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SKINNY LABELS: CHANGING SCENARIO OF INDUCED INFRINGEMENT AND PUBLIC POLICY

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SKINNY LABELS: CHANGING SCENARIO OF INDUCED INFRINGEMENT AND PUBLIC POLICY

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This note will examine how the generic players navigate the drug approval system, the strategies of the innovators to ward off competition, and the public policy surrounding the availability of affordable medical products. It will also discuss the impact and implications of skinny labels on the market entry of affordable life-sustaining products and the landmark case that is changing the scenario altogether. Finally, this note will propose possible alternative methods to increase the affordability and availability of life-sustaining products by making it a win-win situation for innovators, generics, and the public.

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I. INTRODUCTION

A patent is an exclusive right granted for an invention to the inventor. However, when it comes to life-sustaining products, these exclusive rights have a negative impact on people's lives. The government has tried to develop initiatives, such as the Hatch-Waxman Act, to compensate and speed up the entry of affordable medicines into the market. But when one patent addressing one medical condition (indication) blocks the entry of the generic, the use of skinny labels makes it possible for the generic players to carve out the label and enter the market only with indications that are off-patent. This helps bring these unaffordable medical products within reach of the common person who could not otherwise afford them.

This note will examine how the generic players navigate the drug approval system, the strategies of the innovators to ward off competition, and the public policy surrounding the availability of affordable medical products. It will also discuss the impact and implications of skinny labels on the market entry of affordable life-sustaining products and the landmark case that is changing the scenario altogether. Finally, this note will propose possible alternative methods to increase the affordability and availability of life-sustaining products by making it a win-win situation for innovators, generics, and the public.

II. HISTORICAL AND LEGAL OVERVIEW OF THE PROBLEM

The interplay of patents and the drug approval system presents three problems. First, it helps generic players navigate the drug approval system and also keeps the threat of infringement alive. Second, it provides the opportunity for innovators to create strategies to extend a product's life without investing an alleged dollar amount into the invention. Finally, it fails to adhere to public policy calls for the availability and affordability of the products for all those who need them.

The subsequent sections will examine these issues and some ways to amend this system. Public health is of utmost importance for every government, and the availability of affordable life-sustaining products is vital to its effective implementation. Thus, these issues need to be addressed to save more lives and make healthcare affordable.

A. *U.S. Pharmaceutical Industry and Patents*

Patent law is widely acknowledged to encourage ongoing investment in medical advancements and, in theory, ensure the safe and

rapid distribution of medicines to patients.[1] The success rate for new medicines is one in every 5,000 to 10,000 compounds that are developed and tested.[2] The process of acquiring Food and Drug Administration (FDA) approval for a new medicine is extensive, and the estimated time to develop and get approval for a new drug is ten to fifteen years.[3] Development and pre-clinical testing of a new compound are required before an Investigational New Drug (IND) Application[4] can be submitted to the FDA, and the FDA approval process continues throughout the commercial manufacturing process.[5] Only one in every five FDA-approved drugs ever produces revenues that will match or exceed their Research and Development (R&D) costs.[6] The total risk that a pharmaceutical company faces is that only one in every 50,000 drugs identified will produce a return on the upfront R&D investment, and that return will not be realized for at least fifteen to twenty years.[7]

Patent laws incentivize investment in these new inventions.[8] The United States Patent Act is the most extensive patent statute globally and has consistently affirmed the patentability of pharmaceuticals.[9] This extensive protection has facilitated the growth of the pharmaceutical industry, operating within the parameters of both the free market and the FDA.[10] The promise of having exclusive market share is what makes the hefty upfront financial and time investments,

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[1] *See* Naomi A. Bass, *Implications of the Trips Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 GEO. WASH. INT'L L. REV. 191, 215–16 (2002).

[2] *See* Jaime B. Herren, *Trips and Pharmaceutical Patents: The Pharmaceutical Industry vs. the World*, 14 INTELL. PROP. L. BULL. 43, 45 (2009); *see also* PhRMA, Biopharmaceutical Research Industry Profile 2022 (2022).

[3] *See* PhRMA, *supra* note 2.

[4] The innovator needs to submit an IND for experimental drugs showing promise in clinical testing for severe or immediately life-threatening conditions while performing the final clinical work, and before the FDA review occurs. *Investigational New Drug (IND) Application*, FOOD AND DRUG ADMIN., https://www.google.com/url?q=https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application&sa=D&source=docs&ust=1709868602702802&usg=AOvVaw0CDHZtuwJW47v8022kI-eY (last visited Sept. 1, 2023).

[5] *See* PhRMA, *supra* note 2.

[6] *See id.*

[7] *See* Herren, *supra* note 2, at 46.

[8] *See id.*

[9] *See id.*; *see also Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (finding "anything under the sun made by man" as patentable subject matter).

[10] *See* Herren, *supra* note 2, at 46.

amounting to $1.3 billion per drug, worthwhile.[11] Without such assurances, the one in 50,000 chance of finding a new medical compound is excessively risky for the average investor.[12]

Investing in pharmaceutical research and development represents a significant portion of future drug sales, with approximately fifteen to nineteen percent of revenues being reinvested directly into the research and development of new medications.[13] This implies that for every full-price payer—including governments who subsidize medications—presumably fifteen to nineteen cents of every dollar spent by patients and their insurance companies on name brands go directly into pharmaceutical R&D.[14] Pharmaceutical advocates predict that the absence of patent protection for pharmaceuticals would "delay the discovery, production, and distribution of medicines which could go beyond treatment to prevention and cure."[15]

B. *Patent Linkage*

Patent linkage pertains to the connection between the market authorization of a generic medication and the patent standing of its branded counterpart.[16] It mandates that approval for marketing a generic drug cannot be given until the patent term for the branded equivalent expires, or until it is determined by the relevant authority that the patent for the branded drug will not be violated or is invalid, unless expressly permitted by the patent holder.[17]

When submitting an Abbreviated New Drug Application (ANDA) for the approval of a generic drug, a manufacturer must certify one of the following four conditions: (1) that the drug lacks patent protection; (2) that the patent has already lapsed; (3) the expiration date of the patent and the assurance that the generic drug won't enter the market until after the patent expires; or (4) that the patent is neither infringed nor valid.[18] In the case of grounds one and two, the FDA may approve the generic immediately, and for ground three, the FDA will

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[11] *See id.*

[12] *See id.*

[13] *See id.*

[14] *See id.*

[15] Bass, *supra* note 1, at 216.

[16] *See* Avneet Heer, *Patent linkage: Balancing patent protection and generic entry*, DRUGPATENTWATCH, https://www.drugpatentwatch.com/blog/patent-linkage-resolving-infringement/ (last visited Sep. 1, 2023).

[17] *See id.* Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the Orange Book) "documents information on approved drugs, discontinued drugs and corresponding patents."

[18] *See id.*

likely approve it upon the expiration of the patent term.[19] Concerning the fourth condition, when certifying that the patent is neither infringed nor valid, the applicant is required to inform the patent holder of its application and provide the reasoning behind these assertions.[20] The patent holder has a forty-five day period following the notice to initiate an infringement lawsuit; if such a lawsuit is filed, an automatic thirty-month suspension of marketing approval for the drug is implemented.[21] If the patent expires during this thirty-month period, the thirty-month period elapses, or the court declares the patent invalid within thirty months, the FDA can provide prompt approval for the generic drug.[22] If the patent is confirmed as valid and infringement is established, approval for the generic drug will not be granted until the patent's term ends.[23]

Most new drugs are protected by one or more patents, and those patents are required to be listed in the Orange Book. In particular, the FDA mandates the inclusion of patents related to drug substance (active ingredient), drug product (formulation and composition), and method-of-use, all which must be listed in the Orange Book.[24] Crucially, the FDA does not conduct a thorough review of the accuracy of patent information before it is published.[25] The FDA views its role in listing patent information as primarily administrative and clarifies that it lacks the necessary resources and expertise to verify the accuracy of every patent listing submitted by a New Drug Application (NDA) holder.[26] Thus, once listed, the patent can only be invalidated through the costly process of litigation. Most every FDA-approved indication linked to the product has individual patents listed for the product.

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[19] *See id*.

[20] *See id*.

[21] *See* Heer, *supra* note 16.

[22] *See id.*

[23] *See id.*

[24] *See* S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. U.L. REV. 1673, 1681 (2022); *see also* 21 C.F.R. § 314.53(b) (2022).

[25] *See* Tu & Lemley, *supra* note 24.

[26] *See id.*; *see also* 21 C.F.R. § 314.53(b) (2022); *AaiPharma Inc. v. Thompson*, 296 F.3d 227, 237 (4th Cir. 2002) (noting that the FDA does not substantively review the correctness of the patent information before publication); *Teva Pharm., USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008); *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001); 21 C.F.R. § 314.53(e) (2022).

C. *Skinny Label (Carve-Outs)*

An innovator's new drug approval is limited to using the drug for a specific indication (medical condition), at a specific dose, by a specific route of administration, often in a specific population.[27] As per FDA regulations, all of this information must appear on the drug's labeling.[28] Pharmaceutical manufacturers are prohibited from promoting their products in a way that deviates from the approved New Drug Application (NDA) or drug labeling.[29]

The Hatch-Waxman Act guides non-infringing uses.[30] Once a pharmaceutical composition loses its patent protection and has FDA-approved unpatented uses, an Abbreviated New Drug Application (ANDA) can be submitted; this application can leverage the label of the branded manufacturer's previously approved drug as a foundation, while excluding or carving out any patented subject matter.[31] The resulting "skinny labels" have carved out methods of treatment covered by any remaining patents, allowing a generic manufacturer to sell a generic product without infringement.[32] Codified in 21 U.S.C. § 355(j)(2)(A)(viii), this operation of creating skinny labels is also referred to as a "section viii carveout."[33]

While the FDA will not approve a generic drug that infringes a patent, the Administration does not determine listing the patents.[34] By contrast, it relies on the innovator to register any patents that cover a

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[27] *See* 21 U.S.C. § 355 (2018); *see also* 21 C.F.R. §310.3(g)–(h) (2020).

[28] *See* 21 C.F.R. §§ 201.50, 201.51, 201.55, 201.56, 201.57 (2019); *see also id.* § 201.58 (providing that applicants can request the FDA to waive labeling requirements).

[29] *See* David A. Simon, *Off-Label Innovation*, 56 GA. L. REV. 701, 719 (2022).

[30] *See id.*; *see also* Wendy H. Shacht, *The "Hatch-Waxman" Act: Selected Patent-Related Issues*, EVERYCRSREPORT.COM (Apr. 1, 2002), https://www.everycrsreport.com/reports/RL31379.html.

[31] *See* Simon, *supra* note 29, at 732; *see also* 21 U.S.C. § 355(j)(2)(A)(viii) (2018).

[32] *See* 21 U.S.C. § 355(j)(2)(A)(viii) (2018); *see also Abraxis Bioscience, Inc. v. Navinta LLC*, 625 F.3d 1359, 1362 (Fed. Cir. 2010).

[33] Garrett T. Potter, *Beefing Up Skinny Labels: Induced Infringement As A Question of Law*, 97 NOTRE DAME L. REV. 1707, 1714–15 (2022); *see also GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1327 (Fed. Cir. 2021).

[34] *See* Jonathan B. Turpin & Leah M. Brackensick, *LockeLord QuickStudy: FTC Challenges 100+ Patents, Bringing Attention to Orange Book patent Listing Requirements*, LOCKE LORD LLP (Nov. 8, 2023), https://www.lockelord.com/newsandevents/publications/2023/11/properly-list-patents-in-the-fdas-orange-book.

compound or method of use, so that the FDA may incorporate this information into the Orange Book.[35] The FDA also requires NDA holders to submit a list of patents for the drug, including patents for the active ingredient, formulation, and method of use or indications.[36]

Mainly, the FDA requires that generic labels be exactly the same as those for the Reference Listed Drug or Innovator (RLD).[37] However, ANDAs (the generic equivalent of NDA) can instead choose to include a "section viii statement," which informs the FDA that the ANDA holder is omitting or carving out an indication for the generic that is covered by the RLD's method-of-use patent in the Orange Book without sacrificing safety and effectiveness.[38] The FDA often approves such carveouts because they allow immediate ANDA approval, rather than tentative approval until all the RLD's patents expire.[39]

Correspondingly, the generic developer will carve out the patent-protected indication from the drug label to create a skinny label to avoid infringing the patent.[40] In practice, however, physicians still often prescribe skinny-labeled generics for patent-protected uses because generics are cheaper and equally effective as brand-name drugs.[41] Courts have acknowledged that while skinny labels do not directly infringe the method-of-use patents for brand-name drugs, they can induce prescribing physicians to infringe.[42]

III. OVERVIEW OF THE CURRENT LAWS IN PLACE

This Part provides an overview of the medicine approval system. First, this section will introduce the U.S. Patent System,

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[35] *See Approved Drug Products with Therapeutic Equivalence Evaluations: Orange Book*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book (last visited Sep. 1, 2023).

[36] *See* Sara W. Koblitz, *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, FOOD & DRUG L. INST., https://www.fdli.org/2021/06/glaxosmithkline-llc-v-teva-pharmaceuticals-usa-inc/ (last visited Sep. 1, 2023).

[37] *See* Joseph W. Arico et al., *Skinny Labels and the Line Between Mere Information and Inducement to Infringe in ANDA Litigation*, BLOOMBERG L., https://news.bloomberglaw.com/health-law-and-business/skinny-labels-and-the-line-between-mere-information-and-inducement-to-infringe-in-anda-litigation (last visited Sep. 2, 2023).

[38] *See id.*

[39] *See* Koblitz, *supra* note 36.

[40] *See* Arico et al., *supra* note 37.

[41] *See id.*

[42] *See id.*

including the conditions of obtaining a patent, licensing, patent marking, and infringement of patents. Second, this Part will discuss the relationship between the U.S. Pharmaceutical market and the patent system. Third, this Part will address the role of the FDA in the approval of a medicine for the U.S. market. Lastly, this Part will examine the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.

A. *Patent System*

Article I, section 8 of the U.S. Constitution grants Congress the authority to pass legislation concerning patents, which states: "Congress shall have power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[43] Using this authority, Congress has periodically passed different laws concerning patents.[44] The initial patent legislation was passed in 1790.[45] The patent laws underwent a general revision, which was enacted on July 19, 1952, and which came into effect on January 1, 1953.[46] It is codified in Title 35 of the United States Code.[47]

Additionally, on November 29, 1999, Congress enacted the American Inventors Protection Act of 1999 (AIPA), which further revised the patent laws.[48] The patent law specifies the subject matter for which a patent may be obtained and the conditions for patentability.[49] Typically, individuals have the freedom to create, utilize, sell, or import anything they wish without needing government permission.[50] A patent, however, provides an individual "the right to exclude others from making, using, offering for sale, or selling or importing [an] invention."[51] Additionally, a patentee cannot "make, use, offer for sale, sell, or import his or her own invention if doing so

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[43] U.S. CONST. art. I, § 8, cl. 8.

[44] *See id.*

[45] *See* U.S. PAT. AND TRADEMARK OFF., GENERAL INFORMATION CONCERNING PATENTS 2 (2014), https://www.uspto.gov/sites/default/files/inventors/edu-inf/BasicPatentGuide.pdf [hereinafter USPTO].

[46] *See id.*

[47] *See id.*

[48] *See id.*

[49] *See id.*

[50] *See id.* at 24.

[51] USPTO, *supra* note 45, at 25 ("Since the patent does not grant the right to make, use, offer for sale, sell, or import the invention, the patentee's own right to do so is dependent upon the rights of others and whatever general laws might be applicable.").

would infringe the prior rights of others."[52] To obtain a patent, the inventor must meet certain conditions.

1. Conditions for Obtaining a Patent

An invention is any new or useful process, machine, article of manufacture, or composition of matter.[53] The United States Patent and Trademark Office (USPTO) grants the inventor property rights to their invention by issuing a patent.[54] In essence, a new patent's term spans twenty years from the filing date of the patent application in the United States, or in exceptional circumstances, from the filing date of a preceding related application, contingent upon the payment of maintenance fees.[55]

In order to be eligible for patent protection, United States patent law requires that an invention be new, useful, and non-obvious.[56] The assessment of whether a claimed invention satisfies the criteria of novelty and non-obviousness is conducted by comparing it to the existing body of disclosed information within the relevant field.[57] This information is commonly referred to as "prior art."[58] The most frequently utilized prior art typically comprises patents that have already been issued or published by patent offices worldwide.[59] The subject matter sought to be patented must be sufficiently different from what has been used or described before that it may be said to be non-obvious to a person having ordinary skill in the area of technology related to the invention.[60]

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[52] *Id.* at 1.

[53] *See id.* An improvement on any of these items also can be an invention. *See id.*

[54] *See id.* ("The right conferred by the patent grant is, in the language of the statute and of the grant itself, 'the right to exclude others from making, using, offering for sale, or selling' the invention in the United States or 'importing' the invention into the United States. What is granted is not the right to make, use, offer for sale, sell or import, but the right to exclude others from making, using, offering for sale, selling or importing the invention.").

[55] *See id.*

[56] *See* 35 U.S.C. §§ 101, 102, 103.

[57] *See* BRUCE LEHMAN, THE PHARMACEUTICAL INDUSTRY AND THE PATENT SYSTEM 4 (2003), https://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf.

[58] *Id.*

[59] *See id.* If the subject matter being sought for patenting isn't precisely depicted in the prior art and contains one or more distinctions from the most closely related existing entity, a patent may still be denied if these distinctions would be considered obvious. *Id.*

[60] *See id.*

2. Assignments and Licenses

A patent constitutes personal property that can be sold, mortgaged, bequeathed through a will, or transferred to the heirs of the patent holder upon their demise.[61] In patent law, the transfer or sale of a patent or a patent application is facilitated through a written instrument.[62] This type of document is commonly known as an assignment, and it has the capability to transfer the complete interest in the patent.[63] Upon assignment of the patent, the assignee assumes ownership of the patent and possesses the identical rights as those held by the original patentee.[64] In the medical industry, these assignments are commonly related to active pharmaceutical ingredients, manufacturing technologies, packaging, and so on.

3. Patent Marking

A patent holder who manufactures or sells patented items, or someone acting on behalf of the patent holder, must mark the articles with the word "patent" along with the patent number.[65] Marking can be done even if the patent is pending.[66] According to the patent marking statute, 35 U.S.C. § 287, patent holders can claim damages from an infringer starting from the time when the infringer was made aware of the infringement and persisted in infringing.[67] Proper marking gives the infringer constructive notice. In the absence of marking, a patent holder can only collect damages from the moment the infringer received explicit notification, such as through a warning letter or the initiation of an infringement lawsuit.[68] The consequence of not marking the patent is that the patent holder may not be able to claim damages from an infringer unless the infringer was properly informed of the infringement and persisted in infringing after receiving notice.[69]

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[61] *See* USPTO, *supra* note 45, at 26.

[62] *See id.*

[63] *See id.*

[64] *See id.*

[65] *See id.* at 27.

[66] *See id.* at 27–28.

[67] *See* USPTO, *supra* note 45, at 27; *see also* Mark W. Rygiel, *Patent Marking Basics*, STERNE, KESSLER, GOLDSTEIN & FOX, https://www.sternekessler.com/news-insights/publications/patent-marking-basics (last visited Sept. 14, 2023).

[68] *See* USPTO, *supra* note 45, at 27–28. In the pharmaceutical industry, aside from patent marking, the Orange Book is regarded as a means of providing notice to generic competitors by listing comprehensive product information, including patents, for a particular product. *See id.*

[69] *See id.*

4. Infringement of Patents

Patent infringement entails the unauthorized creation, utilization, offering for sale, or sale of any patented invention within the United States or its territories, or the importation of any patented invention into the United States throughout the patent's term.[70] If a patent is infringed, the patent holder has the option to seek legal recourse in the relevant federal court.[71] The patent holder can request the court for an injunction to halt the ongoing infringement and may also seek damages as a result of the infringement.[72] In such a suit, the defendant has the option to challenge the validity of the patent, which is subsequently determined by the court.[73] The defendant may also claim that the actions taken do not amount to infringement.[74]

B. *Role of FDA in Approving the Products*

The FDA is responsible for protecting public health by regulating pharmaceutical and biological products, along with other human consumption products. Regardless of whether the product is a drug under investigation, a new drug, or a generic or biosimilar, each type of product has to go through the approval process of the FDA.[75]

1. Investigational New Drug (IND)

Current federal legislation mandates that a drug must have an approved marketing application before it can be transported or distributed interstate.[76] As sponsors typically intend to distribute the investigational drug to clinical investigators across multiple states, they must seek an exemption from this legal requirement.[77] The IND

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[70] *See id.*

[71] *See id.*

[72] *See id.*

[73] *See* USPTO, *supra* note 45, at 27–28.

[74] *See id.* at 27.

[75] *See How Drugs are Developed and Approved*, U.S. FOOD AND DRUG ADMIN. (Oct. 24, 2022), https://www.fda.gov/drugs/development-approval-process-drugs/how-drugs-are-developed-and-approved (last visited Sept. 14, 2023). A biosimilar, or biosimilar drug, is a medicine that is very close in structure and function to a biologic medicine. *See Biologics: More Treatment Choices*, U.S. FOOD AND DRUG ADMIN. (Aug. 17, 2023) https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices.

[76] *See Types of Applications*, U.S. FOOD AND DRUG ADMIN. (Oct. 23, 2014), https://www.fda.gov/drugs/how-drugs-are-developed-and-approved/types-applications (last visited Sept. 14, 2023).

[77] *See id.*

application is the mechanism by which this exemption is formally secured from the FDA.[78]

2. New Drug Application (NDA)

When the sponsor of a new drug deems that sufficient evidence regarding the drug's safety and effectiveness has been gathered to satisfy the FDA's criteria for marketing approval, that sponsor submits a New Drug Application (NDA) to the FDA.[79] The application must encompass data from distinct technical perspectives for review, encompassing chemistry, pharmacology, medicine, biopharmaceutics, and statistics.[80] For tracking purposes, every NDA is assigned a unique NDA number.[81] Upon approval of the NDA, the product becomes eligible for marketing in the United States.

3. Abbreviated New Drug Application (ANDA)

When presented to the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, the data comprising the Abbreviated New Drug Application (ANDA) helps facilitate the review and eventual approval of a generic drug product.[82] Generic drug applications are termed "abbreviated" as they typically do not necessitate the inclusion of preclinical (animal) and clinical (human) data to demonstrate safety and efficacy.[83] Instead, a generic applicant must scientifically prove that its product and the innovator's are bioequivalent, meaning they perform similarly.[84] Upon approval, the applicant is permitted to produce and distribute the generic, thus offering a safe, effective, and cost-efficient alternative to America's public.[85]

4. Biologic License Application (BLA)

Biological products are authorized for marketing in accordance with the provisions outlined in the Public Health Service (PHS) Act.[86]

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[78] *See id.*
[79] *See id.*
[80] *See id.*
[81] *See id.*
[82] *See* U.S. FOOD AND DRUG ADMIN., *supra* note 76.
[83] *See id.*
[84] *See id.*
[85] *See id.*
[86] *See id.* Biological products include vaccines, blood and blood components, allergenics, somatic cells, gene therapies, tissues, and recombinant therapeutic proteins. *See What are "Biologics" Questions and Answers*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/about-

The Act mandates that any company producing a biologic for interstate commerce must possess a license for the product.[87] A biologics license application is a submission comprising detailed information about the manufacturing processes, chemistry, pharmacology, clinical pharmacology, and medical effects of the biologic product.[88] Upon meeting FDA requirements, approval of the application is granted and a license is issued, thus permitting the company to market the product.[89]

5. Biosimilars

A biosimilar product is a medication that closely resembles another biological medicine that has already been approved.[90] In contrast to generic products, the FDA does not require identical biosimilars, but only mandates that a biosimilar must be highly similar to the reference product.[91] Additionally, a biosimilar must show no clinically significant variances in efficacy, safety, or potency when compared to its reference product.[92] This route is termed "abbreviated" because the safety and efficacy data required for the approval of a biosimilar by the FDA is typically a lesser quantity than what would be needed for the approval of the original biologic.[93]

C. *The Hatch-Waxman Act*

The Hatch-Waxman Act—enacted in 1984—amended the Federal Food, Drug, and Cosmetic Act.[94] The Hatch-Waxman Act aimed to accomplish two conflicting objectives.[95] Title I aimed to

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fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers (last visited Mar. 3, 2024); *see also Biologic*, NAT'L INSTS. OF HEALTH, https://toolkit.ncats.nih.gov/glossary/biologic/ (last visited Sept. 1, 2023).

[87] *See id.*

[88] *See* U.S. FOOD AND DRUG ADMIN., *supra* note 76.

[89] *See id.*

[90] *See Biosimilars: How the Approval Process Differs from a Standard ANDA*, PROPHARMA (Sept. 9, 2020), https://www.propharmagroup.com/thought-leadership/biosimilars-how-the-approval-process-differs-from-a-standard-anda.

[91] *See id.*

[92] *See id.*

[93] *See id.*

[94] *See* Reid F. Herlihy, *The Federal Circuit's Interpretation of the Hatch-Waxman Act: Allowing Generics to Induce Infringement*, 15 FED. CIR. BAR J. 119, 121 (2005).

[95] *See* Herlihy, *supra* note 94, at 121; *see also Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003).

encourage the accessibility of more affordable generic drugs.[96] At the same time, Title II aimed to provide enhanced patent protection to brand-name drug companies in order to stimulate research into new drugs and applications.[97] Before the enactment of the Act, brand-name drug manufacturers experienced significant delays before receiving the benefit of their patents, due to the requirement of obtaining FDA approval through filing an NDA prior to promoting the usage of their product.[98] So, these companies secured patents for their innovations prior to seeking FDA approval.[99] As a result, the patent term of a producer would diminish while awaiting approval through the extensive NDA process.[100] To remedy this inefficiency, Congress passed 35 U.S.C. § 156, providing a patent term extension for pioneering drug manufacturers undergoing review by the FDA.[101]

Prior to the Hatch-Waxman Act, generic drug manufacturers were required to obtain NDA approval before they could market generic versions of previously approved drugs.[102] The NDA procedure is expensive and demands comprehensive efficacy and safety data from the generic manufacturer.[103] Furthermore, it was deemed an act of infringement to utilize or produce a patented product, even if solely for testing purposes in preparation for FDA approval.[104] This essentially prolonged the brand-name company's patent term, as it mandated that a generic manufacturer wait until the expiration of a drug's patent before initiating testing for FDA approval of a generic version.[105] In reaction to this consequence, Congress established 35 U.S.C. § 271(e)(1), permitting generic companies to utilize, produce, or sell a patented invention for purposes related to development and submission for FDA approval.[106] According to this provision, a generic manufacturer can utilize patented drugs or methods to prepare for

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[96] *See* Herlihy, *supra* note 94, at 121 (citing H.R. REP. No. 98-857, pt. 1, at 14 (1984)).

[97] *See id.*; *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990).

[98] *See* Herlihy, *supra* note 94, at 121.

[99] *See id.*

[100] *See id.*

[101] *See Eli Lilly & Co.*, 496 U.S. at 670–71.

[102] *See Warner-Lambert Co.*, 316 F.3d at 1357.

[103] *See id.*; *see also* Herlihy, *supra* note 94, at 121.

[104] *See Eli Lilly & Co.*, 496 U.S. at 670.

[105] *See* Herlihy, *supra* note 94, at 121–22.

[106] *See id.* at 122. This provision is commonly referred to as the Bolar Exemption in the United States. *See id.* Internationally, it is referred to as the "safe harbor" provision. *Id.*

approval without violating a patent.[107] As a result, once the patent of the brand-name company expires, a generic company can expedite the launch of the generic version of a drug onto the market.[108]

Congress also amended the FDA approval process to incorporate ANDAs.[109] An ANDA must demonstrate that the generic drug is already listed, shares the same active ingredient as the listed drug, will be administered in the same manner as the listed drug, and is bioequivalent to the listed drug.[110] According to 21 U.S.C. § 355(b)(1), the Act permits all patent holders to include relevant patents on drugs and their uses in the Orange Book when submitting an NDA.[111] This provision of the Act was established to streamline the resolution of infringement disputes concerning an innovator's patent.[112] Upon submission, 21 U.S.C. § 355(j)(2)(A)(vii) mandates that the ANDA applicant certify any of the following: (1) no analogous patent information is listed in the Orange Book; (2) the analogous patent has expired; (3) the analogous patent will expire before the generic product is marketed; or (4) the analogous patent is invalid or will not be infringed upon by the production, use, or sale of the drug.[113] The fourth provision of this regulation is referred to as a "paragraph IV certification."[114]

Congress also introduced 35 U.S.C. § 271(e)(2)(A) to establish an "artificial act of infringement" triggered by the submission of an ANDA containing a paragraph IV certification.[115] Essentially, 35 U.S.C. § 271(e)(2)(A) enables a brand-name company to file a lawsuit against a generic manufacturer for infringement prior to FDA approval, even before the generic company engages in any sales or promotion.[116] The Hatch-Waxman Act has created unintentional problems for innovators and generic players by linking patents to every indication of the product. Moreover, the process of listing a patent does not end with product approval. Innovators keep listing the patents for every

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[107] *See id.*

[108] *See id.*

[109] *See* 21 U.S.C. § 355(j) (2000).

[110] *See* Herlihy, *supra* note 94, at 122. *See generally* 21 U.S.C. § 355(j)(2)(A); Laura Giles, *Promoting Generic Drug Availability: Reforming the Hatch-Waxman Act to Prevent Unnecessary Delays to Consumers*, 75 ST. JOHN'S L. REV. 357, 362 (2001).

[111] *See* Herlihy, *supra* note 92, at 122; *see also* 21 U.S.C. § 355(b)(1).

[112] *See Warner-Lambert Co.*, 316 F.3d at 1358.

[113] *See Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1341 (Fed. Cir. 2003).

[114] *Id.*

[115] *Eli Lilly & Co.*, 496 U.S. at 678.

[116] *See* Herlihy, *supra* note 92, at 119.

discovery related to the product that is already in the market. The problem arises when one or two indications are still patented, while others can have generic approval. The government tried to solve this problem by allowing the use of skinny labels, but created another murky situation instead.

IV. ANALYSIS

This section will address the primary issues presented by the interplay of patents and the FDA approval system. First, it will discuss how a solution to bring generic medicines to market by using skinny labels is becoming a war zone. Second, it will address the evolving concept of induced infringement. Third, it will discuss the landmark case of *GSK v. Teva*, in detail. Fourth, it will explore the role of the FDA in creating this messy situation. Finally, it will put forth major policy issues and possible solutions to the problem.

Generally, skinny labels are approved unless they cause the generic to be less safe or effective than the brand-name drug for all remaining, non-protected uses.[117] Such skinny labels, or "carve-outs," offer generics an efficient strategy to circumvent feeble or restricted patents that brand-name companies might attach toward the end of a drug's patent term in an attempt at retaining their exclusive market dominance for all uses of the drug.[118] Nevertheless, innovator companies have the option to submit citizen petitions, contending that the carve-out should be invalidated.[119] These petitions primarily contend that the proposed carve-out includes information pertaining to the safety or effectiveness of the drug, asserting that such information cannot be omitted from the label.[120]

A generic company might be making strenuous efforts to circumvent the Hatch-Waxman litigation process by eliminating specific applications from the label, recognizing that physicians might still prescribe the drug for all purposes, regardless.[121] However, there are evident instances where brand-name companies make minor alterations to labeling or obtain fragile method-of-use patents, only to subsequently submit citizen petitions to hinder subsequent carve-out

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[117] *See* 21 C.F.R. § 314.127 (2015).

[118] *See* Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. on LEGIS. 499, 549 (2016).

[119] *See id.* at 550.

[120] *See id.*

[121] *See id.* However, the FDA has refused to accept this as a rationale for not approving a carve-out, even in cases where the reference listed drug holder says off-label use could implicate safe and effective use of the drug. *See id.* at 550 n.289.

requests.[122] Innovators will persist in searching for methods to secure their market dominance, particularly in light of potential competition from generic alternatives.[123] Another strategy is to sue the generic manufacturer by alleging induced infringement.

A. *Induced Infringement*

"Patent infringement consists of 'unauthorized making, using, offering for sale, or selling any patented invention within the United States, or importing into the United States any patented invention during its term.'"[124] The patent owner retains the right to initiate legal action in federal court to halt the infringement and seek monetary compensation demonstrating either literal or indirect infringement.[125] In 1952, indirect infringement was formally established through two subcategories: induced infringement and contributory infringement.[126] This codification aimed to alleviate the substantial uncertainty and confusion regarding the extent of indirect infringement caused by numerous court decisions.[127] Regarding induced infringement, according to the United States Code, if a party engages in activities that aid and abet patent infringement, it constitutes a sign of induced infringement,[128] and anyone who actively induces infringement of a patent shall be held liable as an infringer.[129] Demonstrating induced infringement necessitates fulfilling three criteria: (i) confirmation of direct infringement by a third party; (ii) establishment of the inducing party's deliberate intent to cause such direct infringement; and (iii) performance of an affirmative action by the inducing party that effectively encourages the third party to commit infringement.[130] In

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[122] *See id.* at 550–51. "Brand-name companies also have sought to block carve-outs by modifying the 'use codes' associated with a given patent in the Orange Book. Use codes provide a brief description of what use of the drug is covered by the listed patent, and brand-name companies have been accused of trying to broaden the scope of use codes to prevent a section viii carve-out. Like the patents listed in the Orange Book, use code information is not verified by the FDA." Feldman & Frondorf, *supra* note 118, at 551 n.291.

[123] *See* Potter, *supra* note 33, at 1715.

[124] *Managing a Patent*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/basics/manage.

[125] *See id.*

[126] *See* S. Rep. No. 1979, at 6 (1952).

[127] *See id.*

[128] *See* Potter, *supra* note 33, at 1719.

[129] *See* 35 U.S.C. § 271(b) (2018).

[130] *See* Potter, *supra* note 33, at 1718; *see also* Corrected Non-Confidential Joint Appendix Volume I of II at Appx 168, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347, 1350 (Fed. Cir. 2020) *reh'g*

2015, the Supreme Court ruled that the specific intent requirement additionally mandates that the alleged inducer possess actual knowledge of the patent's existence and awareness that their induced action would result in direct infringement.[131]

In previous rulings related to generic drug manufacturing cases, the Federal Circuit set a precedent indicating that when a brand manufacturer utilizes a generic drug label's instructions in conjunction with advertising and marketing to demonstrate intent to actively induce infringement, the inquiry extends beyond merely assessing whether those instructions describe the infringing method. Instead, it focuses on whether the instructions promote an infringing use to the extent that an affirmative intent to infringe the patent can be inferred from them.[132] The label must "encourage, recommend, or promote infringement."[133] The Federal Circuit holds that to establish such active inducement, evidence of actual intent to cause the actions constituting infringement is deemed a necessary prerequisite.[134] The recent landmark case that has given new meaning to induced infringement in the pharmaceutical industry is *GSK v. Teva*. This case has brought up new issues and has instilled a new fear of litigation in the generic industry.

B. *GSK v. Teva*

GlaxoSmithKline (GSK) is the pharmaceutical company that markets and distributes the medication carvedilol, a beta-blocker under the brand name Coreg.[135] As of 1997, the FDA had granted approval for carvedilol to be used in the treatment of hypertension and congestive heart failure (CHF).[136] Subsequently, in 2003, the FDA

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granted, opinion withdrawn (Feb. 9, 2021), *on reh'g*, 7 F.4th 1320 (Fed. Cir. 2021) (providing jury instructions outlining the requirements for a showing of induced infringement).

[131] *See Commil USA, LLC v. Cisco Sys.*, 575 U.S. 632, 642 (2015); *see also Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 765–66 (2011). The Federal Circuit has established that inducement necessitates actively encouraging another party's infringement, rather than merely demonstrating awareness of the direct infringer's actions.

[132] *See* Potter, *supra* note 33, at 1719.

[133] *Eli Lilly & Co. v. Teva Parenteral Meds.*, Inc. 845 F.3d 1357, 1368 (Fed. Cir. 2017) (internal quotation marks omitted) (quoting *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015)).

[134] *See Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990).

[135] *See GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1323 (Fed. Cir. 2021). Patent use code U-233 corresponded to "decreasing mortality caused by congestive heart failure." *Id.* at 1324.

[136] *See id.*

extended approval for carvedilol to encompass a third indication: the reduction of cardiovascular mortality in patients with left ventricular dysfunction following a myocardial infarction, commonly referred to as the "post-MI LVD" indication.[137] Later, in March 2022, Teva submitted an ANDA to the FDA seeking approval for its generic version of carvedilol, intended for all three indications.[138]

Shortly before Teva launched its generic carvedilol in 2007, it provided certification to the FDA, stating that its label would not incorporate the indication defined in use code U-233 until the expiration of the compound patent.[139] In 2011, subsequent to GSK's removal of specific patents, such as the compound patent, from the Orange Book, the FDA instructed Teva to revise its labeling to incorporate the details associated with the delisted patent and the corresponding use code (U-313).[140] The FDA instructed Teva to provide labeling that mirrors the content of the approved GSK Coreg labeling, encompassing the package insert as well as any necessary patient package inserts and/or Medication Guide.[141] The FDA also asked Teva to furnish information regarding its stance on the reissued patent.[142]

Teva updated its label to incorporate the indication for treating patients with congestive heart failure by administering carvedilol to improve survival rates and decrease the risk of hospitalization.[143] Furthermore, the indications for post-MI LVD and hypertension remained unchanged on the label.[144] In reply to the FDA's inquiry regarding its position on the reissued patent, Teva conveyed to the FDA its belief that it was not required to "provide certification to the reissued patent," since it had already obtained final approval of its ANDA before the patent's reissue.[145]

In July 2014, GSK filed a lawsuit against Teva and Glenmark Pharmaceuticals USA, the two primary suppliers of generic carvedilol, in the District of Delaware, asserting that each had induced infringement of the reissued patent.[146] The district court found that it would be unreasonable for a juror to conclude that Teva's post-MI LVD indication directly caused or encouraged infringement of this

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[137] *See id.*
[138] *See id.*
[139] *See id.*
[140] *See GlaxoSmithKline LLC*, 7 F.4th at 1324.
[141] *See id.*
[142] *See id.* at 1324–25.
[143] *See id.* at 1325.
[144] *See id.*
[145] *Id.*
[146] *See GlaxoSmithKline LLC*, 7 F.4th at 1325.

particular claimed use.[147] GSK filed an appeal, asserting that there was substantial evidence backing the jury's verdict of induced infringement and requested the reinstatement of the verdict.[148]

The court sided with GSK, acknowledging that despite Teva's section viii certification attempting to exclude one heart failure indication and its removal of the indication from its partial label, there was significant evidence supporting the jury's determination that Teva induced doctors to infringe on the method of use claimed in the reissued patent.[149] The court also determined that there was significant evidence supporting the jury's conclusion that Teva's partial label endorsed an infringing use (via the post-MI LVD indication) and that Teva's marketing materials encouraged the prescription of carvedilol in a manner that would result in infringement of the reissued patent.[150]

C. *Role of the FDA*

The FDA played a significant role in this case. In her dissenting opinion, Judge Prost noted, "it's unclear what Teva even did wrong," primarily because it expressly followed FDA regulations.[151] A skinny label for a generic drug must be "the same as the labeling approved for the listed drug."[152] The only significant change a skinny label may make is to exclude still-patented indications.[153] Along with these ANDA requirements, generic manufacturers must also comply with FDA regulations for all drug labels, including indication and usage statements,[154] dosage and administration information,[155] drug interactions,[156] and so on. Importantly, the FDA also requires the identification of relevant clinical studies that led to the drug's approval.[157] The "Clinical Studies" section "must discuss those clinical studies that facilitate an understanding of how to use the drug safely and effectively."[158]

For generic drugs, that means that the skinny label must always include references to the original clinical trial for which the branded drug gained approval. FDA regulations required Teva's skinny label to

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[147] *See id.*
[148] *See id.* at 1326.
[149] *See id.* at 1327.
[150] *See id.*
[151] *Id.* at 1360–61 (Prost, J., dissenting).
[152] 21 U.S.C. § 355(j)(2)(A)(v).
[153] *See id.*
[154] *See* 21 C.F.R. § 201.57(c)(2).
[155] *See id.* § 201.57(c)(3).
[156] *See id.* § 201.57(c)(13).
[157] *See id.* § 201.57(c)(15).
[158] *Id.* § 201.57(c)(15).

reference the CAPRICORN trial.[159] By following the explicit requirements of the FDA, Teva was found liable for induced infringement. On the denial of Teva's petition for rehearing *en banc*, three different dissents noted this inherent conflict. It is unclear what Teva "should do differently."[160] This decision has made the generic manufacturers cautious of applying for skinny labels, as it can open a Pandora's box of lawsuits.

D. *Public Policy*

Policy considerations support rebalancing patent rights and generics' public health benefits. In passing the Hatch-Waxman Amendments, Congress foresaw exactly the issue in the present case and created pathways for generic developers to avoid this kind of infringement.[161] In an amicus curiae brief for *GSK v. Teva*, former Congressman Henry Waxman, a co-sponsor of the Hatch-Waxman Amendments, maintained that the exact situation in the case at hand was considered by Congress members drafting the amendments.[162] Congress acknowledged that even if a drug received authorization for limited applications, physicians would inevitably prescribe it for alternative uses, potentially infringing on patents.[163] Moreover, two years before the passage of the Hatch-Waxman Amendments, the FDA clarified, "[o]nce a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling."[164]

In *GSK v. Teva*, Teva acted as Congress intended.[165] Teva waited until GSK's composition-of-matter patent on Coreg had expired and filed a section viii statement that carved out GSK's patented method of use for treating CHF.[166] In its marketing materials, Teva noted carvedilol's AB-rated therapeutic equivalence to Coreg, as the FDA had assigned, but did not expressly mention any infringing uses for the drug.[167] In all this, the Dissent supported a finding that Teva manifested an intent to *avoid* inducing infringement of GSK's

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[159] *See* Appendix, *GlaxoSmithKline LLC*, 976 F.3d 2a, 7a.

[160] *GlaxoSmithKline LLC*, 7 F.4th at 1360 (Prost, J., dissenting).

[161] *See* Brief for Former Congressman Henry A. Waxman as Amici Curiae Supporting Petitioners at 4–5, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Nos. 18-1976, 18-2023).

[162] *See id.*

[163] *See id.* at 5–6.

[164] Use of Approved Drugs for Unlabeled Indications, 12 FDA Drug Bull., at 4–5 (1982).

[165] *See GlaxoSmithKline LLC*, 976 F.3d at 1358 (Prost, C.J., dissenting).

[166] *See id.* at 1357 (Prost, C.J. dissenting).

[167] *See id.* at 1354 (Prost, C.J. dissenting).

patent.[168] Yet, the Federal Circuit majority seemingly deferred to GSK's expert testimony, which asserted that reasonable physicians would interpret Teva's marketing materials noting equivalence with Coreg as encouraging the use of carvedilol for any indication for which Coreg had been approved.[169] This included prescriptions for the patented use of treating CHF, due to a close connection between patients with Post-MI LVD and CHF.[170]

In July 2022, Teva filed a petition for writ of certiorari with the Supreme Court.[171] Amici curiae briefs were submitted on behalf of Teva by various pharmaceutical companies, industry groups, and former U.S. Representative Henry Waxman.[172] In February 2023, the Supreme Court asked the Biden Administration for its opinion on whether to reconsider the verdict.[173] In March of that year, the administration's solicitor general, Elizabeth Prelogar, informed the justices that the case presented an appropriate opportunity to tackle the broader existential issue for the industry regarding skinny labels.[174] However, in May 2023, the petition was denied by the Supreme Court.[175] As is their custom, the justices did not explain their rationale for rejecting the case.[176] However, the court did note that Justice Brett Kavanaugh would have granted it a review.[177] The Supreme Court's

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[168] *See id.* at 1342 (Prost, C.J., dissenting).

[169] *See id.* at 1330.

[170] *See* Appendix, *GlaxoSmithKline LLC*, 976 F.3d 2a, 70a.

[171] *See* Petition for Writ of Certiorari, *Teva Pharmaceuticals USA, Inc. v. GlaxoSmithKline LLC*, (No. 22-37), available at https://www.supremecourt.gov/DocketPDF/22/22-37/229830/20220711182924194_cert%20petition.pdf.

[172] *See* The Federal Circuit Blog, *Case Update - GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.* (Feb. 23, 2021), https://fedcircuitblog.com/2021/02/23/case-update-glaxosmithkline-llc-v-teva-pharmaceuticals-usa-inc/.

[173] *See* Fraiser Kansteiner, *UPDATED: After Supreme Court Rejection, Teva Mulls Options in GSK 'Skinny Label' Feud*, FIERCE PHARMA (May 15, 2023), https://www.fiercepharma.com/pharma/after-supreme-court-rejection-teva-reaches-end-line-long-running-skinny-label-feud-gsk.https://www.fiercepharma.com/pharma/teva-takes-skinny-labels-legal-odyssey-to-supreme-court-report.

[174] *See id*.

[175] *See* Denial of Petition for Writ of Certiorari, *Teva Pharmaceuticals USA, Inc. v. GlaxoSmithKline LLC*, 143 S. Ct. 2483 (Mem) (No. 22-37).

[176] *See* Dan McCue, *The Well News, Justices Refuse to Hear 'Skinny Label' Drug Patent Case*, THE WELL NEWS (May 15, 2023), https://www.thewellnews.com/supreme-court/justices-refuse-to-hear-skinny-label-drug-patent-case/.

[177] *See id.*

decision holds potentially dire consequences for all generics with carved-out skinny labels. Teva complied with the applicable FDA regulations and made no representations specific to CHF, but was nevertheless liable for infringement. Thus, generic manufacturers who intend to use skinny-labeled drugs currently on the market are now vulnerable to similar litigation.

To maintain the balance of the dual goals of the Hatch-Waxman Act and the prevention of similar litigation strategies by other brand-name pharmaceutical companies,[178] an amendment to the induced infringement law is necessary. Further, The profit desired by the innovator of the pioneering drug would not experience significant impact from this exemption.[179] In return for providing innovator companies with exclusivity periods and patent term extensions, the Hatch-Waxman Act provided safe harbors and the simplified ANDA process for generics, particularly towards the end of patent terms.[180] Congress explicitly struck this balance and created the ANDA process, including the "same" label requirement, to accelerate the entry of generic drugs. Eliminating induced infringement liability under these very specific facts—when a generic manufacturer's only inducing act is creating a skinny label that is "the same as"[181] the brand label—does not invalidate or diminish the value of the brand company's otherwise valid patent.[182]

The brand company may bring patent infringement claims, including induced infringement claims, "against potential infringers in other circumstances."[183] For example, if a generic company advertises its generic drug for still-patented indications, or distributes press releases that reference the branded drug's full label, the generic company may be found liable for induced infringement. In this same scenario, a generic company that uses label-specific language in its advertisements might also be liable for copyright infringement.[184] However, if the reference to such information is only on the label, it should not be sufficient to support a finding for induced infringement.

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[178] *See, e.g.*, Brief for the Association for Accessible Medicines as Amicus Curiae Supporting Defendants, *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, No. 20-cv-01630 (D. Del. Aug. 20, 2021).

[179] *See id.*

[180] *See* Jonathan A. Bell, *Generic Drugs and the Future of "Skinny Labels"*, 35 HARV. J.L. & TECH. 659, 686 (2022).

[181] 21 U.S.C. § 355(j)(2)(A)(v).

[182] *See SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 29 (2d Cir. 2000).

[183] *Id.*

[184] *See id.*

E. *Possible Solution*

First, to curtail the over-incentivized system, the patent linkage needs to be limited. The patents that are linked to approved innovator products should be examined once again to improve their quality. Once linked to the product, the patent should enter the re-examination phase at the USPTO. This will eliminate meritless patents listed in the Orange Book. Further, it will reduce the cost of litigation by preventing innovators from listing such patents. It will also help generics to save money and resources wasted on litigating these patents. Moreover, it will encourage faster generic entry into the market, which was prevented by innovators by engaging generics in meritless litigation cases. Additionally, the cost of re-examination or the cost of litigating the meritless patent should be allocated to the innovator. It will make them responsible for the patent evaluation and avoid patent hoarding.

Second, the FDA should develop a system of keeping a record of secondary patents filed and granted for each product. The FDA should also make it necessary for innovators to mark the product with all the patents related to the product. The Orange Book gives notice to generics only of the listed patents. However, listing all related patents will help to give notice to generic competitors of all the patents that the innovator can assert for that product. This will decrease the fear of litigation and will also make the patent product linkage system transparent. The patents filed after product approval should not have any impact on the generic entry. This will motivate the innovators to focus their money and efforts on new inventions rather than monopolizing the existing products.

Further, introducing provisions, like a compulsory license for a patented indication if generic players are available and setting the reasonable price of the life-sustaining products if no generic players have filed for an ANDA or biosimilar product, may help resolve the conflict between generics and innovators. Compulsory licensing refers to a government "allow[ing] for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government."[185] Consultation is generally required to "obtain authorization from the right holder on reasonable commercial terms and conditions."[186] It will allow the innovator to recoup the R&D cost but limit the profits acquired at the cost of human life. Thus, innovators should be encouraged to license their products or launch their generic versions. It

[185] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197.

[186] *Id.*

will increase the availability of medicines and will help distribute the cost among the masses. Innovators will be able to recoup R&D costs through volumes, rather than just value.

Finally, keeping public policy at the forefront, the FDA should come up with clear regulations on what will be considered an act of induced infringement. The FDA should be held liable in cases where a generic company followed FDA regulations and requests, but ended up in expensive litigation suits with the innovator. Increasing the FDA's accountability will help it to scrutinize the skinny label with a microscopic view to flag any possible infringement materials. Moreover, before approval, the FDA should consult with innovators to reassure them that they don't have any concerns with the skinny label. If any such issues are flagged, they should be resolved by stipulation of all parties involved, rather than ending up in million-dollar lawsuits.

V. CONCLUSION

The patent system was created to incentivize innovation. Food-drug regulations control the safety of public health. However, the interplay of these two forces has created a rabbit hole for the affordability and availability of life-sustaining products. Either generic players get lost in navigating this rabbit hole, or they pay a hefty price to get through. In return, the public pays the price of this navigation by paying a high price for these medicines. The intent behind these laws keeps the public in mind, but when manufacturers start exploiting the system, the government needs to amend the law. The basic intent of the Hatch-Waxman Act was to create a balance between incentives for innovation and the availability and affordability of medical products to the public. However, the anti-competitive strategies used by innovators and the risky path of litigation for generics do not justify it.

Primarily, the actions of innovators need to be monitored. The cost reaped to enhance future inventions should not be channeled to increase the monopoly of existing products. It fails the very provision of the Constitution that gave birth to the patent law, by not promoting the progress of science but promoting anticompetitive strategies. These strategies sound fair for normal consumer products in the free market, but when it comes to life-sustaining medical products, it is scary.

Moreover, the provision of skinny labels was an amendment to the Hatch-Waxman Act to promote generic products in the market. However, innovators' anticompetitive strategies have choked its very purpose. It sits at the intersection of the patent system and the FDA, and evolving case law is making it a bigger mess. The recent holding in *GSK v. Teva* has posed a big threat to the existing generic pharmaceutical market in the U.S. Though the Hatch-Waxman Act

tried to create a meaningful balance between generic manufacturers and innovators, the scale seems imbalanced in the current scenario. In the current scenario, generic manufacturers can be held liable for infringement, regardless of their intentions—just for complying with FDA regulations.

Thus, such labeling regulations need more clarity to create a balance between innovation, availability, and affordability of life-sustaining products. Preserving the rights to intellectual property for novel treatment methods shouldn't hinder the entry of generic drugs into the market. The system should adhere to public policy and advance the goal of increasing the availability and affordability of medicines for all those who need them.