INCENTIVIZING INNOVATION AND RECLAIMING BALANCE IN THE PHARMACEUTICAL INDUSTRY: A CASE FOR SECONDARY PATENTS

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ABSTRACT

In the pharmaceutical industry as it exists today, brand-name companies are often criticized for attempting to minimize competition and raise drug prices. In response to this reaction, incentives have been put in place to benefit generic drug companies. These existing incentives create an imbalance, favoring generic companies. However, the balance should be restored to account for the important role that brand companies have in the industry, specifically with the innovation they provide by investing in the research and development of new and improved products. The need for innovation in the industry stems from the greater need of the public to have drug products to treat illnesses and ailments. This Note proposes that a maximized innovation incentive for brand companies can be created by further expanding on already-existing incentives, specifically focusing on the role of secondary patents in the industry.

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I. INTRODUCTION

The pharmaceutical industry has a high-cost, low success-rate model for new drug research and development. For example, a new drug product may cost up to $2.6 billion dollars from its initial research phase to its market approval stage, and there is less than a twelve percent chance of gaining market approval for those products that do make it

to clinical development.[1] Further, the majority of non-capitalized costs are incurred by pharmaceutical companies during early stage development, creating high up-front costs for early research of new, potential drug products.[2] While facing failure at every turn, large pharmaceutical companies continue to invest in early-stage research and development despite the heavy financial burden and low success rate of developing a new drug. These companies play a critical role in healthcare, creating invaluable new drugs that are used to treat patients. Although there are certain systems in place to encourage these companies to continue their innovative roles, these systems may currently be insufficient. Therefore, to continue encouraging the innovation that drives the creation of invaluable drugs, pharmaceutical companies should have a maximized incentive to bear the unreturned costs and chance of failure in new drug research and development.

The pharmaceutical industry as a whole is incentivized to innovate through exclusivity grants provided by the patent law system and the Food and Drug Administration (FDA). Exclusivity provided by the patent law system provides pharmaceutical companies the ability to prevent third parties from making, selling, or using the new drug claimed in the patent; however, due to the timeline of filing for a patent application and ultimately getting a new drug product to market, pharmaceutical companies do not

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[1] Thomas Sullivan, *A Tough Road: Cost to Develop One New Drug is $2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less than 12%*, POLICY & MEDICINE (Mar. 21, 2019), https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html [https://perma.cc/4M2Y-Y4X5].

[2] Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 23–25 (2016); Ed Price, *Want to Know Why Early Drug Development Costs So Much*, PCI (Mar. 22, 2019), https://www.pcisynthesis.com/want-to-know-why-early-drug-development-costs-so-much/ [https://perma.cc/5BSP-ZRJL].

necessarily enjoy a full patent term.[3] Meanwhile, the FDA's grant of exclusivity allows the owner of the new drug to have exclusive rights on the market for an amount of time typically between six months and seven years.[4] The downfall of this innovation incentive is that it only comes into existence once a new drug has FDA approval, a checkpoint that the majority of potential products never reach.[5]

Taking a closer look at the U.S. patent law system reveals another means to incentivize the industry beyond the initial patent granted (the primary patent) for a drug product. This incentive is the granting of secondary pharmaceutical patents. In the pharmaceutical context, a primary patent is one that typically covers the active pharmaceutical ingredient of a new drug, while a secondary patent is one that can cover other aspects of a drug product such as the form of the active compound, a method of use, a dosage, or a formulation.[6]

While there is widespread concern in the industry regarding secondary patents and the potential for unfairly extending patent protection for products beyond the initial twenty-year patent term, this Note will argue that more readily granting secondary patents serves to incentivize innovation—specifically with respect to product improvement—without unfairly creating a market monopoly on previously patented drug products. Further, this Note will argue that encouraging such secondary patents, coupled with other already existing incentives, can create a maximized

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[3] Angélique McCall & Gene Quinn, *The FDA Process, Patents and Market Exclusivity*, IPWATCHDOG (Mar. 12, 2017), https://www.ipwatchdog.com/2017/03/12/fda-process-patents-market-exclusivity/id=79305/ [https://perma.cc/2R8V-8MJG].

[4] *Id.*

[5] *Id.*

[6] María José Abud Sittler et al., *An Empirical Analysis of Primary and Secondary Pharmaceutical Patents in Chile* 2 (Nat'l Bureau of Econ. Research, Working Paper No. 20995, 2015).

incentive that will adequately encourage brand pharmaceutical companies to continue investing time and money into risky, early-stage innovation for new drugs.

It is important to acknowledge that this Note does not seek to disregard the tension between brand and generic interests. Generic companies serve an invaluable purpose by creating market competition and, consequently, lowering consumer costs, among other things. These are valuable considerations, and a balancing of these interests is critical for maximizing public good. However, this Note will argue that the balance currently weighs too far in favor of generic companies, which ultimately stifles innovation in the industry by limiting brand companies' ability to recoup costs and collect profits. The underlying logic of the argument being that the more brand companies profit, the more they will reinvest their increased profits in further research. This reinvestment could lead to a significant increase in groundbreaking new drug innovations and product improvements. Therefore, this Note does not seek to invalidate the important purpose of generic companies, but rather argues that because current incentives tip the balance too far in the favor of generics, a correction is needed. Specifically, the correction would provide greater incentives for brand companies to continue developing innovative products for the benefit of the consumers.

In advocating for this correction, Section I of this Note outlines the structure of the pharmaceutical industry with respect to the competition created between brand and generic companies, the role that the Hatch-Waxman Act of 1984 serves in creating such competition, and the current problems faced by brand companies. Section II outlines the current innovation incentives, exclusivities provided by the patent law system and the FDA, with an analysis of the pros and cons of each. Section III explores a method for maximizing innovation incentives for brand companies, ultimately drawing a conclusion that the best way to do so is

by supplementing currently existing incentives with a greater emphasis on secondary patents and the role they should play.

II. STRUCTURE OF THE PHARMACEUTICAL INDUSTRY

A. Brand vs. Generic

The pharmaceutical industry is comprised of brand companies and generic companies, each of which serve a different role in the industry. Brand companies are those that serve to invest in research and development to create new pharmaceutical products while generic companies produce imitator copies of the brand-name pharmaceutical products.[7] To comply with FDA requirements, generic companies must produce drug products that are the same as brand-name drugs in their dosage form, safety, strength, administration route, quality, and performance character.[8] As generic products are copies of brand products, the generic drugs cannot be introduced to the market until the brand company's patent(s) and FDA exclusivities have expired.[9] Yet, generic companies benefit from the investment made by brand companies because generic medicines do not have to repeat clinical trials that were done for the original brand product; rather, to comply with the FDA, a generic company may submit an abbreviated application to gain FDA approval, relying on the clinical data obtained by the testing of the brand product.[10]

This distinction between brand and generic companies, and their products, creates competition within

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[7] Fiona M. Scott Morton, *Barriers to Entry, Brand Advertising, and Generic Entry in the U.S. Pharmaceutical Industry*, 18 INT'L J. INDUS. ORG. 1085, 1090–92 (2000).

[8] *Generic Drug Facts*, FDA, https://www.fda.gov/drugs/generic-drugs/generic-drug-facts [https://perma.cc/2CVC-GSTG].

[9] *Id.*

[10] *Id.*

the pharmaceutical market. Generic companies have the ability to enter the market at a lower price with generic products, but brand companies have the opportunity to enter the market first. While it may seem like a fair trade-off, the brand pharmaceutical companies may actually benefit less. This trade-off, as it exists today, was established through the creation of the Hatch-Waxman Act, which provides a path for generic manufacturers to challenge patent validity of a brand product more readily.[11]

B. The Hatch-Waxman Act

The Hatch-Waxman Act was passed by Congress in 1984 and has resulted in an overall increase in pharmaceutical competition between brand and generic companies.[12] One of the primary goals of the Act is to facilitate the approval of generic drugs, thus encouraging a larger presence of generic drugs on the market.[13] The Act also provides generic companies an avenue to challenge brand-name patents prior to obtaining market entry; this can ultimately allow the generic company to avoid simultaneous challenge to, and infringement of, brand products.[14]

One way generic companies can challenge a brand company's patent is through a Paragraph IV certification, where the generic company files an Abbreviated New Drug Application (ANDA).[15] When a generic company files an

[11] Henry Grabowski et al., *Recent Trends in Brand-Name and Generic Drug Competition*, J. MED. ECON. 1, 1–2 (2013).
[12] *Id.*
[13] *Id.* at 2.
[14] Garth Boehm et al., *Development of the Generic Drug Industry in the Hatch-Waxman Act of 1984*, 3(5) ACTA PHARMACEUTICA SINICA B 297, 298 (2013).
[15] Meredith H. Boerschlein & Shana K. Cyr, *Intricacies of the 30-Month Stay in Pharmaceutical Patent Cases*, FINNEGAN (Mar. 25, 2018), https://www.finnegan.com/en/insights/articles/intricacies-of-the-30-

ANDA to seek FDA approval of a generic drug, it must certify "that each listed patent (a) has expired (a Paragraph II certification), (b) will expire before the generic drug is marketed (a Paragraph III certification), or (c) is invalid, unenforceable, or will not be infringed by the generic drug (a Paragraph IV certification)."[16] When a generic company files a Paragraph IV certification, it is required to notify the owner(s) of the branded drug and the owner(s) of the related patents for that drug.[17] The patent owner(s) may then sue the generic drug company for patent infringement within forty-five days of such notice.[18] When the suit is filed, a thirty-month stay is triggered for the FDA, preventing it from approving the generic product for the market until the end of the stay.[19] Does such a stay favor brand companies? Yes. It allows the brand company to remain on the market without competition while the infringement suit is ongoing. However, generic companies also have an incentive to trigger such a suit. The first generic product of its kind on the market receives 180 days of exclusivity before other generics of the kind may enter the market, *and* a court may shorten the thirty-month stay if the patent owner fails "to reasonably cooperate in expediting the action."[20]

The Hatch-Waxman Act also incentivizes innovation with brand companies by creating a data exclusivity provision that provides for a period of time, either four or five years after a brand product's FDA approval, where the FDA cannot receive generic applications that rely on the

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month-stay-in-pharmaceutical-patent-cases.html [https://perma.cc/26XG-GEFB].

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] *Id.*; *Exclusivity and Generic Drugs: What Does it Mean?*, FDA, https://www.fda.gov/files/drugs/published/Exclusivity-and-Generic-Drugs--What-Does-It-Mean-.pdf [https://perma.cc/WN5M-6KB8].

brand product's clinical trial data.[21] In addition, the Act creates an opportunity for inventors to receive an additional time period of patent term protection, called patent restoration, to compensate the inventor for some of the time it took the product to obtain FDA approval while the patent term was running.[22] Patent restoration can add up to five years of life to a patent, but the extension cannot result in the remaining patent term exceeding fourteen years after FDA approval of the product has been obtained.[23]

These benefits are recognized and utilized by brand companies, yet the ultimate ability of generic companies to challenge patent validity of brand products advantages generic companies under the Act.[24] Therefore, despite the targeted innovation incentives for brand companies, the Hatch-Waxman Act serve to benefit generic companies more than brand companies, creating the present issue of brand companies lacking an adequate incentive for further innovation.

C. The Major Obstacles for Brand Companies

Within the last ten years, the presence of generic pharmaceuticals rose to account for eighty-eight percent of the prescriptions filled in the United States.[25] In today's pharmaceutical market, "nearly every brand pharmaceutical item has, or will have, a generic competitor."[26] This stands

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[21] Grabowski et al., *supra* note 11, at 2.
[22] *Id.*
[23] *Id.*
[24] *See* Boehm, *supra* note 14, at 298 ("[D]espite all the attempts by the brand industry to counter generic product development and use after the enactment of the Hatch-Waxman Act, generic drugs have risen to become a significant majority of the US prescription pharmaceutical market by volume.").
[25] Joseph Muha, *Pharmaceutical Patents: What are the Differences?*, 19 W. MICH. U. COOLEY J. PRAC. & CLINICAL L. 209, 209–10 (2018).
[26] *Id.* at 214.

in stark contrast to the thirty-five percent of brand name products that had a generic version of the same product competing with it on the market prior to the implementation of the Hatch-Waxman Act.[27] This may be because generic companies now have an easier avenue to invalidate brand products' patents through litigation, allowing generic companies to obtain market entry without fear of infringing those patents. This incentive for generic companies to bring lawsuits against brand companies was created by certain provisions of the Hatch-Waxman Act.[28]

In the current pharmaceutical industry, brand companies argue that they do the heavy-lifting with respect to the development of new and important, lifesaving drugs. To develop a new product, the brand company must take steps to identify potential drug targets, synthesize and then characterize prospective chemical compounds, perform in vivo and in vitro studies followed by clinical testing phases, communicate extensively with the FDA to obtain approval, and establish a market for the new product.[29] While substantially investing in the new drug development process, brand companies may view generic companies as "free-riding" their work as generic companies take advantage of

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[27] *Id.*

[28] *See* Margaret K. Kyle, *Competition Law, Intellectual Property, and the Pharmaceutical Sector*, 81 ANTITRUST L.J. 1, 7 (2016) ("The first generic firm to challenge a patent successfully on the grounds that it is invalid or not infringed … receives 180 days of exclusivity, during which time the FDA approves no other generic. The Hatch-Waxman Act created the 180-day exclusivity 'prize' explicitly for the purpose of rewarding challenges to weak pharmaceutical patents. Without such a prize, a patent challenge is costly for the generic firm that attempts it, and successfully invalidating a patent creates a public good for all other generic firms.").

[29] Dmitry Karshtedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 IOWA L. REV 1129, 1146–47 (2019).

the clinical testing data that the brand product obtained through the brand companies' resources.[30]

In addition, when a drug product receives regulatory approval, the FDA lists the new drug in the book *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to in the industry as "the Orange Book."[31] If the product is listed in the Orange Book, the pharmaceutical company owning that product is required to submit patent information, which is outlined to include, for example, the "patent number for each drug for which a reasonable claim of patent infringement could be made," to be included in the book listing.[32] The listings in the book are required by statute to be updated at least every thirty days.[33] This requirement serves to put the public on notice of the patents associated with any FDA-approved product. However, by providing notice to the public, the listings also draw the attention of generic companies, giving competitors the opportunity to identify the "most valuable patent assets" for any given product.[34] It is typically from these listings that litigation ensues regarding pharmaceutical patent validity.

The heavy financial burden of early-stage research and development, coupled with the requirement of essentially putting competitors on notice of its most valuable assets, poses significant hurdles for brand companies to profit from their innovation. If brand companies are given a means of protecting various aspects of their inventions, blocking competitors from using their obtained data, *and* keeping a competitor product off the market for a set period

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[30] *Id.* at 1147.
[31] Carlos A. Garcia & Jonathan Stroud, *Ships in the Night: Resolving Administrative Conflict Between FDA- and Patent-Related Legislation*, 68 AM. U. L. REV. 1111, 1131 (2019).
[32] *Id.*
[33] *Id.*
[34] *Id.*

time, the brand companies may be more willing to continue investing larger amounts of money in innovation. As innovation is the core of the pharmaceutical industry, the need for brand companies to continue serving in this revolutionizing capacity is apparent so that the public can ultimately access new and improved products.

III. INNOVATION INCENTIVES

Current innovation incentives for pharmaceutical companies include FDA exclusivities and patents. Each serves its own role to incentivize innovation but falls short of providing an adequate incentive on its own. However, a closer look into FDA exclusivities and patents shows that an expansion upon each option's most basic grants could provide a solution to maximize brand company innovation incentives.

A. The FDA Exclusivity Incentives

There are two types of FDA exclusivity that are relevant to the pharmaceutical industry: data exclusivity and market exclusivity. While seemingly similar, the two serve different purposes. Generally, data exclusivity prohibits generic companies from referencing data produced by a brand company for a period of time, while market exclusivity prevents competition over a specific product on the market.[35] These regulatory exclusivities are awarded for an FDA-approved product and are only of "commensurate scope with the drugs" that are approved.[36] Granted regulatory exclusivity "may or may not run concurrently and may or may not cover the same aspects of the drug product"

[35] John R. Thomas, *The End of "Patent Medicines"? Thoughts on the Rise of Regulatory Exclusivities*, 70 FOOD & DRUG L.J. 39, 48–49 (2015).
[36] *Id.* at 43.

as does the granted patent(s) for that same product.[37] It is the FDA's role to automatically grant regulatory exclusivities as part of a "routine judgment."[38] Once the exclusivity is granted, the FDA withholds other new drug applications that are either directed at that product type or use the brand company's generated data, preventing them from obtaining market approval for the specified period of exclusivity.[39]

A drug product is required to undergo extensive testing to obtain FDA regulatory approval.[40] The required submission data for the FDA includes the results of extensive clinical trials demonstrating that the new drug is both safe and effective.[41] It is this data that is protected by the FDA's grant of data exclusivity.[42] During the specified period of data exclusivity, which can last only up to five years in the United States, the FDA will not accept an application for a generic product that uses the data produced from the brand pharmaceutical's clinical trials.[43] The goal of allowing for a time period in which generic companies cannot rely on the safety and efficacy data that the brand product used in obtaining market authorization is to allow for the brand company to recover some of its costs expended as a result of having to perform extensive testing for clinical trials.[44] In this way, exclusivities incentivize innovation because brand companies, in theory, may take the profits resulting from the exclusivity and reinvest in further research once the initial research investment costs have been

[37] McCall & Quinn, *supra* note 3.
[38] Thomas, *supra* note 35, at 43.
[39] *Id.*
[40] Paul Grootendorst et al., *Patents and Other Incentives for Pharmaceutical Innovation*, ELSEVIER ENCYCLOPEDIA OF HEALTH ECON. (forthcoming).
[41] *Id.*
[42] *Id.*
[43] Kyle, *supra* note 28, at 4.
[44] *Id.*

recovered. However, with this exclusivity, competitors are not prevented from doing their own research and submitting new drug applications for a similar product based on the independent safety and efficacy research performed.[45]

In contrast, market exclusivity creates a barrier for competitors to even enter the specific market of a new product for a specified period of time.[46] Market exclusivity is only available for certain types of drug products, and the exclusivity can vary depending on the drug type.[47] For example, an orphan drug, one that treats a disease or condition affecting fewer than 200,000 people in the United States, is afforded up to seven years of market exclusivity.[48] Meanwhile, a pediatric drug, a brand-name drug that has been clinically studied and approved for pediatric patients, may receive an extra six months of exclusivity in addition to any other market exclusivity awarded for the drug product.[49] Once again, the goal of providing market exclusivity for some drug products is to encourage new drug innovation by halting generic competition for the specified period of market exclusivity, thus allowing brand companies to collect additional profits that may ultimately be invested in new drug research and development.[50] The objective of awarding this type of exclusivity is to apply it to drug products that are limited in treatment scope, such as is the case with an orphan drug product, because it protects the product from all market competition for a given time period. In this way, this exclusivity serves as a research and development incentive for brand companies in these specific, narrow market areas.

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[45] Gene Quinn, *Fact vs. Fiction: The Truth on Biologics and Biosimilars*, IPWATCHDOG (Dec. 6, 2009), https://www.ipwatchdog.com/2009/12/06/fact-vs-fiction-the-truth-on-biologics-and-biosimilars/id=7579/ [https://perma.cc/VPB3-R4GT].

[46] *Id.*

[47] *Exclusivity and Generic Drugs: What Does it Mean?*, *supra* note 20.

[48] *Id.*

[49] *Id.*

[50] *Id.*

B. Limitations of the FDA Exclusivity Incentives

Utilizing exclusivities as an innovation incentive has its limitations. First and foremost, new pharmaceutical innovations are only eligible for these exclusivities once they have become FDA-approved.[51] While brand companies strive to develop new drug products from start to finish, it is uncommon for a new product to make it through the demanding stages of early clinical development and clinical trials to ultimately obtain market approval.[52] Therefore, providing this avenue as a primary incentive to innovate in the early stages of product development is unrealistic. Brand companies are aware of the reality of frequent failure in the industry and thus may not be fully incentivized to innovate across a broad spectrum of projects based solely on the guarantee of certain FDA exclusivities for FDA-approved products.

Second, the applicability of the exclusivity and the effect of each exclusivity type on the industry vary, and yet, the two are sometimes conflated.[53] However, the important distinction is: data exclusivity may be available for any new drug product with a new active pharmaceutical ingredient while market exclusivity is only available for certain types of drug products.[54]

Market exclusivity, in theory, prohibits competition with a newly approved product that is granted such exclusivity.[55] In contrast, data exclusivity only prevents competitors from relying on a brand company's data for approval, rather than prohibiting them from competing by

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[51] Thomas, *supra* note 35, at 43.
[52] *See* Sullivan, *supra* note 1.
[53] *See* Quinn, *supra* note 45.
[54] *Id.*; *Exclusivity and Generic Drugs: What Does it Mean?*, *supra* note 20.
[55] *Id.*

keeping their products off the market.[56] With data exclusivity available, competitors are still able "to conduct their own costly research and development, including clinical trials, and create their own [products]."[57] This distinction is critical in understanding the role of the exclusivity types. Yet, the thought of market exclusivity still raises some concerns about restricting pharmaceutical competition and the potential consequences it can have on the industry and consumers. [58] Hence, the existence of these exclusivities and their role in incentivizing brand companies remains limited in scope and, therefore, should not be the only means of encouraging innovation with brand companies.

C. The Patent Incentive

Patents are critical to many industries, not just the pharmaceutical industry. The current United States patent law system incentivizes innovation by rewarding an inventor with the right to exclude others from using her invention for the length of the patent in exchange for public disclosure and full relinquishment of the invention to the public domain at the close of the patent term. A patent is awarded for an invention that covers a new, useful, and non-obvious process, machine, manufacture, or composition of matter.[59] The patent serves to protect the claimed invention from public use, in the form of an exclusionary right, for the length of the patent term, which is twenty years from the date of filing.[60] In exchange for the exclusionary right, the

[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] 35 U.S.C. § 101 (1952); 35 U.S.C. § 102 (2015); 35 U.S.C. § 103 (2011).
[60] Grootendorst et al., *supra* note 40.

inventor is required to disclose the invention to society.[61] This quid pro quo is the fundamental core of the patent law system.[62]

With respect to the unique role that patents play in the industry, it must be recognized that the pharmaceutical industry is distinct in three ways: "[f]irst, the marginal costs of production are generally relative to the fixed cost of development, and the cost of imitation is also usually low;" second, "the cost structure of pharmaceutical development explains why patents are cited as more important in drugs and chemicals than in all other sectors;" and third, the amount of government intervention in the market is widespread.[63] Pharmaceutical companies attempt to utilize patents in an effective way to help protect their inventions from competitors, as do players in many other industries. However, the types of patents and the strategy for obtaining them differs for the pharmaceutical industry as a result of the industry's unique characteristics.

The original patent granted on a new drug, specifically on the active pharmaceutical ingredient or the molecule itself (the drug's primary patent) is often especially valuable because it is extremely difficult for competitors to invent around this patent.[64] Companies often also seek secondary patents, commonly referred to as improvement patents, which cover other aspects of the pharmaceutical product such as a manufacturing process, a dosage form, a method of use, or a formulation, for example.[65] In contrast with primary patents, these secondary patents are typically deemed to be weaker than the primary patent, lacking in

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[61] Brent A. Olson, *Obtaining a Patent – Formal and disclosure requirements – 35 U.S.C.A. § 112*, 20A1 MINN. PRAC., BUSINESS LAW DESKBOOK § 17:15 (2019).
[62] *Id.*
[63] Kyle, *supra* note 28, at 1–2.
[64] Karshtedt, *supra* note 29, at 1154; Kyle, *supra* note 28, at 2.
[65] Kyle, *supra* note 28, at 7; Sittler et al., *supra* note 6.

substance and subsequent legal protection, resulting in the majority of litigation disputes involving pharmaceutical patents.[66] Further, it is likely easier for competitors to invent around these secondary patents, and it may be easier to invalidate them through the existence of prior art.[67] These secondary patents often serve as "an imperfect barrier to generic entry," but still remain valuable to brand companies and are critical in crafting a solution for pharmaceutical innovation.[68]

D. Limitations and Criticisms of the Patent Incentive

There has been recognition of the patent incentive limitations for pharmaceutical companies. First, a patent only grants protection over the invention for a limited amount of time, thus keeping generic competitors off the market only for the life of the patent term.[69] In addition, the financial burden of filing for and maintaining patents could sometimes deter pharmaceutical companies.[70] Further, because companies may be focused on only exploring opportunities that can be afforded patent protection, the existence of the patent incentive may shift the focus of research and development, driving it only into areas of patentability, rather than into areas of high social importance or need.[71] These factors all motivate and mold the

[66] Kyle, *supra* note 28, at 7.
[67] *Id.*
[68] *Id.*
[69] Paul Grootendorst et al., *New Approaches to Rewarding Pharmaceutical Innovation*, 183(6) CMAJ 681, 681 (2011).
[70] *Id.* See also *USPTO Fee Schedule*, USPTO (Mar. 1, 2020) https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule [https://perma.cc/MD5F-V3XN] for a list of the filing and maintenance fees required for a patent depending on the owning entity of the patent.
[71] Grootendorst et al., *supra* note 69, at 682.

pharmaceutical industry in a variety of ways, shaping the way brand companies, in particular, innovate and focus on certain types of drugs.

The role that secondary patents play in the critique of this incentive is important. Many critiques of the patent law incentive focus on the role of secondary patents, claiming that brand companies use secondary patents as a means of extending patent protection past the initial period of patent exclusivity as determined by the expiration of the primary patent.[72] Further, the fact that most pharmaceutical patent litigation is a result of secondary patents is concerning to some critics.[73] In addition, secondary patents, resulting from follow-on innovation, are ultimately viewed as having marginal value, with critics suggesting that the lesser value makes them less deserving of protection than primary patents.[74] Some even argue that the patentability requirements are lowered for secondary patents, meaning that the amount of novelty required for the invention is lowered.[75] This, however, is not the case, as will be explored later.

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[72] Christopher M. Holman, *Inside Views: Why Follow-on Pharmaceutical Innovations Should be Eligible for Patent Protection*, INTELL. PROP. WATCH, https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/ [https://perma.cc/5ABK-Y34F].

[73] Karshtedt, *supra* note 29, at 1154.

[74] Holman, *supra* note 72.

[75] *See* Christopher M. Holman et al., *Patentability Standards for Follow-On Pharmaceutical Innovation*, 37(3) BIOTECHNOLOGY L. REP. 131, 136 (2018) (suggesting that some critics argue that secondary patents lack novelty because the follow-on inventions do not necessarily directly improve the therapeutic properties of a drug, thus indicating that there is an existing argument that such follow-on innovation does not meet the novelty or utility patentability requirements).

IV. THE HIDDEN SOLUTION TO RESTORE BALANCE IN THE INDUSTRY

As discussed in this Note, the current incentives for innovation have their criticisms, weaknesses, and overall flaws. Yet, upon a closer look at the currently available avenues, the best chance of maximizing social welfare with respect to pharmaceuticals may be to further incentivize innovation for brand companies by finding an optimal combination of the current incentives. By providing incentives that cover multiple facets of the innovation process, brand companies will have a variety of avenues that will better incentivize the major financial, time, and resource investments on new product development. Secondary patents play a critical role in crafting this overall incentive plan for brand pharmaceutical companies. They provide protection to inventions later in the process, whereas protection is provided by primary patents upfront and by FDA exclusivities upon a product's initial market entry. Therefore, the best means to incentivize innovation in the pharmaceutical industry is to not only maintain existing incentives like primary patents and exclusivities, but to also allow for and, in fact, encourage brand companies to obtain secondary patents on follow-on innovation, follow-on products, and overall product improvements.

A. Recognizing the Importance of Secondary Patents

Patents remain a primary focus for the pharmaceutical industry as a means to protect new drug inventions and to provide an opportunity to recover some of the expended upfront costs of the extensive preclinical and clinical testing phases.[76] Primary patents are often robust

[76] Karshtedt, *supra* note 29, at 1152–53.

and serve to initially protect the invention.[77] However, this initial patent term is not enough to allow a patent owner to effectively recover from the upfront time lost from the initial filing date and the high likelihood of failure in bringing a new drug product from early stage development to market.[78] The FDA's Hatch-Waxman Act solution of allowing for a patent restoration term, adding up to an additional five years of patent life onto the natural end of the patent, seeks to remedy this initial time lost as a result of the regulatory approval process.[79] However, this extension still may not provide for enough time or incentive for brand companies to expend such extensive resources on new product research and development when the chance of failure for bringing a new product through the FDA approval process is so high. This is where the use of secondary patents comes in.

The name "secondary patent" leaves the notion in a reader's mind that these types of patents are not as important as "primary patents."[80] This is not an accurate depiction of the relative connection between primary and secondary patents. Rather, the first patent filed for a product which often covers the new molecule or new active pharmaceutical ingredient is simply referred to as the "primary patent," while additional patents covering other aspects of the same product or follow-on innovation are referred to as the secondary patents.[81] The categorization of primary verses secondary patents arises solely out of the timeline of when the patents for a given drug product are filed and ultimately obtained. However, regardless of the informal category given to the various types of pharmaceutical patents, a patent will not issue unless it satisfies the requirements of patentability as determined by the United States Patent and

[77] *Id.* at 1153.
[78] *Id.*
[79] Grabowski et al., *supra* note 11, at 2.
[80] *See* Karshtedt, *supra* note 29, at 1152–55.
[81] *Id.* at 1153–55.

Trademark Office (USPTO).[82] In that sense, an application is required to meet all patentability requirements before the patent will be issued. Therefore, a secondary patent should not be deemed lesser than a primary patent in that respect.

It is true that the subject matter of secondary patents may be deemed "weaker."[83] This categorization, however, is based on the idea that it is easier to invalidate and "invent around" these patents in comparison to the patent covering the very specific new molecule or active ingredient itself.[84] The categorization should not take away the importance of secondary patents for brand companies or the subject matter covered in the patents.

Opponents of secondary patents in the industry suggest that pharmaceutical companies use these patents as a means of extending protection on the initial product itself.[85] This argument stems from the idea that secondary patents can essentially be used to double-patent, or patent the exact same invention twice.[86] However, as the USPTO will not issue a patent unless the requirements of patentability are met, specifically that the invention must be novel, the existence of secondary patents is not equivalent to double patenting.[87] There are also steps that competitors can take to invalidate a patent that it believes to be an attempt at

[82] *Id.* at 1155.
[83] Kyle, *supra* note 28, at 7.
[84] *Id.* (stating that secondary patents may be weaker "either in a legal or a technical sense," and providing the example of a competitor finding a meant to "invent around" a patent obtained for a specific manufacturing process for a product).
[85] *See* Karshtedt, *supra* note 29, at 1129–30 (stating that "secondary patents covering the new version of the drug enable [pharmaceutical companies] to maintain some effective market power over the active ingredient for which original, primary patent protection has expired").
[86] *See* MPEP ch. 800 § 804 (8th ed. Rev. 7, Sept. 2008) (outlining that double patenting is not permitted).
[87] *See* Karshtedt, *supra* note 29, at 1155.

patenting the same idea twice.[88] In fact, competitors do take advantage of the opportunities afforded to them to invalidate patents. For example, they often choose to litigate. Because a majority of these litigation challenges target brand companies' secondary patents, this suggests that competitors are effectively policing the improper use of secondary patents.[89] Therefore, there is little evidence that double patenting is as significant an issue as some allege that it may be.

Opponents of secondary patents also suggest that the heightened amount of litigation disputes regarding these patents indicates that their existence in the industry adds little to no value.[90] While there is likely a portion of secondary patents that do not add significant value and do just give rise to additional litigation, this is certainly not the case for all inventions contained within secondary patents. In fact, there have been breakthrough product discoveries, improvements, and treatment options that have resulted through follow-on research and the subsequent secondary patents obtained as a result.[91] This path is not uncommon,

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[88] Kyle, *supra* note 28, at 7 ("Establishing the existence of prior art may invalidate a secondary patent, particularly if it represents an attempt to patent the same idea twice.").

[89] *Id. See also* C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1386 (Mar. 22, 2013) (finding that when the lawsuit was pursued to completion, not including settlement, brand companies are more likely to have their secondary patents invalidated in comparison to the primary patent (active-ingredient patent), where secondary patents are invalidated 68% of the time in comparison to the primary patents which are invalidated only 8% of the time).

[90] *See* Holman, *supra* note 72 (contending that there is a "flawed premise that follow-on innovation is of marginal value at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient").

[91] See *id.* for examples of breakthrough inventions that have occurred as a result of follow-on innovation, including AZT (zidovudine) which began as a failed attempt at a cancer drug, but was later discovered as

as many products are initially discovered in an attempt to create a treatment for one disease or condition, and are later used in research and identified as potential drug candidates for a different disease or condition.[92] This occurs as a result of "[p]harmaceutical development [being] prolonged and unpredictable, and frequently a safe and effective drug occurs only as a result of follow-on innovation occurring long after the initial synthesis and characterization of a pharmaceutically interesting chemical compound."[93] It is this precise innovation that is incentivized by the ability of a company to obtain a secondary patent for its research efforts.[94]

It is nearly impossible to reconcile the pro and con arguments for secondary patents in the pharmaceutical industry with respect to the value that these secondary patents add. Proponents of secondary patents focus on the ability to incentivize follow-on innovation through the encouragement of awarding secondary patents.[95] This argument highlights the valuable results of such follow-on innovation with respect to "new uses of existing active ingredients in new therapeutic areas, new formulation, new modes of delivery, new combinations of known active ingredients," and others.[96]

Meanwhile, one argument against the allowance of secondary patents is that their existence adds minimal value from the brand companies' perspective because these patents do not protect more than ancillary aspects of a drug

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treatment to fight AIDS. AZT has since been referred to as "the first breakthrough in AIDS therapy."

[92] *Id.*

[93] *Id.*

[94] *See id.* (suggesting that drug products that failed in an initial attempt to treat a condition may not have been revisited for other uses if the companies lacked the incentive of patenting follow-on innovation).

[95] *See id.*

[96] Sittler et al., *supra* note 6.

product.[97] Yet another argument against allowing secondary patents is that their existence provides an excessively valuable means for brand companies to extend the patent protection on a given drug product by granting patents for inventions with minimal novelty in an improvement or aspect of the original drug product.[98]

Inherent in these oppositions is the conflict between whether or not value is added to the industry through the incorporation of these secondary patents. The existence of such conflict, coupled with the fact that competitors are spending the time and money to seek to invalidate these secondary patents, suggests that there is, in fact, some merit to the concept of secondary patents having value.[99] Why would a company expend significant resources to challenge a worthless aspect of a competitor's product? Why would a company defend its secondary patent, rather than settle the case, if the patent added no value or it was not a smart

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[97] Holman, *supra* note 72.

[98] *Id.*; *see Abuse of the Patent System is Keeping Drug Prices High for Patients*, ASS'N FOR ACCESSIBLE MEDICINES, https://accessiblemeds.org/campaign/abuse-patent-system-keeping-drug-prices-high-patients [https://perma.cc/RGV8-EDYR] ("AbbVie Inc.'s rheumatoid arthritis drug HUMIRA® (adalimumab) is the best-selling prescription drug in the world, with over $12 billion in U.S. sales per year. Humira was approved in 2002, and it now makes more money annually than all of the NFL teams, combined. The initial patent on the product expired in 2016, but within three years before expiration, the company applied for and obtained over 75 patents that would extend its monopoly to 2034 – and keep this enormously expensive treatment inaccessible to many patients. To break Abbvie's perpetual monopoly, companies must engage in time-intensive, expensive patent litigation, thus allowing the drug company to continue to profit as a result of its tactics.").

[99] *See* Chris Neumeyer, *Managing Costs of Patent Litigation*, IPWATCHDOG (Feb. 5, 2013), https://www.ipwatchdog.com/2013/02/05/managing-costs-of-patent-litigation/id=34808/ [https://perma.cc/H4S4-RH27] ("[T]he cost of an average patent lawsuit, where $1 million to $25 million is at risk, is $1.6 million through the end of discovery and $2.8 million through final disposition.").

business decision to do otherwise?[100] The direct conflict of opposing views with respect to the value of secondary patents favors the proponent's argument that secondary patents have inherent value.

Another misconception regarding secondary patents is the idea that the subject matter is but the same original invention covered by the primary patent with a simple and insignificant change.[101] This is incorrect. Why would the USPTO grant a patent on an invention that was neither novel nor new, thus not meeting all criteria of patentability? Clearly, in a perfect world, the USPTO would not grant a patent on something that added no innovation to what previously existed. While, from an outside perspective, "pharmaceutical innovation can appear deceptively simple," in reality, "the path to meaningful follow-on innovation is tremendously challenging, unpredictable, and more often than not results in failure."[102] In addition, breakthroughs have been made by essentially recycling old failed products

[100] The underlying reasoning for this may be apparent in the Hatch-Waxman Act's allowance of 30-month stays when a patent owner brings suit after a generic company files a Paragraph IV certification. This stay may encourage an increase in patent litigation and may result in brand companies sometimes filing suit in response to a paragraph IV certification just to maintain its spot on the market without competition. The financial aspect of the industry, taking into consideration the cost of an infringement suit and the profits made while being the sole product of its kind on the market, must be considered when answering these questions.

[101] *See Abuse of the Patent System is Keeping Drug Prices High for Patients*, *supra* note 98 ("The patent system exists to protect the intellectual property of innovators. Too often, however, some brand-name drug companies attempt to patent features of drugs that do not represent true innovation, Some attempt to bury competition from generic and biosimilar drugs indefinitely by finding ways to repackage existing inventions in later patents. These 'patent thickets' chill competition by discouraging competitors from entering a market because of the exorbitant cost of litigating meritless patents.").

[102] Holman, *supra* note 72.

and attempting to implement them in a new treatment field. Without some sort of incentive to allow for financial gain, why would a company undertake a highly expensive and challenging project that is prone to failure? Secondary patents play a critical role in encouraging companies to face the risk of uncertainty in exploring different applications and means of improving current or failed drug products because they allow brand companies a greater opportunity to recoup their costs, make a profit, and recycle their profits into new groundbreaking research and innovation.

B. Encouraging the Secondary Patent Incentive

Encouraging the granting of secondary patents to further incentivize brand pharmaceutical companies to continue innovating should not pose significant challenges. Patents, specifically primary patents, already play a well-accepted, critical role within the pharmaceutical world.[103] In addition, secondary patents already exist and are utilized in the Unites States pharmaceutical industry, even though they are less accepted than primary patents. The industry has relied on pharmaceutical patents to protect its innovations, where the patents vary in scope, importance, and coverage.

Secondary patents can be used in many different ways within the industry. One example of secondary patent utilization is in the protection of follow-on innovation of already existing products or active drug ingredients. This follow-on innovation, which involves furthering research and development of already existing and patented pharmaceutical inventions, can lead to new drugs or products that would otherwise not have come to fruition

[103] *See* Karshtedt, *supra* note 29, at 1152 ("The conventional wisdom has it that patents play a critical role in drug development and, more generally, that chemical and pharmaceutical patents are the success story of the patent system.").

without the promise of patent protection for such innovation. Once a patent is obtained for such follow-on innovation, the company does not then forget about the patented pharmaceutical advancement.[104] Instead, follow-on innovation can lead to the development of follow-on products, products that ultimately make their way to the market. These follow-on products are then also patented.[105] It is noted that "[c]onsistent with the incremental nature of the innovation these [follow-on] products normally embody, brand companies tend to protect them with patents that are narrower than those directed to the pioneering versions."[106] Therefore, brand companies are utilizing patents for follow-on products in the same capacity that should be applicable for follow-on innovation, secondary patents that address specific aspects of a new drug product, such as dosage form or method of administration. Rewarding such follow-on innovation can drive the increase of follow-on products and new uses of existing products, ultimately serving the public good.

By encouraging the use of secondary patents for follow-on innovation, over time, the industry will likely adapt to creating secondary patents that are narrower and more targeted in scope than the broad primary patents. After all, why would brand companies willingly invite lawsuits over weak patents? Because these secondary patents only address a narrow aspect of the new drug product broadly covered by the primary patent, the existence of intellectual property protection for that narrower and more specific feature of the product should not pose a major threat of significantly extending market exclusivity and halting market competition, one of the most commonly raised concerns regarding the existence of secondary patents in the

[104] *Id.* at 1154.
[105] *Id.*
[106] *Id.*

pharmaceutical industry.[107] Rather, it will be beneficial to the industry to make it known to brand pharmaceutical companies that this avenue of incentive for intellectual property protection is available for their follow on innovation, proportional in scope to the "incremental nature" of the innovation itself.[108] This opportunity for patent protection serves to encourage the companies' upfront investment in researching new drug products and new applications of existing products.

How can the industry as a whole become more accepting of such secondary patents? The question poses itself in the face of certain pushback from generic companies and those who think that brand companies already restrict competition.[109] This sentiment has been reflected in guidance published by the United Nations, leaving a negative impression of secondary patent usage and its perception in the context of the pharmaceutical industry.[110] This cultural shift can start by influential organizations, such as the United Nations, publishing guidance reflecting an attitude of encouragement and acceptance of the important

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[107] *See generally* Douglas L. Rogers, *Double Patenting: Follow-on Pharmaceutical Patents that Suppress Competition*, 14 NW. J. TECH. & INTELL. PROP. 317 (2017).

[108] Karshtedt, *supra* note 29, at 1154.

[109] *See* Rogers, *supra* note 107, at 320.

[110] Holman et al., *supra* note 75, at 132–34 (The United Nations Development Program (UNDP) issued *Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective* in 2015. The *Guidelines* address "recommendations" on how patent examiners should examine secondary patents, with the goal of protecting public health and promoting access to medicines. In addressing this goal, the *Guidelines* call for heightened patentability requirements, which would serve to deny patent protection to currently protected aspects of pharmaceutical innovation and advancements. The document suggests that secondary inventions, or follow-on innovation, categories that should be *per se* unpatentable include polymorphs and combination products, for example.).

role that secondary patents can play in the pharmaceutical industry.[111]

In addition, Congress should create an avenue that provides a disincentive for challenges of secondary patents in instances where such secondary patents are legitimate. A means of accomplishing the disincentive of challenging legitimate secondary patents could be consistently rewarding attorney's fees to the prevailing party in frivolous lawsuits.[112] This could help ensure that the only challenges to those secondary patents are legitimate ones, overall decreasing the amount of unnecessary litigation and money expended to defend the patents.

Brand companies also play a part in growing the prevalence and respectability of secondary patents. They should be more strategic in bolstering their secondary patents, making an effort to draft narrow patent claims for the claimed follow-on innovation, working with USPTO patent examiners to effectively prosecute the patent applications, and utilizing post-grant procedures with the USPTO.[113] By intending to draft narrower claims for the

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[111] Guidance issued specifically calling for types of currently protected follow-on innovation to be deemed *per se* unpatentable significantly imposes a negative perception of follow-on innovation for the pharmaceutical industry. In particular, the strong presence of the United Nations makes such guidance even more influential.

[112] See Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. 545, 554 (2014) which outlines the current allowance of attorneys' fees for the prevailing party under the Patent Act. The case defines the term "exceptional," where attorneys' fees are only awarded in such exceptional cases. However, this note seeks to suggest that this "exceptional" standard is too stringent in such patent cases and that attorneys' fees should be rewarded to the prevailing party more often in pharmaceutical patent litigation cases.

[113] While some of these suggestions may be utilized by brand companies already, this Note seeks to argue that they could be used more often in a strategic way. In using these procedures, however, the brand companies may lose some breadth in their patent claims and may open themselves up to invalidation by initiating USPTO post-grant proceedings. Yet,

follow-on innovation from the beginning of the patent application stage, brand companies can make an increased effort to target what the precise new innovation itself is that is worthy of a patent; this could, in theory, lead to less challenges of the patent later on. After a patent grants, the patent owner can also take certain steps to ensure that the patent is a strong as it can be. In particular, the brand companies can utilize a USPTO post-grant proceeding called an ex parte reexamination to strategically bolster a granted patent.[114]

To create the maximized innovation incentive for brand companies, it requires not only a combination of various incentives, specifically encouraging secondary patents to play a larger role in the industry, but it also requires a shift in mindset from influential players within and outside of the industry, penalties for bringing unnecessary lawsuits, and brand companies taking an offensive role in protecting its patents. The proposed solution can be implemented through a variety of targeted changes but requires cooperation amongst the parties in the pharmaceutical industry, taking particular care to ensure that a competitive balance is maintained between brand and

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these options do have their benefits and could be more regularly utilized by the brand companies in specific instances where strengthening certain secondary patents is desired.

[114] *See* Charles E. Van Horn et al., *Effective Uses of Reissues and Reexaminations in the United States*, FINNEGAN (June 2009), https://www.finnegan.com/en/insights/articles/effective-uses-of-reissues-and-reexaminations-in-the-united.html [https://perma.cc/WT6W-2APW] ("Before the USPTO grants a reexamination request, it reviews the request and the prior art submitted with the request to determine whether the request raises a substantial new question of patentability. If the USPTO denies the request, it has, in effect, determined that the prior art submitted with the request does not invalidate the patent. … Alternatively, the USPTO may grant the reexamination request but affirm the validity of the patent during reexamination. In both cases, the reexamination strengthens the patent, making it harder to attack its validity later on.").

generic companies and working collectively towards maximizing public benefits.

C. Effect on Generic Companies

In creating a solution to help brand companies, the impact on generic companies cannot be overlooked. While the encouragement of secondary patents for brand company innovations will negatively impact generic companies, it is, from this author's perspective, necessary to reestablish an acceptable balance in the pharmaceutical industry. With the ever-growing presence of generics on the market, the growing ease for generic companies to challenge brand companies' patents, and the large investments required by brand companies to further pharmaceutical developments, there is an imbalance favoring generic companies that may be unduly stifling innovation. It is critical that the balance between brand and generic companies be restored to ensure that evenly matched competition in the industry continues to drive pharmaceutical advancements and innovative efforts. With any luck, if this balance is restored, brand companies will expend even more money on research and innovation with little adverse effect to the generic industry. To maintain a proper, competitive balance in the pharmaceutical market, generic and brand companies both need their individual advantages balanced with respect to each other.

V. CONCLUSION

If done "right," secondary patents can serve as the critical piece of a maximized incentive for brand pharmaceutical companies. While there is no clear "right" solution here, there are considerations that must be addressed in crafting an effective, long-term, maximized incentive solution. First, patents, both primary and secondary, alone will not be enough to incentivize brand companies adequately. This is because of the significant

amount of time lost in a patent's life, upfront, as a result of the amount of time it takes to gain FDA approval for a new product. Therefore, a combination of incentives is the clear way to maximize motivation for brand companies to continue innovating. Second, a maximized incentive can be created by utilizing already existing data exclusivities and the patent law system as long as secondary patents become a more widely accepted and used tool. Third, in crafting a maximized solution, while brand companies are the primary focus in creating the incentive solution, they are not the only party that will be affected. Generic companies' role in the greater structure of the pharmaceutical industry cannot be overlooked. Thus, the incentive solution presented here is only offered as an option designed to restore the balance between brand companies and generic companies so that innovation is not unduly stifled moving forward. Secondary patents can serve as a key piece of such a maximized incentive solution to ensure that pharmaceutical innovation continues to progress by giving brand companies a motivation to more heavily invest in costly time-intensive research to develop new, life-saving drug products.