innovation Prize Fund, while enhancing access to such medicines by eliminating legal monopolies on the

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105. Id.
106. S. 1137 § 2.
107. Id. § 2(2).
108. Id. § 2(3).
109. Id. § 2(4).
110. S. 1137 § 2(5).
111. Id. § 2(6).
manufacture, distribution, and sale of such medicines.  

Section Four defines the various terms used throughout the bill, including definitions for “biological product” and “drug” as defined in section 351 of the Public Health Service Act and section 201 of the Federal Food, Drug, and Cosmetic Act, respectively.  

Section Five is entitled “Elimination of Exclusive Rights to Market Drugs and Biological Product” and represents one of the core provisions of the Bill.  

Because of the exclusivities provided by both the patent laws and FDA regulations, drug companies have little incentive to develop truly ground-breaking new medicines, relying rather on “me-too” versions which can extend the monopoly provided by patents and thus justify continuing high prices for drugs that offer incremental improvement over its predecessor.  

As commentators note:

The prescription drug industry lacks the price discipline present in most industries because of its tripartite nature in which the drivers of demand (physicians) are largely insulated from the economic purchasers (government or private health plans). In most industries, an incremental improvement would justify only an incremental change in price. . . . Drug manufacturers [however] . . . are able to maintain market share while launching line extensions that offer only minimal benefits over older, now-generic versions even

112. Id. § 3.
113. Id. § 4.
114. Id. § 5.
115. Id. § 5(b).
116. Love & Hubbard, supra note 17, at 1523; Nussbaum & Radice, supra note 60, at 249. “Me-too” drugs are those drugs which treat the same condition as a pioneer drug through the same therapeutic mechanism. CBO REPORT, supra note 46, at 2 box 1.
though the new products cost 900 [percent] more than older generic products.117

Specifically, this section would prohibit any person from having exclusive rights to “manufacture, distribute, sell, or use a drug, a biological product, or a manufacturing process for a drug or biological product . . . including the exclusive right to rely on health registration data . . . ”118 However, this provision also contains a large exception:


Instead of rewarding companies with periods of exclusivity to recoup development costs, the incentive mechanism would be prize-based, with prizes replacing post-FDA approval exclusivities.120 In light of the exceptions noted in Section Five, the bill does not seek to eliminate the patent or FDA system of exclusivities, but rather provide a separate incentive mechanism by offering prizes to drug developers.121 Because the bill requires drug-makers to relinquish exclusivity, competitors would have greater access to the pioneer’s product, and could further improve or copy the product without fear of infringement.122 This would not, however, relieve the competitor of the obligation to obtain a

117. Nussbaum & Radice, supra note 60, at 249.
118. S. 1137 § 5(a).
119. Id.
120. Id.
121. Love & Hubbard, supra note 17, at 1532. H.R. 417 § 4(a) and S. 1137 § 5(a) are identical.
122. See S. 1137 § 5.
license to use the product, as it most likely would still be under patent protection.\(^{123}\)

Sections Six through Eight address funding of the prize system, as well as general oversight and administration of the system.\(^{124}\) The Bill would create a Board of Trustees comprised of officials from various regulatory agencies, including the Centers for Medicare & Medicaid Services, the FDA, National Institutes of Health (NIH), Centers for Disease Control (CDC), and representatives of the health insurance, biotechnology, and pharmaceutical industries.\(^{125}\) The Board’s primary duties would entail making findings and presenting these findings to Congress, such that prizes would be appropriately distributed.\(^{126}\)

Sections Nine through Thirteen provide additional details regarding budget allocations, eligibility guidelines, identification of priority research areas, and transitional rules.\(^{127}\) In order to be eligible for the prize, the person must be the first to (1) receive FDA approval for a new drug or biological product or (2) obtain a patent on a new manufacturing process.\(^{128}\) Additionally, as a means to spur open source knowledge sharing, persons involved in such collaborative development efforts would also be eligible for a prize.\(^{129}\) In determining the size of the payout, the bill sets forth various criteria including: (1) the number of patients who would benefit from the product or process, including global diseases; (2) the incremental therapeutic benefit of the product or process as compared to pre-existing treatments; (3) the degree to which the product or process addresses priority health care needs such as global infectious diseases, severe illnesses with small client populations (i.e. orphan drug classification) and neglected diseases impacting primarily the poor in developing countries; (4) any improved efficiency in manufacturing processes; (5) the extent to which knowledge of the new product or process has been openly

\(^{123}\) Love & Hubbard, supra note 9, at 170.
\(^{124}\) S. 1137 §§ 6-8.
\(^{125}\) ld. § 7.
\(^{126}\) ld. § 8.
\(^{127}\) ld. §§ 9-13.
\(^{128}\) ld. § 9.
\(^{129}\) ld.
shared; (6) expected life cycle benefits for which drug resistance remains an obstacle (i.e. antibiotics); and (7) the need to stockpile against potential future threats. Of these criteria, the Bill gives special consideration to products that address priority health care needs, such as the global AIDS pandemic and neglected diseases. Moreover, in an attempt to promote open-source development, the Bill also gives special consideration to those products developed in an open collaborative environment, rather than maintaining secrecy as is required when pursuing patent protection.

As noted above, because companies would be relinquishing marketing exclusivity, competitors would be free to develop derivatives of a pioneering product without fear of an infringement lawsuit. This competition would erode the ability of a pioneer company to recoup costs over a period of time. In order to protect the innovators from coat-tail riders who use the pioneer drug as the basis for a further improvement, Section Nine also allows the pioneer to continue to receive prize payments for a period of ten years. In essence, the bill would maintain the financial incentive for a period of time roughly matching the current effective patent term for brand name pharmaceuticals. Again, the ongoing prize payment would offset the decreased revenues associated with increased competition, and the pioneer would maintain an incentive to keep developing new products. However, in awarding prizes, no person would receive more than 5 percent of the total prize fund in any given year.

Sections Fourteen through Sixteen establish the creation of an arbitration procedure for resolving conflicts, the requirement of

130. S. 1137 § 9.
131. Id. § 10.
132. Id. § 11. The AIA outlines various bars to patentability, including knowledge or use of the invention, offers for sale of the invention, and any printed publication describing the invention prior to filing. AIA, Pub. L. No. 112-29, § 3, 125 Stat. 284 (2011).
133. S. 1137 §§ 9, 13.
134. See Knocke, supra note 14, at 178.
annual audits by the General Accounting Office (GAO), and Congressional reporting requirements. 136

Sections Seventeen and Eighteen provide more details on the funding of the Prize. 137 Section Seventeen would authorize budget appropriations beginning in fiscal year 2013, with the allocation not to exceed 0.55 percent of that year’s GDP. 138 In the event that funds remain after an award cycle, the remainder would revert back to the Treasury. 139 Section Eighteen represents additional funding mechanisms. 140 This section would require that “[e]ach covered entity engaged in the business of providing health insurance shall pay to the Secretary . . . a fee.” 141 This fee would be calculated as a percentage of the health insurance company’s (1) net premiums and (2) Federal outlays for reimbursement of health care costs. 142 As defined by this section, a “covered entity” is any entity providing “health insurance for any United States health risk.” 143

IV. ANALYSIS

A. Proponents and Opponents

As proponents of prize-based incentive systems note, the bill addresses the major issues confronting drug prices today. 144 As such, an area in which the bill would potentially have the most dramatic impact would be in the promotion of generic competition. Under the prize system, because a pioneer company would cede exclusivity after receiving FDA approval for a new drug, generic

136. Id. §§ 14-16.
137. Id. §§ 17-18.
138. Id. § 17.
139. Id.
140. Id. § 18.
141. Id.
142. Id.
143. Id.
144. See Love & Hubbard, supra note 9, at 157, 160; Love & Hubbard, supra note 17, at 1532
manufacturers would be able to enter the market immediately. While these generics would still have to negotiate licensing arrangements with the pioneer company, the pioneer would be compelled to grant these licenses, rather than retain exclusive marketing rights to the product. As seen in the aftermath of Hatch-Waxman's implementation, allowing generics earlier entry would indeed stimulate healthy competition, dramatically increasing the number of products available to the consumer. Consequently, this would decrease the price of a drug from supra-competitive monopoly prices to supply and demand driven marginal costs.

Of course, there will inevitably be opponents. Notably, the pharmaceutical industry is well-funded and actively engaged in lobbying efforts, making the passage of legislation directed towards changing the current system even more difficult. Yet, the primary argument against implementing a prize system do not relate to using a prize system per se, but rather with the difficulties in determining the actual size of the prize. As noted by one commentator, "[i]f the prize is too low, then the system will inadequately stimulate R&D investment. If the prize is too high, then costs such as resource duplication and favoritism will be exacerbated." Like the bill introduced in 2005, the current version of the legislation fails to provide details on how the value of a prize will be determined, instead merely noting that it would be up to a panel. Because of the lack of predictability in determining the size of a prize, the participants would not be able to accurately determine how to allocate resources in pursuit of the goal.

146. Love & Hubbard, supra note 9, at 170.
147. Saha, supra note 94, at 17.
148. Id.
149. See Love & Hubbard supra note 9, at 162.
150. Wei, supra note 57, at 32.
151. Wei, supra note 57, at 32.
Another criticism of the prize system is the creation of inefficiencies. Because prizes are open to the general public, there is a high likelihood of multiple parties working towards the same goal simultaneously, something which the patent system prevents. In the patent system, because a follower knows exactly what has been patented, he can either design around the pre-existing invention, or attempt to create something entirely new. This ensures that resources are directed towards new developments, rather than towards the same possible solution. Yet this very duplication of resources can also serve as a source driving accelerated innovation.

B. Theoretical Impact of the Medical Innovation Prize Fund

1. Reflecting Competition

In theory, a prize system should effectively de-link R&D and marketing costs when pricing a new drug. That is, if one examines the cost of the generic version of a brand name drug, the cost is substantially less than the brand name. This is because the generic does not need to go through the financially taxing process of discovery, development, and clinical trials before applying for FDA approval. Rather, the generic need only prove that it is the equivalent to the brand name. Upon this showing, the generic is then allowed to rely on the pioneer’s clinical trial data. As a result, the generic does not need to factor in R&D costs into the ultimate price of the drug, unlike the name brand. The prize system seeks to work in a similar manner: the prize itself is meant to cover the costs of R&D, thus allowing a company to price the

153. Wei, supra note 57, at 39.
154. Id.
156. See Love & Hubbard, supra note 17, at 1534.
157. Weiswasser & Danzis, supra note 78, at 594.
158. Weiswasser & Danzis, supra note 78, at 594.
159. Id.
160. See CBO REPORT, supra note 46, at 3.
drug independently of such costs. Like the generics that follow, the brand name drug’s price would then theoretically reflect competitive forces, including supply and demand, and marketing/sales costs. Moreover, because a pioneer company could no longer exclusively market its product, generic competition would be able to enter the market much earlier. As seen in the aftermath of Hatch-Waxman, such competition is quite effective at driving down the costs of medications.

2. Addressing the Costs of Failure

Part of the necessity of exclusivity is to recover the costs of failure, the costs of clinical trials which do not work and represent lost money. Pfizer’s new product pipeline provides an example of the high costs of failure. The company has approximately fifty new molecular entities in its current pipeline. The estimated cost to develop a single drug is $27 million per year. On a yearly basis alone, this translates into approximately $1.35 billion. Multiply this by the six to twelve years it takes to make it through clinical trials, and the total costs are $8.1 billion. At the current rate of FDA approval, only about 10 percent (five out of fifty) of those new drug candidates will actually receive FDA clearance and

161. See Love & Hubbard, supra note 9, at 160.
164. Reichman, supra note 41, at 9-10.
165. A large company such as Pfizer has over 50 new molecular entities in various phases of clinical trials. Pfizer, Inc., Pfizer Pipeline August 2011 (2011), available at http://www.pfizer.com/research/product_pipeline/product_pipeline.jsp. A new molecular entity is essentially the equivalent of a New Chemical Entity, where the active compound has never been used in any products. See supra note 65. Some of Pfizer’s products are also biologics, which includes a wide range of products such as vaccines, blood and blood components, allergens, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Vaccines, Blood & Biologics, U.S. FOOD & DRUG ADMIN. (last visited Oct. 23, 2011), http://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/Consumers/default.htm.
generate revenues. Consequently, the yearly cost of failure alone could reach in excess of $1 billion. Considering the sheer costs involved in developing new molecular entities alone, it is not surprising that a company like Pfizer would want the ability to charge monopoly prices. Indeed, at monopoly prices, those approved drugs could generate revenues in the hundreds of millions of dollars on an annual basis, if not billions. This revenue could then be used to cover the cost of the failed drugs. Assuming a generic version’s price to be roughly 50 percent of the branded version, if the new drug were priced for a competitive market, the revenues would be cut in half, with a greater proportion of those revenues going towards R&D failure costs, and decreasing profitability of the marketed drug.

Again, the Bill addresses this concern simply by recognizing that failure costs are an integral part of R&D costs. That is, when a company talks of its R&D costs, it is not talking about the costs of developing a successful drug only, but also the costs of all the failed candidates as well. By offering a prize upwards of $4 billion annually for ten years, the Bill would be able to offset the costs of failure as part of the R&D expenditures, decreasing the need for a company to generate blockbuster-type revenues. However, because R&D costs vary between companies, it is unclear whether the prize would be adequate to completely offset R&D costs, or just partially offset those costs.

168. Epstein, supra note 42, at 463.
169. Saha, supra note 94, at 22 tbl.1. Prices for generics varies with the number of competitors in the market, ranging from as little as 30 percent to as high as 75 percent of the branded product price. Id.
171. See CBO REPORT, supra note 46, at 48.
3. Addressing Incremental Improvements

A major criticism of the current patent system revolves around the incentives to generate incremental improvements to existing products.\footnote{174. See Nussbaum & Radice, supra note 60, at 249.} This “incentive” becomes stronger when combined with additional factors, including deadweight loss, the inability to effectively price discriminate, and the relative inelasticity of demand in the pharmaceutical market.\footnote{175. See Cotropia & Gibson, supra note 26, at 928-29; Love & Hubbard supra note 17, at 1548-49; Patricia M. Danzon, The Pharmaceutical Industry, in ENCYCLOPEDIA OF LAW & ECONOMICS 1055, 1056 (Boudewijn Bouckaert & Gerrit De Geest, eds., 2000).} As noted earlier, deadweight losses arise from monopolies because pricing does not reflect demand.\footnote{176. Id.} Because a company can, and will, charge higher prices than the market would ordinarily support, there will inevitably be a population which needs a drug, but simply cannot afford it.\footnote{177. Gifford, supra note 18, at 112-13.} Theoretically, implementing price discrimination strategies would mitigate such losses: a company would sell a product at its most profitable price to various segments of the consumer population.\footnote{178. Love & Hubbard, supra note 17, at 1548.} If one segment could afford higher prices, the company would charge higher prices to that segment. If another segment could only afford lower prices, the company would charge those lower prices. Everyone would pay what they could afford, and deadweight losses would disappear.

However, price discrimination as a means to reduce deadweight losses is less effective in pharmaceutical markets.\footnote{179. Id.} First, there is the general issue of accurately assessing what each consumer segment could pay, a difficult task at best.\footnote{180. Id.} Second, pharmaceutical demand is relatively inelastic.\footnote{181. See Gifford, supra note 18, at 113 (noting that price discrimination is effective if the market exhibits elastic demand curves); John A. Vernon, Joseph H. Golec, W. Keener Hughen, The Economics of Pharmaceutical Price Regulation and Importation: Refocusing the Debate, 32 AM. J.L. & MED. 175, 183 (2006). Elasticity refers to the ability of demand to change depending on
markets where consumers pay out of pocket for a product, consumers do not necessarily pay for drugs directly.\textsuperscript{182} Rather, drug providers purchase the majority of drugs, and insurance covers the bulk of the cost.\textsuperscript{183} Perhaps most importantly, oftentimes spending on drugs is not discretionary: a person who needs a drug will opt for that drug regardless of price if it is the only available treatment or perceived to be the most effective treatment.\textsuperscript{184} Moreover, in the pharmaceutical market, demand remains relatively constant regardless of the price.\textsuperscript{185} Because a company cannot, or need not, effectively price discriminate, it will continue to charge higher prices than the market would otherwise support.

Further, the producer does not have to invest nearly as many resources into a modification, as opposed to a brand new product, yet still charge supra-competitive prices.\textsuperscript{186} Consequently, the producer has more of an incentive to merely continue minimally improving his pre-existing product line.\textsuperscript{187} "If marketed heavily, such products can fetch high prices, so long as they are perceived to be roughly as good as another high-priced medicine."\textsuperscript{188}

Indeed, recent studies have exposed an ongoing decrease in the development of innovative new pharmaceuticals, with only 8 percent of potential drugs making it through the FDA approval process.\textsuperscript{189} Moreover, from the period between 1990 to 2004, only 22 percent of new drug approvals fell under the category of “priority” review, where the new drug offers a “significant price at a given output level. See N. GREGORY MANKIW, PRINCIPLES OF ECONOMICS 94 (2d ed. 2000), available at http://www.swlearning.com/economics/mankiw/principles2e/rep/dl/ch05.pdf.

\textsuperscript{182} See CBO REPORT, supra note 46, at 5.
\textsuperscript{183} Id.
\textsuperscript{184} See MANKIW, supra note 180, at 94.
\textsuperscript{185} See Vernon, supra note 180, at 183; Patricia M. Danzon, The Pharmaceutical Industry, in ENCYCLOPEDIA OF LAW & ECONOMICS 1055, 1056 (Boudewijn Bouckaert & Gerrit De Geest, eds., 2000).
\textsuperscript{186} Love & Hubbard, supra note 17, at 1523. See Nussbaum & Radice, supra note 109 (noting that pharmaceutical companies charge upwards of 900% more for even minor improvements).
\textsuperscript{187} Love & Hubbard, supra note 17, at 1523.
\textsuperscript{188} Id.
\textsuperscript{189} Epstein, supra note 42, at 461.
improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease.” While some might consider the incremental improvements acceptable in the face of having no alternative, the fact remains that “me-too” drugs carry substantial costs. This is partially due to the fact that “[o]nce regulators like the United States FDA determine that products have few incremental benefits over existing medicines, they are likely to require more proof that the products don’t cause harm to patients. Companies also need larger trials to claim that small differences in efficacy are statistically significant.”

The bill addresses the incremental improvement incentive provided by patent exclusivity by tying prize sizes to the extent of improved health outcomes. In other words, if a follow-on product provides only minimal improvements in terms of efficacy, then the prize would be smaller. Conversely, if the follow-on product delivered significantly improved efficacy, then the prize would be proportionally larger. Importantly, the increase, or lack thereof, in efficacy would be measured against a pre-existing competing treatment, rather than a placebo. By tying the size of the prize to outcomes, the bill would provide an incentive to use a pioneer drug, and then modify it to make substantial improvements, rather than merely incremental improvements.

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190. Love & Hubbard, supra note 17, at 1523 (quoting CTR. FOR DRUG EVALUATION & RESEARCH, MANUAL OF POLICIES AND PROCEDURES 6020.3 (2007)). While some blame the current system for this lack of innovation, other commentators have noted that previous advances have already addressed “simpler” diseases, leaving those diseases which have complicated causes, such as cancer or Alzheimer’s. Epstein, supra note 42, at 461-62.

191. Love & Hubbard, supra note 17, at 1524.

192. Id.


194. A “follow-on” product is one which is derived from the original drug, and may, or may not, have improved therapeutic properties. Tufts Center for the Study of Drug Development: Publications Glossary, TUFTS UNIV. (last visited Oct. 27, 2011), http://csdd.tufts.edu/library/publications_glossary. The difference between a me-too drug and a follow-on is that a me-too targets the same therapeutic mechanism as the original, but may do so with a compound unrelated to the original. See CBO REPORT, supra note 46, at 2 box 1.

195. Id.
Further, the bill also provides a level of protection for the pioneer product. By providing upwards of ten years of payments, the pioneer need not worry about losing its market share to even vastly improved versions. Rather, the pioneer would be guaranteed payment even if competition reduced its market share to zero. As a result of tying prizes to improvements, it would redirect R&D resources away from minimally beneficial changes (in order to protect market share), to those which have significant impacts on health outcomes.

However, at first glance, the prize system seems to provide an incentive to only pursue drugs which have a high probability of success in clinical trials (i.e. low toxicity with some efficacy compared to a placebo for FDA approval; improved efficacy versus a competing drug for the prize). A similar problem to the incremental improvement of the patent system would arise—the cost of going into a high-risk clinical trial cannot be economically justified unless the probability of successful clinical trials and FDA approval surpasses a certain threshold. Consequently, the incentive is to introduce only incremental improvements to drugs with known safety and efficacy profiles in order to mitigate the risk of new drug development. At some point, the odds of actually capturing a prize (i.e. being first to FDA approval) would have to skew significantly in favor of success in order to justify the upfront costs.

Yet, the above analysis reflects one of the more intriguing contradictions in innovation. While it would appear that large, well-established companies would have the knowledge and resources to engage in expensive innovation projects, a significant amount of innovation arises from start-up ventures. Smaller companies may be willing to spend such high upfront costs in order to achieve longer-term goals: recognition and reputation.
With increased consumer awareness and goodwill, a small company creates the potential to grow. Indeed, an analysis of revenue generation over time, from start-up to well-established company, typically shows significant losses in the first five to ten years of existence.\footnote{CBO REPORT, supra note 46, at 46 fig.7.} In other words, these fledgling companies and their backing investors are willing to take on significant risks and the likelihood of many years of red ink to develop a potentially ground-breaking new therapy or treatment, regardless of the low probability of success.

Prizes have successfully exploited this high-risk mentality of innovators and entrepreneurs to propel leaps forward in technology, at least in the private sector. A prime example of this came in the form the Ansari X-Prize, offering $10 million to the first team to develop an aircraft capable of space flight.\footnote{Adler, supra note 198, at 16.} Combined, the participating teams invested over $100 million dollars of private funds to develop their respective designs.\footnote{Id.} Indeed, Paul Allen, the co-founder of Microsoft, reportedly spent nearly $20 million dollars funding the winning team, twice the prize award.\footnote{Id.} Even though from a rational economics perspective, the odds of winning the prize compared to the upfront costs required for development warranted a no-go, the prize was a resounding success.\footnote{See id.} Perhaps even more importantly, the prize spurred development by numerous competitors, and helped launch the private sector’s space-flight industry.\footnote{Id.}

The legislation proposed would offer a similar incentive: a prize would be given to the first person to get FDA approval for a new drug in certain designated categories, such as neglected or global diseases.\footnote{Medical Innovation Prize Fund Act of 2011, S. 1137, 112th Cong. § 9 (2011).} In theory, the incentive of a prize should spur innovation by a wide number of entities, not just major life...


201. CBO REPORT, supra note 46, at 46 fig.7.
203. Id.
204. Id.
205. See id.
206. Id.
sciences corporations, but also academic researchers. Thus, this would increase the amount of competition, and ultimately result in the development of more potential new breakthroughs.

4. Global Health Priorities and Neglected Diseases

The drug industry frequently cites the necessity of exclusivity as the primary means of recouping upfront investments, without which there would be no development to begin with.208 Thus, the patent system serves to promote innovation. However, because the drug industry relies so heavily on monopoly pricing, these companies have little incentive to invest R&D resources in minimally profitable drugs, even though there might be a pressing need.209 The most noteworthy examples arise from diseases affecting predominantly poor countries, such as malaria.210 In these cases, the population that actually needs the treatment has little means of affording such treatment. If a drug company goes ahead and develops a treatment, then it would be unable to charge prices sufficient to recoup the R&D costs, even with patent protection in hand.211 There is simply no mechanism to reward the time and effort required for effective new treatments. Consequently, there is little development geared towards treating such diseases since “[w]hen marketing exclusivity is the reward, investors rationally target research investments to address the problems of patients who have the highest incomes and can pay the highest prices.”212 That is, exclusivity compels an inventor to develop products which guarantee him a return on investment—those products for which there is adequate consumer demand. In the absence of such demand, even the longest period of monopoly would be useless, as revenue could not be generated in the first place.

Neglected diseases with small affected populations exhibit a related shortcoming. Because the affected population is small, the

208. See Burk & Lemley, supra note 36, at 1616.
209. Love & Hubbard, supra note 17, at 1527.
210. Id.
211. Id.
212. Id.
potential for large profits decreases unless a company can charge a price high enough to offset that smaller population. However, once that company charges supra-competitive prices, deadweight losses begin to appear. In other words, a company would be able to charge supra-competitive prices for a neglected disease, but because of the high price, there will inevitably be a subset of the population which requires the treatment, but cannot afford it. This lack of access may arise either because the consumer is uninsured or underinsured, or because the insurance company will not cover the costs. Consequently, the company is not generating optimal revenues for the product, and the consumer is not receiving effective treatment. In this case, patent exclusivity itself generates inefficiencies to the detriment of society.

The proposed prize system would provide an adequate incentive to engage in programs targeting these neglected and other non-profitable diseases, be it in the United States with small target populations, or in foreign countries with populations unable to afford monopoly-driven prices. By providing a mechanism to recoup initial investments, theoretically, companies would be more willing to engage in R&D targeting these low revenue diseases. Moreover, because the amount of the prize would be linked to the population size and the relative impact of the disease, it would be possible that the prize payout could increase profitability, especially considering that marketing and sales costs would be minimal in such areas. Here, the prize may provide a sufficient

213. Large pharmaceutical companies such as Pfizer are beginning to recognize the importance of these smaller niche markets. Jonathan D. Rockoff, *Pfizer’s Future: The Niche Blockbuster*, THE WALL ST. J., Aug. 30, 2011, at B1. As an example, Pfizer’s Xalkori treatment for lung cancer is effective in a small subset of patients with an ALK gene abnormality—only 6,000 patients yearly in the United States have this lung cancer-associated abnormality. *Id.* Pfizer is planning on charging $115,000 per patient per year. *Id.*


216. Gifford, *supra* note 18, at 86.

217. Theoretically, if the R&D costs remain fixed and covered by prize awards, and the marketing costs substantially decreased, then the overall profitability of the drug increases, assuming that manufacturing costs are minimal.
incentive to drive increased innovation when compared to traditional non-profit motivations, such as altruism.\footnote{218} Under the prize system, the "costs" rationale weakens, as the prize award would be sufficient to cover the drug development costs, thus providing the much-needed motivation to pursue low-revenue opportunities.

Additionally, in the author's own estimation, because the target population is less impacted by marketing efforts, the company would be able to spend less on the associated marketing costs, potentially removing a significant cost from the equation. This removal of marketing costs would provide additional incentive to pursue such neglected diseases, as profit margins theoretically would be higher. That is, since the associated costs reflect primarily R&D and marketing expenditures, with manufacturing costs contributing minimally, the removal of high marketing costs decreases the total associated costs. With lower costs, more of the generated revenue remains unencumbered, resulting in higher profit margins.

5. The Unpatented and Unpatentable

In certain cases, a new pharmaceutical product may exist in the absence of a patent, be it because the inventor did not believe it to be patentable, wanted it in the public domain, or simply failed to overcome the statutory hurdles for patentability. Whatever the reason may be, under traditional rationales, the drug has little chance of extensive development owing to its inability to recover costs.\footnote{219} Without patent protection, particularly in the case of small molecules, as soon as the product became public knowledge, it would be subject to duplication.\footnote{220} Owing to the relative ease of copying small molecules, competitors better situated than the inventor would be able to engage in the R&D necessary for

\footnote{218} See Lee, supra note 27, at 682.
\footnote{219} See Cotropia & Gibson, supra note 26, at 926-27; Adams & Brantner, supra note 39, at 131.
\footnote{220} See CBO REPORT, supra note 46, at 3; Moore supra note 47, at 16 (noting that small molecule drugs are structurally simple, making synthesis of the drug simpler).
eventual FDA approval.\textsuperscript{221} In this case, the prize system may provide the necessary financial incentives to continue with development of the otherwise unpatentable product.

6. Biologicals and Bypassing the Anticommons

Under the anticommons theory of patents, patent holders control the rights to a scarce resource, and have the ability to exclude others from using that resource.\textsuperscript{222} In the biotechnology and pharmaceutical fields, the anticommons effect appears most readily when “upstream” research tools are patented, thus hindering the ability for subsequent researchers to use those tools for future product development.\textsuperscript{223}

In the rapidly progressing biotechnology field, this is a real concern.\textsuperscript{224} Because biotechnology treatments involve the use of biological molecules (e.g. proteins, RNA and DNA sequences), these treatments oftentimes involve multiple patentable components.\textsuperscript{225} Imatinib provides an example of a potential anticommons effect.\textsuperscript{226} The development of imatinib hinged on the discovery that a chromosomal fusion causes chronic myeloid leukemia (CML).\textsuperscript{227} In this case, the most basic patentable discoveries would be for the chromosomal fusion of \textit{bcr-abl}, as well as for the normal versions of both \textit{bcr} and \textit{abl} genes.\textsuperscript{228} Further, the protein derived from the fusion would be patentable.\textsuperscript{229} Lastly, any biological compound found to neutralize the effect of

\textsuperscript{221} See CBO REPORT, supra note 46, at 3.
\textsuperscript{222} Lee, supra note 27, at 673.
\textsuperscript{223} \textit{Id.} at 674. “Upstream” refers to basic research tools and products which are used to develop the actual finished, or “downstream,” products. See Heller \& Eisenberg, \textit{supra} note 67, at 698.
\textsuperscript{224} Burk \& Lemley, \textit{supra} note 36, at 1624-25.
\textsuperscript{226} Imatinib (Gleevec) is a tyrosine kinase inhibitor used in the treatment of various types of cancer, such as chronic myeloid leukemia. \textit{Gleevec}, NOVARTIS (last visited Sep. 29, 2011), http://www.gleevec.com.
\textsuperscript{227} Shiu, \textit{supra} note 223, at 426.
\textsuperscript{228} See \textit{id}.
\textsuperscript{229} See \textit{id}.
the BCR-ABL protein fusion would be patentable. If multiple parties had independently patented the various components involved in the development of CML, then a potential anticommons issue could have arisen. That is, if the patent holder for the \textit{bcr} gene refused to license his patent, then the invention of imatinib may not have occurred. Additionally, if those upstream patent holders did license their patents, they would expect royalties in return, potentially making downstream innovation prohibitively expensive. Moreover, imatinib may target more enzymes than just BCR-ABL, targets which may already be patented. The owner of imatinib would have to negotiate with each of the other target owners simply to test whether imatinib would be effective against those targets. Again, further development of imatinib could be blocked by a non-willing patent owner, or made significantly more expensive if royalties were necessary for that additional development.

Ultimately, the impact of the bill on alleviating the concerns of the anticommons in biotechnology depends on the interpretation and implementation of the bill’s exclusivity provisions. In theory, by compelling owners to relinquish exclusive rights to the various patents needed to construct an effective final product, the problem of the anticommons disappears—all parties seeking to utilize those upstream patents for downstream innovation would have ready access. However, because the prize system as envisioned still would require potential interested parties to negotiate licensing deals with the upstream owners, the issue of compounding fees making the final product prohibitively expensive would remain. The prize system does offer a possible workaround to such issues in the form of collaborative knowledge sharing incentives. This provision would ensure that collaborators deemed necessary to the development of the final innovation would receive a portion of the prize fund. Because the up-stream innovation oftentimes does

\begin{footnotesize}
231. \textit{Id.}
232. \textit{Id.}
234. S. 1137 \textsection 11.
\end{footnotesize}
not have immediate practical value, but instead a wide range of future applications (thus generating its value), the innovator currently has an incentive to patent as early as possible. The innovator knows that the financial rewards will accrue in the form of licensing royalties even in the absence of such immediate practical applications as companies "bet" on those future applications.

By allowing for such upstream innovation to be considered for a portion of the prize fund, these innovators may be more apt to put the invention in the public domain. As stated in the bill, "at least 5 percent of the prize payments from the Fund shall be dedicated to Open Source Dividend prizes." Again, at current 2010-2011 estimated GDP levels, this would translate into roughly $4 billion devoted to open source collaborations on a yearly basis. Ultimately, whether the open-source incentive would work depends largely on the size of the prize, and the likelihood of actually winning the prize. For example, academic non-profit institutions may be more motivated to keep federally-funded research in the public domain and vie for the prize in adhering to their traditional purpose: promoting knowledge for the public good. By keeping research in the public domain, it would be eligible for the prize. But if the prize award were only a one-time deal, then the appeal of longer-term returns through licensing might be more attractive. Simply, the prize award must exceed potential licensing revenues in order to properly incentivize such open collaboration.

C. Implementation and Interpretation Problems

Despite its seeming ability to create meaningful incentives to develop innovative new drugs, the actual implementation of the proposed legislation remains problematic in light of its exceptions.

235. This is an example of the prospect theory of patents. See Kitch, supra note 33; Duffy, supra note 34.
236. S. 1137 § 11.
to relinquishment of exclusivity. As noted, Section Five provides exceptions for exclusivities granted by patents or by the FDA.  

Under Section 271 of the Patent Act, the inventor of an invention, or his assigns, has the right to exclude others from practicing the invention. This is the fundamental precept of patents. Exclusivity is indeed the only right granted under the statute, as exemplified by the patent owner permanently enjoining infringers from using the patented product by judicial order. Moreover, under Hatch-Waxman, the first to receive FDA approval to market a new molecular entity will receive five years of exclusivity. For new uses of a pre-existing drug, the first person to develop and receive approval will receive three years of exclusivity. FDA regulations also provide exclusivities for orphan drug and pediatric drug designations. Even generics are afforded a period of exclusivity under Hatch-Waxman of 180 days, provided the generic prevails in an infringement suit.

In light of the bill’s specific concession to existing statutory exclusivity, not much is left which would be prone to the Bill’s reach. Essentially every drug in development is currently subject to patent exclusivity, including incrementally improved versions and follow-on versions. Because the Bill exempts patent exclusivity, it would be unable to enforce the relinquishment of such exclusivity. In other words, assuming that a patented drug receives FDA approval within its patent term, then the drug-maker is free to continue to leverage its patent-granted monopoly since the Bill expressly allows this. Of course, once the drug goes off-patent, then the drug-maker would have to adhere to the bill’s provisions. However, at that point, the drug-maker no longer has any right to exclusively market the drug under the patent laws. Further, if the drug is truly a new molecular entity, it will most likely be patented and further protected by FDA-granted

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238. S. 1137 § 5.
241. Id.
exclusivity. Again, the Bill’s exceptions seem to negate its own purpose of eliminating exclusivity. More importantly, while the Bill seeks to provide generics with market access almost immediately after a pioneer drug receives FDA clearance, there is no provision in the Bill requiring a pioneer to provide competitors with the information necessary to create an equivalent generic version of a drug.\footnote{244}{See Medical Innovation Prize Fund Act of 2011, S. 1137, 112th Cong. (2011).} The only way a generic would have access would be by obtaining the drug commercially, and then reverse-engineering it—a legitimate exception to patent infringement under Hatch-Waxman.\footnote{245}{The statute states: It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products. 35 U.S.C. § 271(e)(1) (2006). See Jeremiah Helm, The Patent End Game: Evaluating Generic Entry Into a Blockbuster Pharmaceutical Market in the Absence of FDA Incentives, 14 MICH. TELECOMM. TECH. L. REV. 175, 178-79 (2007).} Nothing would change about the way generics gain market entry.

In fact, the Bill would only operate in very limited circumstances. It would only have an impact if a drug is not entitled to exclusivity in the first place. That is, there is no exclusivity if a drug is (1) not patentable; (2) not a new molecular entity; (3) not an orphan drug; (4) not meant for pediatric use; and (5) not a successful Paragraph IV generic under Hatch-Waxman. In these cases, the Bill would have an impact since there would be no patent-granted or FDA-granted exclusivity. Yet, at best, that impact would be minimal, restricting the ability of the drug-maker to negotiate exclusive marketing agreements, something that the maker is not necessarily entitled to by law.\footnote{246}{See 35 U.S.C. § 271 (2006) (granting only a right to exclude).}

Consequently, in order to have any impact whatsoever, one must interpret the bill as either being (1) voluntary, with a company opting for prize consideration while relinquishing its right to
exclude others or (2) involuntary, as a form of compulsory licensing, though not necessarily one in which the licensee can use the patented product without the owner’s consent. In both cases, the awarding of a prize would substitute for patent-granted exclusivity.

In a voluntary system, a company would develop a new drug candidate, obtain a patent on the candidate and then pursue a usual course of drug development: preclinical research and development, followed by clinical trials and FDA approval. If the company opted to compete for a prize, then its ability to exclude others from developing generic or “me-too” versions of the drug would be eliminated. Moreover, the company would be required to grant licenses to any competitor asking for access, though appropriate royalties would still need to be negotiated. Presumably, knowing that the company had relinquished exclusivity, competitors would be able to rely on that company’s own drug data, just as it can under Hatch-Waxman. As a result, competition would be able to enter the market as soon as the drug received FDA clearance, thus ensuring that the price of the drug would reflect competitive supply and demand dynamics, rather than monopoly pricing power.

However, the primary issue with interpreting it as a voluntary system would be in its implementation. That is, if a company can charge supra-competitive prices under patent and FDA exclusivity rules, and generate annual revenues exceeding several billion dollars for a blockbuster, then why would a company ever decide to opt for the prize system? Moreover, if the company knows it can retain such high pricing on its drug by making even minor

250. Love & Hubbard, supra note 9, at 170.
251. Hatch-Waxman § 103; Weiswasser & Danzis, supra note 79, at 593.
improvements, is there any reason for the company to even consider the prize fund, even if it were to receive awards on an annual basis?

Consider the case of Lipitor, the best-selling cholesterol reducing medication in the world for the past few years. Originally developed and marketed by Warner Lambert and eventually purchased by Pfizer, Lipitor sales peaked at $12.9 billion in 2006 and remained over $10 billion in 2010. Considering the staggering numbers involved, there appears to be little motivation to pursue a prize capped at $4 billion at current GDP levels. However, these are total revenues and do not reflect the costs associated with developing and marketing the drug. Companies selling patented drugs tend to engage in extensive marketing campaigns to develop brand recognition in their targets. By doing so, the company seeks to maximize revenues and profits during its period of exclusivity. At the same time, the final price of the drug ultimately reflects these increased marketing expenses. An examination of Pfizer’s financial reports suggest that R&D accounts for only 15 percent of costs, and marketing expenses account for upwards of 30 percent. A report by the Congressional Budget Office also noted that pharmaceutical companies spent approximately $4.7 billion, or one quarter of their promotional expenditures, on direct-to-consumer advertising in

252. Pharmaceutical Sales, DRUGS.COM (last visited Oct. 27, 2011), http://www.drugs.com/top200.html. Pfizer is not necessarily representative of all pharmaceutical companies, as 70 percent of its revenues were derived from blockbuster drugs. Jacquet supra note 172, at 2.


254. See PFIZER INC., supra note 251 (financial reports display total revenues, and then subtract costs to determine profits).

255. Love & Hubbard, supra note 9, at 159.

256. PFIZER INC., 2010 FINANCIAL REVIEW 25 (2010). Note that these are at best rough estimates of costs associated for any given product since companies do not list costs on an individual product basis, only as a whole. Id.
The other $20.5 billion was spent on promotions directed at doctors and other health care professionals. Because of the incentives provided by the prize system, marketing costs could be significantly reduced, thus decreasing the overall costs associated with a drug. That is, the necessity to expend large amounts for marketing purposes would be somewhat attenuated, as marketing costs would have to be proportional to the competitively determined price of the drug. Under the patent system, a company can charge supra-competitive prices, and because revenues are higher, can devote more resources to marketing. Moreover, because the company would want to generate strong brand-loyalty or recognition prior to patent expiration, it would have additional motivation to engage in extensive marketing campaigns. While marketing would remain an important aspect even in a competitive system, overall marketing expenses would be reined in because of price and competition pressures. Since the pioneer company would be charging substantially less in the absence of monopoly-power, it would be able to devote only a smaller portion to marketing. Because there is a reduction in overall costs, a drug-maker could achieve a similar level of profitability for a given drug under the prize system as under the patent system.

As a simple example, assume that a patented drug generates $100. $15 of that revenue would go towards R&D expenses, another $30 towards marketing expenses, and another $30 towards other administrative expenses. This would leave $25 as profit, or a 25 percent profit. The same drug under the Bill’s provisions would cost substantially less, say $50. Assuming that R&D and other costs can be reduced slightly to $10 and $20 respectively, the remaining $20 would have to cover both marketing costs and profits. Thus, if a company wanted to maintain a 25 percent profit

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257. CONG. BUDGET OFFICE, POTENTIAL EFFECTS OF A BAN ON DIRECT-TO-CONSUMER ADVERTISING OF NEW PRESCRIPTION DRUGS 1 (2011).
258. Id. at 2.
259. See Love & Hubbard, supra note 9, at 159.
260. CONG. BUDGET OFFICE, PROMOTIONAL SPENDING ON PRESCRIPTION DRUGS 7 (2009) (noting that companies spend less on promotional activities in markets with larger numbers of competitors).
($12.50), it would have to reduce marketing to 15 percent of revenues ($7.50). Conversely, the company could maintain aggressive marketing practices, but expect significantly reduced net profits. If 30 percent of revenue ($15 out of $50) remained devoted to marketing, then total costs would equal $45, leaving only $5 profit, or 10 percent. While the Bill provides an incentive to decrease marketing expenses, ultimately the decision on profitability rests with a company’s individual business strategy.

Under a non-voluntary system, a similar conclusion ultimately will be reached as under the voluntary adoption of the prize route. However, rather than the company voluntarily licensing its product, the bill could be interpreted as creating a form of compulsory licensing of any patented product. In light of the bill’s deference to the patent laws and FDA-granted exclusivity, the only way to co-exist with these statutory grants of monopoly would be to interpret the bill as requiring compulsory licenses. Because the relinquishment of exclusivity post-FDA approval would be mandatory, it would ensure that all companies with patented drugs would go through the prize system.

Compulsory licensing is not unprecedented, as seen in both domestic regulation as well as through international accord.261 In the United States, the government is permitted to grant itself, and others, a license to use a patented product without the permission of the owner under 28 U.S.C. § 1498, usually due to national emergency (e.g. disease outbreaks).262 Other statutes contain provisions explicitly allowing for compulsory licensing if needed for the greater public good, thus overriding patent exclusivity.263

262. Id. at 863.
263. For example, the Atomic Energy Act compulsory licensing provisions reads in part

Whenever any patent has been declared affected with the public interest . . . any person may apply to the Commission for a nonexclusive patent license to use the invention or
However, the proposed legislation does not contain equivalent provisions. As such, it is difficult to determine exactly how the Bill would implement and enforce a compulsory licensing scheme. Additionally, owing to the considerable political strength of the pharmaceutical industry, it is unlikely that the industry would react favorably to such a scheme.

D. Possible Solutions

While in theory, a prize system appears to be an effective tool both to drive innovation and to drive down costs through competition, the Bill as presented lacks the substance to be truly effective. As noted, in light of the exceptions to patent and FDA-granted exclusivity, there are precious few other forms of exclusivities impacted by the Bill. Because of this, the majority of pharmaceutical companies would still rely on patent protection and FDA-granted exclusivity to continue charging supra-competitive prices. Moreover, as these companies would not be required to relinquish exclusivity, any subsequent generic manufacturers would still have to wait until the original patent expired before entering the market. Alternatively, the generic maker would still have to utilize Hatch-Waxman’s Paragraph IV provision, allowing the generic maker to duplicate a pioneer’s drug and prove non-infringement in court.

discovery covered by such patent, and the Commission shall grant such patent license to the extent that it finds that the use of the invention or discovery is of primary importance to the conduct of an activity by such person authorized under this chapter.


265. Love & Hubbard, supra note 9, at 173.


To make the Bill more effective, some clarity is necessary. Most importantly, it must clearly define how the exclusivity elimination would operate in light of its exceptions. By its terms, does the Bill leave all patent-granted exclusivities in place? Or would it operate along the lines of a compulsory licensing system? Would it be a voluntary system with participants willingly foregoing exclusivity in exchange for a piece of the prize? In order to ease the impact on the health care industry, a voluntary system might be in order. While larger, well-established companies may continue to rely on patent and FDA-granted exclusivity, smaller companies and investors may be more willing to forego the traditional system in favor of a guaranteed payout over ten years. The prospect of guaranteed returns would be even more appealing if the company lacks a strong brand-awareness, or the marketing muscle of its established competitors. If the system were mandatory, then the easiest fix to clarify the Bill would be to introduce a provision similar to the Atomic Energy Act. This would allow the government to compel non-exclusive licenses for those priority areas defined in the Bill.

Additionally, the Bill needs to clearly define the size of the prize. As opponents note, one of the Bill’s flaws rests with the uncertainty of prize sizes. This uncertainty means participants would not know what a reasonable investment would be. While some might consider a $20 million initial investment reasonable for a $10 million prize, would the same investment still be reasonable if it were only a $1 million prize? From the outset, the prize amounts must be clearly noted. Considering that companies routinely estimate revenues for their products on both domestic and international scales, input from established pharmaceutical and biotechnology industry players would be a logical first step in determining the size of individual prizes.

Ultimately, however, making a prediction on the value of any given new treatment will be exceedingly difficult, owing to the complex nature of diseases and disorders. This is precisely why the patent system’s free-market approach is a far more efficient determinant of value. Under the patent system, the public will

268. Nunnenkamp, supra note 261, at n.21.
269. Wei, supra note 57, at 32.
“reward” an invention based on its perceived necessity. The bigger the demand, the bigger the reward, and vice versa. If the Bill were to pass, its most immediate impact would likely be in the areas of the aforementioned neglected/orphan diseases with small populations and global diseases with low profitability. For neglected/orphan diseases, because the population is so small, the ability to generate sufficient revenue to offset costs diminishes. Consequently, a company would have to charge higher prices to offset the smaller population. If the Bill were to pass, then companies would no longer have to worry about recouping R&D costs, as the prize would ideally be sufficient to cover such costs. As a result, those companies would be able to charge lower prices, and still generate adequate profits. Moreover, since the price is more manageable, the extent of deadweight loss also diminishes.

A similar scenario plays out for global diseases primarily afflicting poor populations. Because the prize would cover a substantial portion of a drug’s costs, a company would no longer have to worry about recovering those costs. The result would be a decrease in price at the outset. Couple the decreased costs with increased competition and the final price of a drug decreases even further. The end result in both scenarios is the same: both social benefits and revenues approach maximal levels.

V. CONCLUSION

High prescription drug prices continue to pose a problem for the health care system in the United States. While pharmaceutical companies may be justified in charging higher prices to offset R&D and clinical trial costs, the fact that they continue to charge high prices for even minor incremental improvements remains problematic. The proposed legislation is a strong attempt at addressing several of the underlying structural issues of high drug costs. From a fundamental economic perspective, de-linking R&D costs from the final price of a drug while simultaneously promoting generic competition would serve to drive down costs considerably. However, the economic backdrop is far more complex considering the involvement of private and public health insurance, and drug provider organizations. While it seems unlikely that this Bill will pass, it does help keep the issue at the
top of the healthcare debate. Perhaps some express guidelines regarding the Bill’s implementation—voluntary or compulsory—along with clarification on the determination of prize sizes would ease its acceptance.

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