SKINNY LABELS AND SKINNIER PROSPECTS: HOW A RECENT FEDERAL CIRCUIT COURT DECISION ON PATENT INFRINGEMENT PLACES A WELL-ESTABLISHED GENERIC DRUG PRACTICE IN JEOPARDY

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ABSTRACT

The generic drug industry plays a critical role in ensuring that Americans can access necessary pharmaceuticals. Various laws, like the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch Waxman Act sought to simplify the complicated path to market for generic drug manufacturers. The Court of Appeals for the Federal Circuit's recent decision in *Glaxosmithkline LLC v. Teva Pharms. USA, Inc.* ("*GSK*"), which concerns the use "skinny-labels" to avoid patent infringement, may prove to be an additional hurdle for the generic drugs market. The ruling in GSK weakens the intent and causation requirements of induced infringement that had been established by the Federal Circuit. This Note provides a historical analysis of how the Hatch-Waxman Act simplified generic entry into the pharmaceuticals market as well as the history of induced infringement with a focus on skinny-labels. Moreover, this Note examines the potential impact of the GSK ruling on the generic drug industry as well as possible legislative remedies to address "skinny-label" induced infringement claims. Ultimately, this Author suggests several solutions for protecting the generic drug market in America such as legislative reform to the Patent act or agency-specific changes like a unified

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generic drugs approval process between the Food and Drug Administration and the Patent & Trademark Office.

INTRODUCTION

The Court of Appeals for the Federal Circuit's recent decision in *Glaxosmithkline LLC v. Teva Pharms. USA, Inc.*[1] ("*GSK*") once again demonstrates just how difficult it can be to successfully market generic drugs ("generics") in the United States. In *GSK*, the court held Teva liable for induced infringement of a method-of-use patent held by GSK for its heart failure drug Coreg (carvedilol).[2] Teva marketed its generic carvedilol using what is commonly referred to as a *skinny label*, intentionally "carving out" any patented use from its list of indications.[3] Nevertheless, by piecing together Teva's carvedilol press releases and various sections of the package insert, the court determined there was substantial evidence to support the jury's original finding of induced infringement.[4]

Although the court referred to its decision as a "narrow, case-specific" review,[5] the generic industry has reason to be concerned about the possible implications of the holding. This case weakens the intent and causation requirements of induced infringement that had been established by the Federal Circuit.[6] Manufacturers already face significant challenges in bringing generic drugs to market. Since the passage of the Drug Price Competition and Patent Term Restoration Act of 1984—also known as the Hatch-Waxman Act, which established a cheaper process for generics to obtain Food and Drug Administration ("FDA") approval[7]—brands have been employing strategies to prevent generic entry by abusing the Act itself and the U.S. Patent System.[8] The *GSK* decision could create another hurdle

1. 7 F.4th 1320 (Fed. Cir. 2021).
2. *Id.* at 1341.
3. *Id.*
4. *Id.* at 1335.
5. *Id.* at 1326.
6. *See, e.g.*, *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 631 (Fed. Cir. 2015); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1335 (Fed. Cir. 2016).
7. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, and 282).
8. *See* Kerstin Noëlle Vokinger et al., *Strategies That Delay Market Entry of Generic Drugs*, 177 No. 11 JAMA INTERNAL MED. 1665 (Nov. 2017); KEVIN T. RICHARDS ET AL., CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES (Feb. 11, 2020).

in generics' path to market safe, effective, and low-cost drugs that would save the United States government and consumers billions of dollars every year.[9] Further inhibiting generic entry could lead to a decrease in generic availability and an increase in prescription drug spending, which would have devastating effects on patients who simply cannot afford brand name drugs.

This Note examines the potential impact *GSK* could have on the generic drug industry and possible legislative remedies for addressing skinny-label induced infringement claims. Part I will discuss how the Hatch-Waxman Act made generic entry into the market easier as well as the history of induced infringement, particularly in the skinny-label context. Part II will analyze the *GSK* decision and the potentially devastating effects it could have on the generic market and national pharmaceutical drug spending, while proposing legislative and judicial remedies to negate *GSK*. Finally, the Conclusion reiterates the importance of protecting generic drug access in America.

I. HISTORY

A. Before the Hatch-Waxman Act

The Federal Food, Drug, and Cosmetic Act (the "FDCA"), enacted in 1938 and amended in 1962, gave the FDA authority to regulate the safety of food, drugs, medical devices, and cosmetics.[10] The FDCA required the FDA to approve all new drugs before they could be marketed for sale.[11] New Drug Applications ("NDAs") required, and still require today, data from human clinical trials, meeting certain research standards, that establishes the safety and efficacy of the new drug.[12] Prior to the Hatch-Waxman Act, this data was required of pioneer drugs and their generic counterparts. Because

9. ASS'N FOR ACCESSIBLE MEDICINES, 2020 GENERIC DRUG & BIOSIMILARS ACCESS & SAVINGS IN THE U.S. REPORT 16 (2020), https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf [https://perma.cc/P3BA-48FL]. In 2019 alone, generic drugs saved the US $313 billion dollars. *Id.*

10. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938); Kefauver Harris Amendments, Pub. L. No. 87-781, 76 Stat. 780 (1962).

11. 21 U.S.C. § 355.

12. *Id.*

this was costly, many companies did not have enough financial incentive to make seeking generic approval worth it.[13]

B. The Hatch-Waxman Act of 1984

The primary goal in passing the Hatch-Waxman Act ("Hatch-Waxman") was to encourage and incentivize brand innovation while simultaneously providing generic drugs with easier access to FDA approval and market entry.[14] To encourage innovation, Congress provided incentives to brand companies that developed pioneer drugs.[15] NDAs, which require extensive clinical trial data, became eligible for exclusivity periods of three or five years, during which the FDA cannot receive or approve any generic applications.[16] It also created a patent listing and certification procedure, whereby NDA holders submit all patents that claim the drug or method to the FDA.[17] The FDA publishes this information in its list of Approved Drug Products with Therapeutic Equivalents Evaluations (commonly known as the "Orange Book").[18] Eligible Orange Book patents include active ingredient, formulation and composition, method-of-use, and product by process patents.[19] For method-of-use patents, the holder must also include a *use code*, or a description of the patented uses.[20]

The Abbreviated New Drug Application ("ANDA") is a key feature of Hatch-Waxman. It provides an easier process for approval of generic drugs by permitting the FDA to rely on its determination of safety and efficacy of the brand name drug or reference licensed drug ("RLD").[21] ANDA allows the FDA to approve drugs with the same active ingredient, route of administration, and strength or concentration.[22] As a result, the generic company only has to submit studies showing the generic drug is

13. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011).
14. CONG. RSCH. SERV., R44643, THE HATCH-WAXMAN ACT: A PRIMER 1 (2016).
15. *Id.* at 8-9.
16. 21 U.S.C. §§ 355(b)(1)(A)(viii), (j)(7)(A)(i).
17. *Id.*
18. 21 U.S.C. § 355(j)(7)(A)(i).
19. 21 C.F.R. § 314.53(b) (2016).
20. 21 C.F.R. § 314.53(f)(1)(i)(B) (2016).
21. 21 U.S.C. § 355(j)(2)(A).
22. *Id.*

bioequivalent to the RLD.[23] ANDAs must also address the RLD's Orange Book patents by making one of four certifications:

1) a Paragraph I certification affirming that the RLD has no filed patent information;

2) a Paragraph II certification affirming that the listed patent has expired;

3) a Paragraph III certification affirming the proposed generic will not be marketed until the RLD patent expires; or

4) a Paragraph IV certification claiming the RLD patent is invalid or will not be infringed by the manufacture, use, or sale of the proposed generic.[24]

If the applicant makes a Paragraph IV certification, it must notify the RLD holder within forty-five days so that the patent holder can initiate litigation before approval of the ANDA, in which case approval is automatically stayed for thirty months to give time for resolution.[25]

However, Hatch-Waxman provides an alternative to making one of the above certifications: a Section viii statement—referring to section viii of 21 U.S.C. § 355(j)(2)(A)— that the proposed ANDA does not seek approval for the use covered in a method-of-use patent.[26] Section viii allows the ANDA to "carve out" from its drug label the use asserted by the RLD in the Orange Book use code.[27] Although the FDA usually requires that generics use the same label as the RLD, the regulations specifically allow for this "carve-out" practice which does not infringe on the RLD holder's patent.[28] The resulting generic label is often referred to as a *skinny label*.

In creating the Section viii certification, Congress ensured "that one patented use [would] not foreclose marketing a generic drug for other unpatented ones."[29] Carve-outs are important for bringing low-cost generic drugs to market. They prevent brands from "maintain[ing] de facto

23. *Id.*
24. *Id.* § 355(j)(2)(A)(vii).
25. *Id.* § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(f)(2) (2016).
26. *Id.* § 355(j)(2)(A)(viii). Section viii statements only apply in the context of method-of-use patents. *Id.*
27. 21 U.S.C. § 355(j)(2)(A)(vii).
28. 21 C.F.R. § 314.94(a)(8)(iv) (2016).
29. *Caraco Pharm. Lab'ys., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 415 (2012).

indefinite exclusivity over a pharmaceutical compound by obtaining serial patents for approved methods of using the compound . . . ."[30] Congress knew that carve-outs "would result in some off-label infringing uses."[31] This is because of the widespread and well-accepted practice of automatic generic substitution at pharmacies,[32] which many states actually require as a cost-saving measure.[33] Section viii "enable[s] the sale of drugs for non-patented uses" even if some off-label sales would naturally occur.[34]

C. Pharmaceutical Manipulation of the Patent System

Pharmaceutical drugs can be patented in a number of ways. First is the product patent,[35] which covers the chemical compound. A product patent offers the strongest protection for the drug because it covers all forms and uses of the active ingredient. A product patent will completely prevent generic entry during its twenty-year term. However, there are many more aspects of a drug that are eligible for patent protection, including methods of manufacture, methods of medical treatment, chemical intermediates, formulations, mechanisms of action, packaging, delivery profiles, screening methods, and biological targets.[36] These are referred to as secondary patents.[37] Many secondary pharmaceutical patents cover legitimate improvements to the drug that confer therapeutic benefit. However, the pharmaceutical industry has taken advantage of secondary patent availability through *evergreening*, which "refers to attempts by owners of pharmaceutical product patents to effectively extend the term of those patents on modified forms of the same drug, new delivery systems for the

30. *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012).

31. *Takeda Pharms. U.S.A., Inc.*, 785 F.3d at 631.

32. Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. LEGIS. 409, 500 n.2 (2016).

33. *Id.* at 500-01.

34. *Takeda Pharms. U.S.A., Inc.*, 785 F.3d at 631.

35. Product patents are also called "compound patents," "active ingredient patents," and "composition patents."

36. JOHN R. THOMAS, CONGRESSIONAL RESEARCH SERVICE, PATENT "EVERGREENING": ISSUES IN INNOVATION AND COMPETITION 3–4 (Nov. 13, 2009).

37. Some companies also acquire "tertiary patents," which use medical devices paired with an active ingredient that is or will soon be off patent to further prolong market exclusivity. Priti Krishtel, I-MAK, *The Basics of Drug Patents* (May 16, 2019), https://www.allhealthpolicy.org/wp-content/uploads/2019/05/Krishtel.Slides-AHP-DrugPatentWebinar-051619.pdf [https://perma.cc/T2MQ-FP6F].

drug, new uses of the drug, and the like."[38] Patents obtained for the purpose of evergreening are often weak, meaning they are unlikely to survive the scrutiny of litigation[39] or post-grant proceedings.[40] Of course, the U.S. Patent & Trademark Office ("PTO") is not granting these weak patents intentionally. Rather, several institutional flaws result in weak patents slipping through the cracks, including the PTO's reliance on fees, repeat applications, and time constraints on examiners.[41] Evergreening is only one example of the numerous strategies the pharmaceutical industry employs to circumvent regulation and prevent generic entry.[42]

38. Janice M. Mueller & Donald S. Chisum, *Enabling Patent Law's Inherent Anticipation Doctrine*, 45 HOUS. L. REV. 1101, 1106 (2008). Robin Feldman, director of the University of California Hastings Center for Innovation, examined all drug patents issued between 2005 and 2015 and found that 78% of the drugs associated with new patents were not new drugs. Allie Nawrat, *From Evergreening to Thicketing: Exploring the Manipulation of Pharma Patents*, PHARM. TECH. (Nov. 11, 2019), https://www.pharmaceutical-technology.com/features/pharma-patents-manpulation/ [https://perma.cc/Z7EP-BTKN].

39. James J. Anton et al., *Policy Implications of Weak Patent Rights*, 6 INNOVATION POL'Y AND THE ECONOMY 1, 1 (2006).

40. Third parties can challenge the validity of issued patents via post-grant proceedings that take place before the Patent Trial and Appeals Board. Inter Partes Disputes, America Invents Act, U.S. Patent & Trademark Office (last visited Jan. 28, 2022), https://www.uspto.gov/patents/laws/america-invents-act-aia/inter-partes-disputes [https://perma.cc/9RQ2-M57A].

41. MICHAEL D. FRAKES & MELISSA F. WASSERMAN, HAMILTON PROJECT, *DECREASING THE PATENT OFFICE'S INCENTIVES TO GRANT INVALID PATENTS* 5 (2017), https://www.hamiltonproject.org/assets/files/decreasing_patent_office_incentives_grant_invalid_patents.pdf [https://perma.cc/8LVB-2GF2]. The average examination time for a patent application is nineteen hours. *Id.* at 11.

42. Common strategies employed by pharmaceutical companies include uncompetitive payments to generic companies to delay entry (called "pay-for-delay") and releasing their own generic version of the drug (called an "authorized generic") which eliminates the financial incentive for outside generic companies to enter the market at all. For example, in 2003, generic manufacturer Apotex obtained a 180-day exclusivity period under the Hatch-Waxman Act for its generic version of Paxil, an anti-depressant drug originally developed and marketed by GSK. JOHN R. THOMAS, CONG. RSCH. SERV., AUTHORIZED GENERIC PHARMACEUTICALS: EFFECTS ON INNOVATION 7 (2010), https://crsreports.congress.gov/product/pdf/RL/RL33605 [https://perma.cc/Q27P-BQWN]. During Apotex's exclusivity period, GSK licensed another manufacturer to create an authorized generic version of Paxil. *Id.* Apotex had expected about $575 million in sales from its generic during the 180-day exclusivity period but realized less than half that amount, reporting sales between $150 and $200 million. *Id.* at 7–8. Attorneys for Apotex asserted "that the authorized generic crippled Apotex's 180-day exclusivity—it reduced Apotex's entitlement to about two-thirds—to the tune of approximately $400 million." *Id.* at 8 (quoting Tony Pugh, *Loophole May Dampen Generic-Drug Boom*, SAN JOSE MERCURY NEWS (May 3, 2006) at A1).

D. Induced Infringement

i. Intent

The Patent Act of 1952 codified the existing common law of inducement of patent infringement.[43] However, the section of the Act prohibiting induced infringement[44] does not specify an intent requirement.[45] This would lead to years of judicial interpretation regarding the elements of inducement.[46] In 1990, the Federal Circuit Court established that intent to cause, rather than knowledge of, actual infringement was a requirement for induced infringement liability.[47] Later that year, the court stated: "The plaintiff [in an inducement action] has the burden of showing that the alleged infringer's actions induced infringing acts *and* that he knew or should have known his actions would induce actual infringements."[48] Sixteen years later, the Federal Circuit combined these two precedents in *DSU Med. Corp. v. JMS Co.*, holding that "the inducer must have an affirmative intent to cause direct infringement."[49]

Still, ambiguities existed regarding the extent to which the plaintiff must show that the defendant knew a valid patent existed and that the induced acts infringed that patent.[50] The Federal Circuit attempted to answer these questions in *SEB S.A. v. Montgomery Ward & Co.*, where it held that "deliberate indifference of a known risk" of infringement was enough to satisfy the intent requirement.[51] However, the Supreme Court, despite

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

44. 35 U.S.C. § 271(b) (stating that "[w]hoever actively induces infringement of a patent shall be liable as an infringer").

45. *Hewlett-Packard*, 909 F.2d at 1469.

46. CONG. RSCH. SERV., INTENT STANDARD FOR INDUCED PATENT INFRINGEMENT: GLOBAL-TECH APPLIANCES, INC. V. SEB S.A. 1–3, (2011), https://www.everycrsreport.com/reports/R41976.html [https://perma.cc/6RSQ-UHV7].

47. *Id.*

48. *Manville Sales v. Paramount Sys.*, 917 F.2d 544, 553 (Fed. Cir. 1990) (emphasis in original).

49. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed Cir. 2006).

50. *Compare Kinetic Concepts, Inc. v. Blue Sky Med. Grp.*, Inc., 554 F.3d 1010, 1024-25 (Fed. Cir. 2009) (finding no specific intent to induce infringement where the defendant believed method was in public domain), *with AstraZeneca LP v. Apotex, Inc*., 633 F.3d 1042, 1061 (Fed. Cir. 2010) (finding specific intent to induce infringement where defendant drug manufacturer was aware label was potentially infringing and did not amend label to provide non-infringing instructions).

51. 594 F.3d 1360, 1376-77 (Fed. Cir. 2010), *aff'd sub nom. Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011).

affirming the judgment, held that the Federal Circuit erred in establishing a deliberate indifference test because it:

> [P]ermits a finding of knowledge when there is merely a 'known risk' that the induced acts are infringing [and], in demanding only 'deliberate indifference' to that risk . . . does not require active efforts by an inducer to avoid knowing about the infringing nature of the activities.[52]

The Court instead adopted a "willful blindness" standard and rejected the Federal Circuit's attempt to expand liability for induced infringement.[53]

The Federal Circuit has heard several *skinny label* induced infringement cases since Hatch-Waxman was passed. These cases generally conclude that for a generic to induce infringement with a skinny-labeled product, it "must encourage, recommend, or promote infringement" of the patented method for the intent requirement to be satisfied.[54] When the court has found inducement, the intent element was typically satisfied by the label, which instructed the user to perform the patented method.[55] In *AstraZeneca v. Apotex*, the defendant knew of the potential infringement problem but proceeded to market its generic product.[56] This conduct and the instructing label together, "not merely the planned distribution of the generic drug," supported the finding of intent to induce infringement.[57] In passing the

52. *Glob.-Tech Appliances, Inc.*, 563 U.S. at 770 (2011).

53. *Id.*

54. *Takeda Pharms. U.S.A., Inc.*, 785 F.3d at 631 (inducement claim failed where skinny-label mentioned but did not instruct the patented use); *accord Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003); *Allergan, Inc. v. Alcon Labs.*, 324 F.3d 1322, 1333-34 (Fed. Cir. 2003); *Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1339 (Fed. Cir. 2019); *see also Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1321, 1324 (Fed. Cir. 2012).

55. *See AstraZeneca LP v. Apotex Inc*., 633 F.3d 1042, 1060 (Fed. Cir. 2010); *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1369 (Fed. Cir. 2017) (noting that "the product labeling includes repeated instructions" that "are unambiguous on their face and encourage or recommend infringement").

56. *AstraZeneca*, 633 F.3d at 1060.

57. *Id.* However, in a copyright induced infringement case, the court stated:

> Evidence of active steps taken to encourage direct infringement such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe, and a showing that infringement was encouraged overcomes the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use.

Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 936 (2005) (citation and alterations omitted).

Hatch-Waxman Act, Congress intended to "enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses."[58] The Federal Circuit has stated that "[m]erely describing an infringing mode is not the same as recommending, encouraging, or promoting an infringing use, or suggesting that an infringing use 'should' be performed."[59] Thus, intent in *skinny label* cases has required more than the presence of information regarding an infringing use on the label.

ii. Causation

"Infringement, whether direct or contributory, is essentially a tort, and implies invasion of some right of the patentee."[60] Liability only follows when "the defendant's negligence has a substantial as distinguished from a merely negligible effect in bringing about the plaintiff's harm . . . ."[61] Thus, proof of causation is required for induced infringement liability, but very few courts have actually addressed the causation issue. In considering the type of evidence required to prove causation for induced infringement, the court in *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc*. stated:

> Indeed, we have affirmed induced infringement verdicts based on circumstantial evidence of inducement (e.g., advertisements, user manuals) directed to a class of direct infringers (e.g., customers, end users) without requiring hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material.[62]

Therefore, the standard for causation in induced infringement claims is not concrete, and the decision in *GSK* does little to clarify this issue.

58. *Takeda Pharms. U.S.A., Inc.*, 785 F.3d at 631.
59. *Id.* (citations omitted).
60. *Carbice Corp. of Am. v. Am. Pats. Dev. Corp.*, 283 U.S. 27, 33 (1931).
61. Restatement (Second) of Torts § 431 cmt. b (1965).
62. *Power Integrations, Inc.*, 843 F.3d at 1335 (Fed. Cir. 2016); *See also Ericsson, Inc. v. D-Link Sys.*, 773 F.3d 1201, 1220, 1222 (affirming jury's induced infringement verdict where defendant advertised compliance with an infringing standard); *Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1377 (Fed. Cir. 2005) (affirming jury's induced infringement verdict where defendant distributed "sales literature" and "manuals" that instructed how to use product in infringing manner).

E. GSK v. Teva Facts and Procedural History

GSK developed the beta-blocker drug carvedilol, which it sells under the brand name Coreg®. Carvedilol has been approved by the FDA for three indications of use: hypertension, congestive heart failure ("CHF"), and left ventricular dysfunction following a myocardial infarction ("post-MI LVD").[63] GSK patented the carvedilol compound in 1985 - U.S. Patent No. 4,503,067 ("the '067 patent"), expiring on March 5, 2007.[64] In 1998, U.S. Patent No. 5,760,069 ("the '069 patent")—reissued with minor changes in 2008 as Reissue Patent No. RE40,000 ("the '000 patent")— was issued, which claimed a method of administering a combination of carvedilol and another therapeutic agent to decrease mortality caused by CHF in a patient.[65]

In March 2002, Teva filed an ANDA for FDA approval of its generic carvedilol.[66] It certified under Paragraph III of the Hatch-Waxman Act that it would not launch its product until the '067 patent expired in 2007.[67] Teva also certified under Paragraph IV that the '069 patent was "invalid, unenforceable, or not infringed."[68] Teva then sent GSK a Paragraph IV notice, stating that the claims of the '069 patent were anticipated and/or obvious.[69] GSK did not initiate litigation, and instead filed for reissue of the '069 patent shortly thereafter in 2003.[70] In 2004, Teva received tentative approval of its ANDA "for treatment of heart failure and hypertension," to become effective upon expiration of the '067 patent in 2007.[71]

Just before Teva launched its generic product in 2007, it certified under Section viii of the Hatch-Waxman Act that its label would not include the patented indication defined in use code U-233, which corresponds to "decreasing mortality caused by congestive heart failure," until the

63. *GlaxoSmithKline LLC*, 7 F.4th at 1323 (Fed. Cir. 2021).
64. U.S. Patent No. 4,503,067 (filed Apr. 4, 1983) (issued Mar. 5, 1985).
65. U.S. Patent No. 5,760,069 (filed Jun. 7, 1998) (issued Jun. 2, 1998); U.S. Patent No. RE40,000 (filed Nov. 25, 2003) (issued Jan. 8, 2008).
66. *GlaxoSmithKline*, 7 F.4th at 1323.
67. *Id.*
68. *Id.*
69. *Id.* at 1324.
70. *Id.*
71. *Id.*

expiration of the '069 patent.[72] The label thus included two indications: post-MI LVD and hypertension.[73]

GSK sued Teva in the United States District Court for the District of Delaware for induced infringement of the '000 patent.[74] GSK argued that Teva had caused prescribers to infringe through its marketing statements, data included in the carvedilol package insert, and product manuals.[75] In response, Teva argued that it could not have induced infringement because it had "carved out" the CHF indication from its label under Section viii.[76] Teva also argued that it could not be liable for induced infringement because it did not cause prescribers to infringe the patent.[77] The jury found for GSK and awarded damages for induced infringement, but the District Court granted Teva's renewed motion for judgment as a matter of law ("JMOL"), finding that the verdict was not supported by substantial evidence because GSK failed to prove causation.[78] GSK appealed, and a Federal Circuit panel reversed the district court's grant of JMOL and reinstated the jury verdict.[79] Teva petitioned for rehearing, which the court granted.[80]

The panel issued a *per curiam* opinion, vacating the district court's grant of JMOL and reinstating the jury's verdict and award of damages.[81] The opinion first reviewed all the evidence that could support the jury's

72. *Id.*
73. *Id.*
74. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582 (D. Del. 2018).
75. *GlaxoSmithKline*, 7 F.4th at 1334-35. Teva's press releases and marketing materials advertised its generic carvedilol as "indicated for treatment of heart failure and hypertension," as the "[g]eneric version of [GSK's] cardiovascular agent Coreg®," and as an "AB-rated generic equivalent of [GSK's] Coreg® Tablets." *Id.* at 1324. GSK's cardiology expert testified that the description of the post-MI LVD indication on Teva's label was similar enough to the CHF indication that it satisfied the CHF limitation of the '000 patent. *Id.* at 1328. The expert also testified that "the Dosage and Administration section of the partial label disclosed administering particular dosages that satisfied the 'administering a therapeutically acceptable amount of carvedilol' and administering "daily maintenance dosages" limitations." *Id. "*The post-MI LVD indication on Teva's label explicitly directs the reader to Clinical Studies § 14.1, which showed that patients taking carvedilol in the study had background treatment of ACE inhibitors and diuretics, satisfying the limitation of administering carvedilol in combination with another therapeutic agent." *Id.* The court held the jury could have reasonably found infringement based on the above evidence. *Id.* at 1341.
76. *Id.* at 1325.
77. *Id.*
78. *GlaxoSmithKline*, 313 F. Supp.3d at 597.
79. *GlaxoSmithKline LLC v. Teva Pharm. USA Inc.*, 976 F.3d 1347, 1348 (Fed. Cir. 2020).
80. *GlaxoSmithKline*, 7 F.4th at 1326.
81. *Id.* at 1341.

verdict for GSK.[82] Teva's label and package insert contained the post-MI LVD indication as well as efficacy data, which GSK's cardiology expert testified met the limitations of the '000 patent claim. The Court held this constituted substantial evidence that could prove Teva did not successfully "carve out" the CHF indication from its label and encouraged the infringing use.[83] Additionally, the court determined that Teva's press releases and marketing materials indicating carvedilol's AB-rating could support the jury's finding of induced infringement.[84] Finally, one press release stated that the generic was indicated for heart failure and the other referred to carvedilol as a "cardiovascular agent."[85] Although the press releases were published before the asserted patent issued, the releases remained accessible on Teva's website until 2015 and thus could be used to support the jury verdict.[86]

Importantly, the Court rejected Teva's argument that GSK failed to prove that Teva's actions actually caused doctors to infringe the '000 patent.[87] The Court believed the jury was properly instructed on causation and its finding could reasonably be supported by the label and press release evidence, even though such evidence was circumstantial.[88]

Judge Prost dissented, stating:

> [T]he majority further weakens the intentional-encouragement prong of inducement by effectively eliminating the demarcation between describing an infringing use and encouraging that use in a label. Second, the majority defies basic tort law by eviscerating the causation prong of inducement . . . Third, the majority creates confusion for generics, leaving them in the dark about what might expose them to liability.[89]

82. The opinion distinguishes between two different time-periods of alleged infringement: the "partial label period" and the "full label period." *Id.* at 1325. The distinction is not relevant for the purposes of this Note.

83. *Id.* at 1328–29.

84. *Id.* at 1333. However, the majority noted that it was not concluding "that an AB rating in a true [S]ection viii carve-out . . . would be evidence of inducement." *Id.* at n.7.

85. *Id.* at 1336.

86. *Id.* at 1337.

87. *Id.* at 1339.

88. *Id.* at 1340.

89. *Id.* at 1343 (Prost, J., dissenting).

Judge Prost also criticized the majority's decision for subjecting Teva to liability for inducement based on "thin to nonexistent" evidence, even though it "played by the rules" and carried out the Section viii "carve out" as Congress intended.[90]

II. ANALYSIS/PROPOSAL

The Federal Circuit's decision in *GSK* frustrates the purpose of the Hatch-Waxman Act, and in doing so, could have a devastating effect on the generic pharmaceutical industry. Section viii is at risk of becoming obsolete; the Court penalized Teva despite complete compliance with Section viii and other FDA requirements and eviscerated the causation requirement for induced infringement. Previously certified Section viii generics could face litigation based on this decision, and future generics may delay entry under Section viii. Legislative action will likely be necessary to prevent the damage this decision could cause. Reform directed toward Orange Book maintenance, PTO examination procedures, and the induced infringement statute could mitigate the risks posed by GSK and improve the pharmaceutical patent system as a whole.

A. Section viii in Jeopardy

The Federal Circuit's holding in *GSK* places the Section viii carve-out provision in jeopardy because the evidence used to prove inducement can be found in almost any skinny-label case.

Teva's generic carvedilol received an AB rating[91] from the FDA, which indicates that the generic is proven to be therapeutically equivalent (bioequivalent and pharmaceutically equivalent for the same use) to the RLD.[92] As noted above, ANDAs must submit data proving therapeutic

90. *Id.* at 1342 ("With reasoning sometimes labored, sometimes opaque, the majority strains to prop up a jury verdict that is unsupportable").

91. An AB rating is a therapeutic equivalence code assigned to drugs in the orange book by the FDA. Orange Book Preface § 1.7, Approved Drug Products with Therapeutic Equivalence Evaluations, FDA (42d ed. 2022), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface [https://perma.cc/C7LP-XHLK]. The "A" indicates that the drug is therapeutically equivalent to other pharmaceutically equivalent drugs. *Id.* The "B" indicates that "actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence." *Id.*

92. Kendra Stewart, *From Our Perspective: The Orange Book at 40: A Valued FDA Resource*

equivalence in order to rely on the RLD's clinical trial data for approval.[93] Every approved generic that makes a Section viii certification in its ANDA will be AB-rated. By allowing the jury to consider Teva's statement of its product's AB rating in determining inducement, the Court clearly ignored precedent and directly defied the intent behind Hatch-Waxman. In *Takeda*, the Court stated that "[i]nfringement only exists where there is evidence that goes beyond a product's characteristics or the knowledge that it may be put to infringing uses."[94] An AB rating is merely a characteristic of Teva's generic carvedilol, and thus should not be used to support a finding of inducement. Additionally, one of the primary goals of Hatch-Waxman was to create a system for approving drugs that are therapeutically equivalent to RLDs without infringing the RLD holder's patent(s). The FDA's AB label is part of that system, so to use that label to prove inducement is counterintuitive. The FDA even publicizes its AB ratings,[95] which the court would surely not consider to be inducement.

The court found that the data on the *skinny label*, indicating carvedilol's success in patients also being treated with an angiotensin converting enzyme inhibitor (ACE), a diuretic, and/or digoxin could support a finding of induced infringement.[96] This data was submitted to the FDA by GSK in seeking approval of carvedilol for the CH indication. The data reflects GSK's method claim in the '000 patent, which requires using carvedilol in combination with one of the above drugs.[97] The ANDA was created to allow generics to rely on RLD data for FDA approval.[98] This process makes generic entry economically feasible because generic companies need not conduct costly clinical trials for a compound that has already been FDA approved. Therefore, when a generic company decides to include data on its label or in its package insert,[99] it will necessarily have to choose from data provided by the RLD holder. That GSK's submitted data reflected a

Continually Enhanced by User Input, U.S. FOOD & DRUG ADMIN. (Oct. 26, 2020), https://www.fda.gov/drugs/news-events-human-drugs/our-perspective-orange-book-40-valued-fda-resource-continually-enhanced-user-input [https://perma.cc/VTH6-ZFEG].

93. *See supra* text accompanying notes 20–21.

94. *Takeda Pharms. U.S.A., Inc.*, 785 F.3d at 639 (citation omitted).

95. Petition for Rehearing En Banc at 13, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582 (D. Del. 2018) (No. 18-1976).

96. *GlaxoSmithKline LLC* , 7 F.4th at 1328 (Fed. Cir. 2021).

97. U.S. Patent No. RE40,000 (filed Nov. 25, 2003) (issued Jan. 8, 2008).

98. CONG. RSCH. SERV., R44643, THE HATCH-WAXMAN ACT: A PRIMER 1 (2016).

99. The content of package inserts is regulated by the FDA in 21 C.F.R. § 201.56–57 (2014).

patented use for carvedilol is not a surprise. A pharmaceutical method patent is useless without FDA approval. To penalize a generic company for using data that the Hatch-Waxman Act expressly permits it to use frustrates the purpose of the ANDA. Even if Teva could have chosen other data or simply omitted it, providing efficacy data in a fine print package insert cannot be reasonably assumed to "encourage, recommend, or promote infringement."[100]

Third, Teva relied on GSK's submission to the FDA of the active patents that covered carvedilol. Although, the FDA maintains that ANDA filers should do their own patent search to determine any infringement issues,[101] it is common practice to assume the RLD made truthful and accurate certifications to the FDA regarding relevant patents since they make such certifications under penalty of perjury.[102] By 2003, the FDA had approved carvedilol for three separate uses: hypertension, CHF, and post-MI LVD.[103] It certified that only one of those three uses, CHF, was actively covered by a patent (originally the '069 patent and later the '000 patent) at the time of Teva's launch in 2007.[104] Teva was always aware of the '069 method-of-use patent for CHF, and initially made a Paragraph IV certification that the patent was invalid and therefore could not be infringed.[105] Upon notice of Teva's certification, GSK chose not to litigate, sending a strong message that it also doubted the patent's validity.[106] Regardless, Teva later switched to a Section viii certification based on the three uses identified by GSK. Teva followed the FDA's guidance and

100. *Takeda Pharms. U.S.A., Inc.*, 785 F.3d at 631. After the first *GSK* panel decision, several amici were submitted asserting the same. *See, e.g.*, Brief of Amicus Curiae Former Congressman Henry A. Waxman in Support of Petition for Rehearing En Banc [Corrected] at 11, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582 (D. Del. 2018) (No. 18-1976); Corrected Brief of Amici Curiae Fifty-Seven Law, Econ., Health, and Med. Professors in Support of Cross-Appellant's Petition for Rehearing En Banc at 12–14, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582 (D. Del. 2018) (No. 18-1976); Brief of Amici Curiae Novartis Pharms. Corp. and Sandoz Inc. in Support of Rehearing En Banc at 5, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582 (D. Del. 2018) (No. 18-1976).

101. FDA Response to Comment 7 From Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003), https://www.federalregister.gov/documents/2003/06/18/03-15065/applications-for-fda-approval-to-market-a-new-drug-patent-submission-and-listing-requirements-and [https://perma.cc/9Z6A-FDSN].

102. *GlaxoSmithKline LLC*, 7 F.4th at 1332 (Fed. Cir. 2021).

103. *Id.* at 1323.

104. *Id.* at 1331.

105. *Id.* at 1323–24.

106. *Id.* at 1324.

intentionally carved out the CHF indication, the only use GSK identified as patented at the time.[107] The Court faulted Teva for relying on GSK's certifications of patented use and following the FDA's instructions on how to effectively "carve out" the CHF indication from its label. Essentially, Teva did everything right. It specifically intended to *not* infringe GSK's patent by making the Section viii certification and using the skinny label, but the Court held that the jury could have reasonably found that the post-MI LVD indication was similar enough to the CHF indication as to intentionally induce infringement of the '000 patent.[108] Finding intent to induce when a Section viii certification inherently proves an intent *not* to induce is simply illogical. Most generics rely on the Orange Book and FDA guidance to create skinny labels. If following all relevant laws and regulations can still lead to inducement liability, Section viii is essentially nullified.

B. Generic Availability at Risk

The *GSK* decision will affect generics currently on the market[109] as well as any future generics that could use Section viii to enter the market before a method-of-use patent expires. Section viii generics currently on the market that still have active method-of-use patents for carved-out indications are now at risk for inducement litigation, which is a lengthy, expensive process that can far exceed any profit made on the generic drug. As discussed above, the evidence used to hold Teva liable can be found in almost every skinny-label case, so even generics that followed FDA guidance and legally carved out patented uses could be found liable for inducement. If brands begin

107. *Id.*

108. *Id.* at 1329.

109. A recent case from the Delaware District Court exemplifies the litigation risk posed by *GSK*. In *Amarin Pharma v. Hikma Pharms.*, Amarin sued Hikma for induced infringement using the same arguments asserted in *GSK*. 578 F. Supp. 3d 642 (D. Del. Jan. 4, 2022). Hikma marketed a generic version of Amarin's Vascepa after making a Section viii certification to the FDA that its label would not include Amarin's patented use. *Id.* at 644. Like Teva, Hikma carved out the patented use and referred to its product as the generic equivalent to the RLD in press releases. *Id.* at 646–47. Amarin argued information on Hikma's label taught the patented use and that the press releases (as well as information on Hikma's website stating the product was an AB equivalent) encouraged infringement. *Id.* at 647. The district court cited *GSK* as relevant precedent, but ultimately found "that Amarin's complaint has failed to plead inducement based on Hikma's label or public statements." *Id.* at 647–48. That this case was dismissed is encouraging, but it doesn't negate the fact that Amarin initiated litigation against a generic using the winning arguments from *GSK*.

threatening litigation under *GSK*'s precedent, generics may choose to remove the product from the market rather than risk further infringement if found liable. Even if the generic stays on the market throughout litigation, a finding of liability would force the generic out until the relevant method-of-use patent expires.

Future use of Section viii by generics will undoubtedly be chilled by the decision in this case. *GSK* made it clear that following the rules is no safe harbor. Because generics are sold at a significantly reduced price compared to their branded counterparts, the profits gained are not as significant.[110] Generics may determine that the risk of litigation is too great to justify market entry. Here, Teva only sold $74 million of its generic carvedilol, but was found liable for $235 million in damages, resulting in a net loss of approximately $161 million.[111]

C. Proposal

GSK demonstrates larger flaws in the U.S. Patent System. For years experts have been proposing various legislative solutions to these problems, but the U.S. has yet to adopt even one.[112] The courts have slowly been

110. NEERAJ SOOD ET AL., USC LEONARD D. SCHAEFFER CTR. FOR HEALTH POL'Y & ECONS., THE FLOW OF MONEY THROUGH THE PHARMACEUTICAL DISTRIBUTION SYSTEM (2017), https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC_Flow-of-MoneyWhitePaper_Final_Spreads.pdf [https://perma.cc/7HNR-4NBX].

111. *GlaxoSmithKline*, 7 F.4th at 1340; *GSK v. Teva – Induced Infringement Liability Despite Skinny Label*, COOLEY MEDIA & INSIGHT (Oct. 6, 2020), https://www.cooley.com/news/insight/2020/2020-10-06-gsk-v-teva-induced-infringement-liability-despite-skinny-label [https://perma.cc/7MBT-U8YE].

112. Many commentators have suggested implementing a federal reward program to completely replace pharmaceutical patents. *See, e.g.*, Kelley Chandler, Note, *Patents and the Pharmaceutical Industry: Curbing the Abusive Practices Employed by Blockbuster Drug Companies to Prolong Market Exclusivity*, 29 CORNELL J. L. & PUB. POL'Y 467, 481–82 (2019). In an effort to prevent evergreening, India amended its patent statute as follows:

> The following are not inventions within the meaning of this Act:
>
> [T]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be same substance, unless they differ

reprimanding brands for their anticompetitive tactics, but when one method is prohibited, they find another.[113] Thus, litigation is not the ideal route for reform. With a divided Congress, the sweeping legislative action that would be necessary to reform our pharmaceutical industry is unlikely, so we are left to making small, incremental changes to maintain generic access. I will propose several incremental solutions to eliminate the uncertainty caused by the Federal Circuit's decision.

I will preface this discussion by stating that Teva has petitioned the Supreme Court to grant certiorari,[114] so the decision is subject to change. Additionally, the Biden Administration has stated that it was "committed to taking steps" to protect "skinny labeling."[115] Therefore, judicial and/or legislative action regarding the *GSK* decision is likely in the near future.

The Orange Book could potentially be the subject of meaningful reform. Currently, the FDA alone creates and maintains the Orange Book, but if the FDA and PTO were both responsible for maintaining an accurate Orange Book, the decision in *GSK* likely could have been avoided. One of the main issues in GSK was whether the post-MI LVD indication was encompassed by GSK's CHF method patent. Coordination between the FDA and PTO could have prevented this confusion. The PTO would be able to indicate to the FDA which uses were covered by patents, eliminating the need to rely on the RLD holder's certification.

PTO reform could also help to curb the practice of brands obtaining hundreds of weak patents on a single compound.[116] GSK acquired the '069

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significantly in properties with regard to efficacy.

The Patents (Amendment) Act, 2005, § 3(d) 2005 (India).

For in-depth discussions of possible solutions to other bad-faith strategies used by pharmaceutical companies to delay generic entry and prolong monopoly, *see, e.g.*, Hanna M. Lasting, Note, *Big Pharma, Big Problems: COVID-19 Heightens Patent-Antitrust Tension Caused by Reverse Payments*, 44 SEATTLE U. L. REV. 591 (2021); Brittany Day, Note, *A Modest Proposal: Leveraging Private Enforcement Mechanisms and the Bayh-Dole Act to Reduce Drug Prices in the U.S. Healthcare Industry*, 17 DUKE J. CONST. L. & PUB. POL'Y SIDEBAR 51 (2021).

113. *See* Rongxiang Liu, *Pharma's Strategies on Fighting Generics and Healthcare Reform*, 3 BIOTECH.& PHARM. L. REV. 26, 36–60 (2010).

114. Petition for Writ of Certiorari, *GlaxoSmithKline*, 7 F.4th 1320 (Nos. 2018-1976, 2018-2023).

115. XAVIER BECERRA, U.S DEPARTMENT OF HEALTH & HUMAN SERVICES, COMPREHENSIVE PLAN FOR ADDRESSING HIGH DRUG PRICES: A REPORT IN RESPONSE TO THE EXECUTIVE ORDER ON COMPETITION IN THE AMERICAN ECONOMY 21 (2021).

116. In 2017, the top twelve brand drugs on the market were protected by a total of 848 patents (71 per drug) providing an average of 38 years without generic competition. I-MAK, OVERPATENTED, OVERPRICED: HOW EXCESSIVE PHARMACEUTICAL PATENTING IS EXTENDING MONOPOLIES AND DRIVING UP DRUG PRICES 2 (2018), http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-

patent more than ten years after the compound patent for carvedilol was issued,[117] which strongly indicates the patent was acquired for the purpose of evergreening. When Teva sent a Paragraph IV notice to GSK, asserting that the '069 patent was anticipated and obvious, GSK chose not to sue Teva and instead filed a reissue patent.[118] GSK's actions indicate that it likely knew the '069 patent was weak. Because litigation is expensive, weak patents such as this are not challenged in court, and their owners are afforded an undeserved monopoly.

In their policy proposal aimed at reducing the number of invalid patents issued by the PTO, Frakes and Wasserman propose changes to address systemic problems at the PTO that contribute to weak patents being issued.[119] Adjusting the PTO's fee structure, limiting repeat applications, and increasing examiner time allocations would all allow patents to be examined more closely before issuance, decreasing the number of weak patents granted.

The next solution that could potentially remedy the harm caused by *GSK* is an amendment to 35 U.S.C. § 271(b), the induced infringement provision of the Patent Act. The amendment would state that FDA-approved Section viii skinny labels cannot be used as evidence of indirect infringement. This would ensure that generics who follow FDA guidance are not liable for inducement for legally marketing a skinny-labeled product. Of course, if the label did not conform to the FDA's requirements or the generic instructed or encouraged infringement through other means, it would not fall under this safe harbor. For such an amendment to operate as intended, the FDA may need to issue additional regulations that clearly define Section viii requirements and allow the FDA to give final approval of skinny labels and package inserts. This would ensure generics don't attempt to hide inducing content elsewhere on the label or insert.

Overpatented-Overpriced-Report.pdf [https://perma.cc/WW2S-D26U]. A prime example of over-patenting is Humira, the world's number one selling drug marketed by AbbVie. *Id.* at 3. As of 2017, the company had filed a staggering 247 patent applications for the drug. *Id.*

117. *GlaxoSmithKline LLC*, 7 F.4th at 1323 (Fed. Cir. 2021).

118. *Id.* at 1324.

119. FRAKES & WASSERMAN, *supra* note 39, at 13.

CONCLUSION

Despite the unfortunate reality that significant reform of the U.S. Patent System is unlikely, there are many small, but not insignificant, changes that can be implemented to maintain generic access to the pharmaceutical market. Changes within the FDA and PTO could unify the generic approval process and decrease the number of weak patents issued on therapeutically useless aspects of branded drugs. An amendment to the Patent Act could also protect Section viii generics who follow FDA guidelines from suffering a fate similar to Teva. Additionally, it is likely the Federal Circuit will grant Teva's request for rehearing *en banc*, increasing the likelihood of a second chance to convince the Court that a holding for GSK could be devastating to the generic industry.

Ultimately, generics' ability to enter the market quickly and easily is important because Americans rely on cheap, effective generic drugs every day. For many patients, the cost of brand drugs is prohibitive. If generics leave the market and/or delay market entry based on *GSK*, patients could lose access to life-saving medications. Access to generic drugs not only benefits individual patients, but it also benefits the federal government, which spends billions of dollars every year on prescription drugs for beneficiaries of Medicare and Medicaid.[120] Beyond the superficial need to foster competition in the pharmaceutical industry, this is fundamentally an issue of the health and well-being of our citizens. As a nation, we need to protect generics, but the *GSK* decision does the opposite. If the decision is not reversed on appeal, legislative action will be necessary to maintain access to cost-effective generic medicines.

120. *NHE Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 15, 2021), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet [https://perma.cc/3CKU-YLKV]. In 2020 alone, the federal government spent $348.4 billion on prescription drugs for programs such as Medicare and Medicaid. *Id.*