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THE FUTURE OF HEALTHCARE: *GLAXOSMITHKLINE v. TEVA*'S EFFECT ON MODERN-DAY PHARMACEUTICALS AS WE KNOW THEM

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ABSTRACT

Generic drugs have become a cornerstone of the modern healthcare system. Offered at a more affordable price to the consuming public, they have reached their goal of bringing necessary pharmaceuticals into the homes of millions of Americans. However, the majority decision in *GlaxoSmithKline v. Teva* may have put a wrench in this mission, leaving generic drug manufacturers in the dark, facing inevitable infringement suits from brand name manufacturers for merely following standard labeling schemes. Generic manufacturers have managed to avoid patent infringement through the use of a “skinny labels.” However, the majority panel in *GlaxoSmithKline* held that Teva’s generic label was not a true skinny label, and indirectly infringed GSK’s patent for its brand name cardiovascular agent, Coreg®. This note explores indirect patent infringement, and the majority’s shaky reasoning for finding infringement by Teva. It also looks to several amicus briefs, with diverse perspectives on their support of Teva, for guidance as to the ramifications that this decision has on the future of drug manufacturing and the U.S. healthcare system.



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I. INTRODUCTION

In *GlaxoSmithKline v. Teva*,¹ the Federal Circuit upheld a jury verdict that Teva Pharmaceuticals (“Teva”) induced infringement of a method patent held by GlaxoSmithKline LLC (“GSK”). The panel further held that a manufacturer’s promotion of the generic version of a brand name drug could infringe the patent which covered the brand name drug, where the generic drug manufacturer knows its drug will be substituted for the brand name drug.²

The panel majority decided *GlaxoSmithKline* in an effort to protect a prior jury verdict which was founded on thin evidence, but in doing so lowered the threshold necessary to find patent infringement. This decision has left generic drug manufacturers in the dark, unsure of how to comply with drug regulations, and ultimately leaving them exposed to significant liability, while drastically impacting the U.S. healthcare system.

Part II (“Background”) will provide background information on patent law and the generic drug patent process. Part III (“The Case”) will explain the details of *GlaxoSmithKline*, including the relevant facts, procedural history, analysis, and the majority holding, as well as a dissenting opinion by Judge Prost. Part IV (“Analysis”) will discuss the various issues with the majority’s holding regarding generic drug manufacturing in the future, the public pushback received through amicus briefs, and the decision’s impact on consumers. Finally, Part V (“Conclusion”) will expand on the expected consequences to the healthcare industry and their significance.

II. BACKGROUND

A. Patent Purpose & History

A patent is a form of intangible personal property granted by the government for the purpose of serving the public interest of promoting the progress of science and the

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¹ See generally *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021).

² *Id.* at 1330.

useful arts.³ Abraham Lincoln optimistically described that the system of patents “added the fuel of interest to the fire of genius.”⁴

However, the Supreme Court has explained that patent laws “embod[y] a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation [in an effort to avoid monopolies] are both necessary to invention itself and the very lifeblood of a competitive economy.”⁵ When a patent is granted, it confers upon the owner the right to exclude others from making, using, or selling their invention throughout the U.S for the duration of twenty years from the date of filing. Utility patents are granted to protect new, nonobvious, and useful products, processes, machines, and devices.⁶

The first federal patent law statute was enacted by Congress in 1790.⁷ The current governing rules for patentability are codified in Title 35 of the United States Code (U.S.C.)⁸ and can also be found in Title 37 of the Code of Federal Regulations (C.F.R.).⁹ Subsequently, the United States Patent and Trademark Office (“USPTO”) published the Manual of Patent Examining Procedure (MPEP), which provides detailed information about the filing and examination of a patent application, but does not have the force or effect of law.¹⁰

Inventors who are looking to patent their product or process will file an application with the USPTO. A standard application is a nonprovisional patent application, which is examined and, if it meets the legal requirements, is issued by the USPTO as a US utility patent.¹¹ The application must include (1) a specification, (2) a drawing, if necessary to understand the invention, (3) an inventor oath or declaration, and (4) the filing fee.¹² The specification must conclude with “one or more claims particularly pointing out and distinctly claiming the subject matter.”¹³ An Examining Attorney will analyze the application, in conjunction with a prior art search,¹⁴ and ideally, will administer the patent to the inventor.

³ U.S. CONST. art. I, § 8, cl. 8 (known as the Patent Clause); *see Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1373-74 (2018).

⁴ Jeffrey M. Samuels & Linda B. Samuels, *Lincoln and the Patent System: Inventor, Lawyer, Orator, President*, 3 ALB. GOV'T L. REV. 645, 675 (2010). This quote is from a speech given by Abraham Lincoln. “THE PATENT SYSTEM ADDED THE FUEL OF INTEREST TO THE FIRE OF GENIUS - LINCOLN” is carved above the entrance Herbert C. Hoover building that houses the U.S. Department of Commerce, in Washington D.C., which used to house the USPTO.

⁵ *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

⁶ 35 U.S.C. §§ 154(a)(2), 271(a) (2022). Utility patents filed on or after June 8, 1995, are protected from the issue date until 20 years from the filing date of the earliest nonprovisional US patent application to which the patent claims domestic benefit. Utility patents filed before June 8, 1995, are protected from the issue date until the later of either 17 years from the issue date or 20 years from the filing date of the earliest benefit date; 35 U.S.C. § 101 (2022) (“[N]ew and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”).

⁷ Patent Act of 1790, Ch. 7, 1 Stat. 109.

⁸ *See generally* 35 U.S.C. (2022).

⁹ *See generally* 37 C.F.R. (2022).

¹⁰ *See* USPTO, Manual of Patent Examining Procedure, (9th ed. 2020), <https://mpep.uspto.gov/RDMS/MPEP/current#/current/d0e312906.html>.

¹¹ 35 U.S.C. § 135 (2022).

¹² *Id.* at § 111(a).

¹³ *Id.* at § 112(b).

¹⁴ *See* 35 U.S.C. § 102 (2022) (A prior art search must be made by the inventor, which includes ensuring the claimed invention is not already “patented, described in a printed publication, or in

After a patent expires, the invention enters the public domain, and the public is free to make or use the invention without compensating the inventor.¹⁵

B. Patent Protections in General

Patent infringement is a civil claim that may be brought by a patent owner against another party who the patent holder asserts is using the patented invention without the owner's authorization.¹⁶ Section 271 of the Patent Act (35 U.S.C.) is the statutory provision on patent infringement, which distinguishes between direct and indirect infringement.¹⁷

1. Direct v. Indirect Infringement

Direct infringement is the unauthorized “making, using, selling, offering to sell, or importing” of the *entire* claimed invention.¹⁸ Direct infringement is a strict liability offense, and can occur either where a single entity itself infringes, or the infringement can be attributed to the entity because the “entity directs or controls the actor’s performance” or the “actors form a joint enterprise.”¹⁹

Indirect infringement involves activities that are less than a use of the entire invention, but are nonetheless considered infringement because they assist or support or induces another party to engage in direct infringement.²⁰ There can be no indirect infringement or inducement in the absence of direct infringement.²¹ A finding of inducement is established by showing “that the defendant possessed specific intent to encourage another's infringement” which “requires a plaintiff to show that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements.”²² Further, a defendant's good-faith belief that an asserted patent is invalid is not a defense to inducement.²³ In *Prouty v.*

public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.”).

¹⁵ KINNEY & LANGE, P.A., INTELL. PROP. L. FOR BUS. LAWYERS § 2.29 (2022 ed.).

¹⁶ See 35 U.S.C. § 271 (2022).

¹⁷ *Id.*

¹⁸ *Id.* at § 271(a).

¹⁹ *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015); see 35 U.S.C. § 271(a) (2022).

²⁰ 35 U.S.C. § 271(b) (2022).

²¹ *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921 (2014) (“Liability for inducement must be predicated on direct infringement”); see *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1277 (Fed. Cir. 2004) (quoting *Met-Coil Sys. Corp. v. Korner's Unlimited, Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986)) (“[A]bsent direct infringement of the claims of a patent, there can be neither contributory infringement nor inducement of infringement”); see also *Micro Chem., Inc. v. Great Plains Chem. Co.*, 103 F.3d 1538, 1549 (Fed. Cir. 1997).

²² *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006); see *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990); see also *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1468–69 (Fed. Cir. 1990).

²³ See *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1928 (2015).

Ruggles, (1842), the Court held that a defendant did not infringe if he used fewer than all the elements of the combination of specifications listed in the patent application.²⁴

In the U.S., federal district courts have exclusive jurisdiction over patent infringement claims.²⁵ The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) has exclusive jurisdiction to hear appeals of USPTO decisions concerning the patentability of a pending application or issued patents, and the U.S. Supreme Court has jurisdiction to review Federal Circuit decisions.²⁶

C. Generic Drug Infringement of a Brand Name Drug Patent

1. Indirect Infringement

The success of the pharmaceutical industry can be attributed to the trade-off between innovation and economic competition.²⁷ In the pharmaceuticals space, patent infringement most commonly occurs through inducement or indirect infringement.²⁸ In *Grokster*, the Supreme Court held, in the analogous context of copyright infringement, that

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.²⁹

This holding means that if “the proposed label instructs users to perform the patented method [...] the proposed label may provide evidence of . . . affirmative intent to induce infringement.”³⁰ So, when a plaintiff (infringer) relies on a drug's label

²⁴ 5 DONALD S. CHISUM, CHISUM ON PATENTS § 17.02 (2022) (quoting *Prouty v. Ruggles*, 41 U.S. 336, 337 (1842)) (“[T]his combination, composed of all the parts mentioned in the specification, and arranged with reference to each other . . . and is stated to be the improvement, and is the thing patented. The use of any two of these parts only, or of two combined with a third, which is substantially different, in form or in the manner of its arrangement and connection with the others; is therefore not the thing patented. It is not the same combination if it substantially differs from it in any of its parts.”).

²⁵ 28 U.S.C. § 1338 (2022).

²⁶ 35 U.S.C. § 141 (2022); 28 U.S.C. § 1291 (2022).

²⁷ See Rachel E. Sachs, *The Uneasy Case for Patent Law*, 117 MICH. L. REV. 499, 500 (2018) (“The pharmaceutical industry has long been held out as the paradigm example of the ability of patents to promote innovation.”).

²⁸ *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018) (“[A] patentee does not need to prove an actual past instance of direct infringement by a physician to establish infringement under 35 U.S.C. § 271(e)(2)(A).”).

²⁹ *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005) (discussing that there is no indirect infringement “when a defendant merely sells a commercial product suitable for some lawful use”).

³⁰ *Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1377 (Fed. Cir. 2005) (affirming jury's induced infringement determination when defendant distributed marketing material and manuals that instructed how to use the product in an infringing manner).

accompanying the marketing of a drug to prove intent to induce patent infringement, “the label must *encourage, recommend, or promote* infringement.”³¹

However, the question is not just whether instructions “describ[e] the infringing mode,” but whether “the instructions *teach* an infringing use of the device such that [an inference can be drawn from those instructions] of an affirmative intent to infringe the patent” by way of encouraging, recommending or promoting infringement.³² “While proof of intent is necessary, direct evidence is not required, rather, circumstantial evidence may suffice.”³³ Lastly, a patent owner must show causation between the accused inducer’s actions and the infringing acts of another.³⁴

D. Changes in Legislation to Benefit Drug Manufacturing

Before 1984, new brand-name drugs were required to conduct expensive, time-consuming clinical trials before bringing their products to market.³⁵ Generic drug companies were required to do the same, while simultaneously subjecting themselves to patent infringement liability in the process.³⁶ A generic manufacturer was not allowed to start the pre-clinical and clinical process required for FDA approval of its own version “before all of the relevant patents on the brand-name drug expired.”³⁷ Due to the cost burden and time constraints placed on generic manufacturers, by the late 1970s there were few substitutable generic drugs on the market.³⁸

³¹ *Takeda Pharm. USA, Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015); *see Grokster*, 545 U.S. at 936; *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1365 (Fed. Cir. 2012), 681 F.3d at 1365; 35 U.S.C. § 271(b) (2022).

³² *Toshiba*, 681 F.3d at 1365 (Fed. Cir. 2012) (distinguishing *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321 (Fed. Cir. 2010)); *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 (Fed. Cir. 2009) (emphasis added) (finding the manufacturer’s directions did not indicate intent to infringe, “[t]he question is not . . . whether a user following the instructions may end up using the device in an infringing way. Rather, it is whether [the] instructions teach an infringing use of the device such that we are willing to infer from those instructions an affirmative intent to infringe the patent”).

³³ *DSU Med Corp.*, 471 F.3d at 1306.

³⁴ *Id.* at 1304 (“The plaintiff 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”); 35 U.S.C. § 271(b) (2022).

³⁵ *See* Aaron S. Kesselheim, Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need A Redesigned Approach for the Modern Era?*, 15 *YALE J. HEALTH POL’Y, L. & ETHICS* 293, 297 (2015).

³⁶ *Id.* (“Prior to 1984, the most significant federal legislation affecting the pharmaceutical market was the 1962 Kefauver-Harris Amendments to the Food, Drug, and Cosmetic Act (FDCA).” These Amendments gave the FDA the power to require pharmaceutical manufacturers to prove that their drugs were safe and efficacious by conducting a three-phase process of clinical trials before the drugs could be sold.)

³⁷ *Id.* at 300; *see also* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 *J.L. & TECH.* 389, 395 (1999) (“It was common practice . . . for generic drug companies to seek FDA approval to market generic versions of patented drugs before the relevant patents expired, even though it was necessary to make and use the patented invention and thus commit . . . infringement as part of the process of seeking FDA approval.”)

³⁸ *See* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 *FOOD & DRUG L.J.* 187, 187 (1999) (“After 1962, there was congressional testimony that there were 150 drugs that were off-patent, but for which there were no generics because generic companies simply would not spend the time and money doing the clinical trials to get to market . . .”); *see also* Kesselheim, *supra* note 35, at 300 (explaining that, at the time, “generics accounted for only nineteen percent of all prescriptions”).

In 1984, Congress passed The Hatch-Waxman Act, formally known as the Drug Price Competition and Patent Term Restoration Act of 1984.³⁹ The Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding § 505(b)(2) and § 505(j).⁴⁰ The Act struck “a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.”⁴¹ Its enactment provided an expedited and streamlined process for generic drug approvals and patent litigation involving generic drugs.⁴²

E. FDA Drug Approval Process

The Food and Drug Administration (FDA) regulates the manufacture, sale, and labeling of prescription drugs.⁴³ A brand-name drug manufacturer seeking FDA approval for a drug submits a new drug application (“NDA”), also known as a 505(b)(2) application.⁴⁴ The FDA “may approve a brand-name drug for multiple methods of use—either to treat different conditions or to treat the same condition in different ways.”⁴⁵

To expedite approval of generic drugs and prevent the FDA from authorizing a generic drug that would infringe a brand manufacturer's patent, brand manufacturers are required to submit patent information to the FDA, such as a statement of the drug's components, “pending methods of use,” and the “specific section of the proposed labeling . . . that corresponds to the method of use claimed by the patent submitted.”⁴⁶ Once an NDA is approved, the brand manufacturer provides a description of any method-of-use patent it holds, known as a use code.⁴⁷ The FDA then publishes patent

³⁹ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in 21 U.S.C. § 355).

⁴⁰ *Id.*

⁴¹ *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002); See Jim Frederick, *Hatch-Waxman Act 30 years later: Landmark compromise still resonates*, DRUG STORE NEWS (November 17, 2014), <https://drugstorenews.com/pharmacy/hatch-waxman-act-30-years-later-landmark-compromise-still-resonates>, at 2 (quoting Congressman Henry A. Waxman, “The competition generated through the [Hatch-Waxman] [A]ct not only results in lower priced drugs, but also fosters innovation by encouraging companies to bring new products to market to replace revenues from older products”).

⁴² Drug Price Competition and Patent Term Restoration Act of 1984, *supra* note 39 (the Act sought to amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications, to “amend title 21 U.S.C. § 355 to authorize the extension of the patents for certain regulated products, and for other purposes”); Garrett T. Potter, *Beefing Up Skinny Labels: Induced Infringement As A Question of Law*, 97 NOTRE DAME L. REV. 1707, 1713 (2022) (“The Act also balances the interests of generic drug manufacturers by allowing them to enter the drug market so long as their compound does not infringe a brand manufacturer's patent”); 21 U.S.C. § 355 (2022); 35 U.S.C. § 271(e)(1) (2022).

⁴³ See generally 21 C.F.R. (2022).

⁴⁴ See 21 U.S.C. §§ 355(b)(1); (b)(1)(A)(viii) (2022).

⁴⁵ *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404 (2012).

⁴⁶ 21 C.F.R. § 314.53(c)(2)(O) (2008); *GlaxoSmithKline*, 7 F.4th at 1345 (“Subsequent amendments to the FDA's regulations now require even more detail, underscoring the critical public-novice function of patent declarations”); see, e.g., 21 C.F.R. § 314.53(c)(2)(O) (2022).

⁴⁷ See 21 CFR §§ 314.53(c)(2)(ii)(P)(3), (e) (2022).

numbers, dates, and use codes in an approved drug products list: The Orange Book.⁴⁸ The Orange Book provides notice to generics and the FDA.⁴⁹ However, the FDA “does not attempt verify the accuracy of the use codes that brand manufacturers supply,”⁵⁰ instead they will rely on the manufacturer’s description.⁵¹

F. FDA Post-Approval of Generic Drug

Once the FDA approves a brand manufacturer's drug, under the Hatch-Waxman Act, another manufacturer may seek FDA approval to market a generic version by filing an abbreviated new drug application (ANDA) under 21 U.S.C. § 355(j).⁵² The application is “abbreviated” in that it does not need to include the human clinical data required in a new drug application. Instead, the generic manufacturers must show the generic drug is effectively a duplicate of the NDA drug, the Reference Listed Drug (RLD), that is “bioequivalent.”⁵³ The FDA may then grant tentative approval, pending final approval “anticipated upon expiry of patent protection for the brand product”⁵⁴ and final approval afterwards. By submitting their ANDA the generic is certifying that either there are no patents listed in the Orange Book that they could infringe, or all listed patents have expired (or will expire prior to the ANDA's approval).⁵⁵

However, in anticipation that generic drugs will likely want to launch while patents remain on brand name drugs, “Congress provided two pathways for generics to show that a proposed label will not infringe.”⁵⁶ If a generic drug manufacturer intends to submit an FDA application for a drug or method of use *before expiration* of

⁴⁸ Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676; 36,683 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314) (“[W]e publish patent information after approval of an NDA application in our approved drug products list entitled The ‘Approved Drug Products With Therapeutic Equivalence Evaluations [.]’ . . . popularly as the ‘Orange Book’ because of its orange-colored cover.”).

⁴⁹ *Id.*

⁵⁰ *Caraco Pharm. Lab'ys, Ltd.*, 566 U.S. at 405.

⁵¹ See Applications for FDA Approval to Market a New Drug, *supra* note 48.

⁵² See 21 U.S.C. § 355(j)(2)(A)(ii) (2022) (requiring the generic drug to have the same active ingredient as the brand name drug; 21 U.S.C. § 355(j)(2)(A)(iii) (2022) (requires the generic drug to have the same “route of administration, dosage form, and the strength of the new drug”, with minor differences allowed); 21 U.S.C. § 355(j)(2)(A)(iv) (2022) (requires the generic drug to be “bioequivalent” to the brand name drug).

⁵³ 21 U.S.C. § 355(j)(2)(A)(iv) (2022); 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV) (2022) (a generic manufacturer must make one of four certifications to the FDA, regarding patents for the reference brand-name product: (1) that no such patent exists, (2) that such patent has expired, (3) that such patent will expire by a specified date, or (4) “that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted”); FDA, Orange Book Preface § 1.2 (42nd ed. current as of Jan. 19, 2022), <https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface> (drugs are “therapeutic equivalents if they are pharmaceutical equivalents for which bioequivalence has been demonstrated, and they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling”).

⁵⁴ *GlaxoSmithKline*, 7 F.4th at 1335; see 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd) (2022) (tentative approval means that the application meets the scientific, labeling, and other approval criteria, but some unexpired exclusivity prevents final approval).

⁵⁵ See 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(III) (2022).

⁵⁶ *GlaxoSmithKline*, 7 F.4th at 1323.

the brand-name drug patent, they may file a Paragraph IV certification.⁵⁷ Under Paragraph IV, generic manufacturer must provide a Notice Letter to the brand name manufacturer setting out (1) the existence of the ANDA or Section 505(b)(2) application and (2) a “detailed statement of the applicant’s factual and legal basis that the listed patents are invalid or not infringed.”⁵⁸

Alternatively, a generic drug manufacturer can file a section viii “carve-out” statement, which is typically used when the “brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug.”⁵⁹ Using a section viii statement, a generic manufacturer will market the drug for one or more methods of use *not covered* by the brand's patents, by proposing a label that removes or “carves out” the still-patented methods of use from the brand's approved label.⁶⁰ After the still-patented uses are “carved out,” what remains is a “skinny label,” which may be approved by the FDA for the remaining subset of uses, i.e., those not covered by the brand’s patent.⁶¹

III. THE CASE

A. Facts & Procedural History

In *GlaxoSmithKline*, GSK held a patent for Carvedilol, a beta-blocker, and launched the drug under the brand name Coreg®.⁶² The Food and Drug Administration (FDA) approved carvedilol for three indications of use: 1) treatment of hypertension, approved in 1995, 2) congestive heart failure (“CHF”), approved in 1997, and in 2003, its third approved use was to “reduce cardiovascular mortality in patients suffering from left ventricular dysfunction following a myocardial infarction,” (“the

⁵⁷ 35 U.S.C. § 271(e)(2) (2022) (it is an act of patent infringement to submit an FDA application for a drug claimed in a patent (or the use of which is claimed in a patent) for the purpose of engaging in the commercial manufacture, use, or sale of the drug before expiration of its patent); *see* *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (generic manufacturers will commit a “somewhat artificial” act of infringement); *GlaxoSmithKline*, 7 F.4th at 1344; 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2022) (“Paragraph VI certification states that a generic label will not infringe because the patent ‘is invalid or will not be infringed by the manufacture, use or sale of the [generic] drug’”).

⁵⁸ 21 U.S.C. § 355(j)(2)(B)(i),(iv)(II) (2022).

⁵⁹ *Caraco Pharm. Lab'ys, Ltd.*, 566 U.S. at 406; *see* 21 U.S.C. § 355(j)(2)(A)(viii) (2022) (defining such a statement as, “if with respect to the listed drug ... a method of use patent [listed in the Orange Book] ... does not claim a use for which the [ANDA] applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use”).

⁶⁰ *Caraco Pharm. Lab'ys, Ltd.*, 566 U.S. at 406; *see* 21 U.S.C. § 355(j)(2)(A)(viii) (2022); 21 C.F.R. § 314.94(a)(8)(iv) (2022); *see* Terry G. Mahn, *Generics Behaving Badly: Carve Outs, Off-Label Uses*, LAW360 (Mar. 24, 2009), <https://www.fr.com/files/Uploads/attachments/Generics-Behaving-Badly-by-Terry-Mahn-2009.pdf>.

⁶¹ Jonathan A. Bell, *Generic Drugs and the Future of "Skinny Labels"*, 35 HARV. J.L. & TECH. 659, 665 (2022); *see* 21 C.F.R. § 314.94(a)(8)(iv) (2022); *Caraco Pharm. Lab'ys, Ltd.*, 566 U.S. at 406.

⁶² U.S. FOOD AND DRUG ADMIN., *Coreg CR - Highlights of Prescribing Information* (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022012s010s013lbl.pdf;

GlaxoSmithKline, 7 F.4th at 1323 (beta-blockers work by relaxing blood vessels and slowing heart rate to improve blood flow and decrease blood pressure).

‘post-MI LVD’ indication”).⁶³ Although GSK’s label contained the three separate indications of use, their statement to the FDA only included that they had the patent on the CHF indication.⁶⁴

1. Relevant Patents

U.S. Patent No. 4,503,067 (“The ‘067 Patent”)

The ‘067 Patent was granted in 1985, and covered the compound Carvedilol, which was developed in the 1980s.⁶⁵ It was listed in the Orange Book.⁶⁶

U.S. Patent No. 5,760,0679 (“The ‘069 Patent”)

The ‘069 Patent was granted in 1988, covering a “method of administering a combination of carvedilol and one or more of an ACE inhibitor, a diuretic, and digoxin to decrease mortality caused by CHF in a patient” with an expiration date of March 5, 2007.⁶⁷ The ‘069 Patent was listed in the Orange Book.⁶⁸

U.S. Patent No. RE40,000 (“The ‘000 Patent”)

The ‘000 Patent was the reissued version of the ‘069 Patent method, granted on January 8, 2008.⁶⁹ The patent claims a

method of decreasing mortality caused by CHF by administering carvedilol with at least one other therapeutic agent, *wherein the administering comprises administering to said patient daily maintenance dosages for a maintenance period to decrease a risk of mortality caused by congestive heart failure, and said maintenance period is greater than six months.*⁷⁰

It was listed in the Orange Book, in replacement of the ‘069 patent shortly after the ‘000 patent was issued.⁷¹

⁶³ *GlaxoSmithKline*, 7 F.4th at 1323, 1346 (explaining that the “post-LVD” indication is a condition which “concerns patients who have recently suffered a heart attack (a ‘myocardial infarction,’ or ‘MI’) and whose hearts have trouble pumping blood (‘left ventricular dysfunction,’ or ‘LVD’”).

⁶⁴ *Id.* at 1347, 1349 (“[A]ccording to GSK’s sworn declaration to the FDA (which appropriately tracked the label’s language), only one of these three [indications] was patented—CHF.”).

⁶⁵ *Id.* at 1323.

⁶⁶ U.S. Patent No. 4503067 (issued Mar. 5, 1985).

⁶⁷ *GlaxoSmithKline*, 7 F.4th at 1323.

⁶⁸ U.S. Patent No. 5760069 (issued June 2, 1998).

⁶⁹ U.S. Patent No. RE40000 (issued Jan. 8, 2008).

⁷⁰ *Id.* (emphasis in original); FDA, *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, https://www.accessdata.fda.gov/scripts/cder/ob/results_patent.cfm (last visited Nov. 12, 2022) (this description corresponds to Patent Use Code U-233, which is “decreasing mortality caused by congestive heart failure”).

⁷¹ *GlaxoSmithKline*, 7 F.4th at 1347.

In March 2002, Teva filed an ANDA for FDA approval of its generic carvedilol under a Paragraph IV certification.⁷² This proposed “full label” included all three indications, certifying that it “would not launch its product until the ‘067 patent expired in March 2007.”⁷³ Teva supplied a Paragraph IV certification that the ‘069 patent was “invalid, unenforceable, or un infringed,”⁷⁴ along with notice⁷⁵ to GSK.

In 2004, the FDA determined that Teva had shown its product to be bioequivalent to GSK's and granted it tentative approval of its ANDA, pending resolution of any exclusivity issues, for “treatment of heart failure and hypertension.”⁷⁶ In 2007, the ‘069 patent was soon to expire, and Teva decided to pursue a section viii carve out.⁷⁷ GSK's label had three sets of instructions for its three indications, claiming that the ‘069 patent only covered the CHF indication.⁷⁸

Accordingly, the FDA authorized Teva's 2007 label as long as it omitted the CHF indication—to contain the indication for post-MI LVD and hypertension.⁷⁹ So, Teva certified to the FDA that “its label ‘will not include the indication defined in use code U-233’” until the ‘069 patent expired.⁸⁰ Teva used the skinny label during this “partial label period.”⁸¹ However, Teva's press releases and marketing materials “touted its generic carvedilol as ‘indicated for treatment of heart failure and hypertension,’ as the ‘Generic version of [GSK's] cardiovascular agent Coreg®,’ and as an ‘AB-rated generic equivalent of [GSK's] Coreg® Tablets.’”⁸²

After the generic launch, GSK received its reissued patent, the ‘000 patent, in 2008.⁸³ In 2011, the ‘069 patent was delisted from the Orange Book, and the ‘000 patent was listed as its replacement—GSK again identified only the CHF indication as covered. The FDA then directed Teva to revise its label to include the CHF indication in accordance with the newly delisted ‘069 patent and another GSK delisted patent.⁸⁴ Accordingly, Teva amended its label to “include the indication for treating patients

⁷² *Id.* at 1323; see 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2022).

⁷³ *GlaxoSmithKline*, 7 F.4th at 1323, 1345 (once GSK's post-MI LVD indication was approved in 2003, Teva “likewise updated the label accompanying its pending ANDA to include all three indications”); see 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2022).

⁷⁴ 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2022).

⁷⁵ 21 U.S.C. § 355(j)(2)(B)(i) (2022).

⁷⁶ *GlaxoSmithKline*, 7 F.4th at 1324; see 21 U.S.C. § 355(j)(2)(A)(iv) (2022).

⁷⁷ *GlaxoSmithKline*, 7 F.4th at 1324; see *Caraco Pharm. Lab'ys, Ltd.*, 566 U.S. at 406; 21 U.S.C. § 355(j)(2)(A)(viii) (2022).

⁷⁸ *Id.* at 1345.

⁷⁹ *Id.* at 1347.

⁸⁰ *Id.* at 1324.

⁸¹ *Id.* at 1325 (the “partial label period” ran from January 8, 2008, to April 30, 2011, during which Teva's label only consisted of the post-MI LVD and hypertension indications).

⁸² *GlaxoSmithKline*, 7 F.4th. at 1324 (Teva advertised the generic's use for “treatment of heart failure and hypertension,” noting it was the “[g]eneric version of GSK's . . . Coreg.”; FDA, Orange Book Preface, *supra* note 53 § 1.7 (“AB ratings” are assigned by the FDA for a drug that is considered therapeutically equivalent to another drug).

⁸³ *Id.* at 1324; the ‘000 Patent, *supra* note 69.

⁸⁴ U.S. Patent No. 5902821 (issued May 11, 1999). “[T]he FDA told Teva to ‘revise its labeling to include the information associated with patent ‘821 (delisted) and the associated Use Code (U-313)’”; FDA, *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, *supra* note 70 (U-313 is for “treatment of congestive heart failure.”

with chronic heart failure by administering carvedilol to increase survival and to reduce the risk of hospitalization,” beginning the “full label period.”⁸⁵

On July 3, 2014, GSK sued Teva in the District of Delaware, alleging that they had induced infringement of GSK’s ‘000 patent.⁸⁶ In a seven-day jury trial in 2018, “the jury was asked to determine whether Teva induced infringement of the ‘000 patent based on the [partial label] period and the full label period.”⁸⁷ Teva argued that 1) the indications of the ‘000 patent were invalid and not infringed, 2) they could not have induced infringement in the partial label period because of the CHF carve-out in its 2007 label, and 3) it did not, at any time, induce others to infringe on the ‘000 patent.⁸⁸ The jury found that “the ‘000 patent was not invalid and that Teva induced infringement” in both the partial and full label periods.⁸⁹ GSK was awarded “\$234.1 million in lost profits and \$1.4 million in reasonable-royalty damages.”⁹⁰

Teva filed a renewed motion for judgment as a matter of law (“JMOL”), “arguing that GSK did not present legally sufficient evidence to support a finding of inducement.”⁹¹ The district court granted the motion, finding that “GSK failed to prove Teva’s alleged inducement actually caused physicians to directly infringe by prescribing [Teva’s generic version] for treatment of mild to severe CHF.”⁹² GSK appealed and Teva cross-appealed as to damages.⁹³

The Federal Circuit heard the case in September 2019, and the first majority opinion was rendered in October 2020, reversing the district court’s grant of JMOL.⁹⁴ Teva petitioned for rehearing, which was granted on February 9, 2021.⁹⁵ The October 2020 judgment was vacated, and the opinion was withdrawn.⁹⁶ The majority then issued a second opinion, reaching the same conclusion with different reasoning.⁹⁷

B. Federal Circuit Court Decision

The issue before the Federal Circuit Court was whether Teva induced infringement of the ‘000 patent during the partial label period and the full label

⁸⁵ *GlaxoSmithKline*, 7 F.4th at 1324-25. (the “full label period” ran from May 1, 2011, to June 7, 2015, during which all three indications were on Teva’s label.)

⁸⁶ *Id.* (GSK also sued Glenmark Pharmaceuticals USA, another large supplier of generic carvedilol, but the “action against Glenmark was severed and stayed”).

⁸⁷ *Id.* at 1348.

⁸⁸ *Id.* at 1325.

⁸⁹ *Id.* at 1325.

⁹⁰ *GlaxoSmithKline*, 7 F.4th at 1348.

⁹¹ *Id.*

⁹² *Id.* at 1325; see *GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 313 F. Supp. 3d 582 (D. Del. 2018).

⁹³ *GlaxoSmithKline*, 7 F.4th at 1348.

⁹⁴ *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347 (Fed. Cir. 2020).

⁹⁵ *GlaxoSmithKline*, 7 F.4th at 1326, 1348 (after the majority’s first opinion released, eight amici-briefs, from generic and brand name drug manufacturers, fifty-seven law professors, and Congressman Waxman, surfaced in support of the motion, concerned “about the lack of clarity of [the majority’s] opinion when the patented uses are carved out of the FDA approved label”).

⁹⁶ *Id.* at 1326.

⁹⁷ *Id.* at 1320-42.

period.⁹⁸ The majority concluded that there was substantial evidence to support a jury verdict of induced infringement by Teva and vacated the district court's grant of JMOL.⁹⁹ On the discussion of induced infringement, the majority discussed the partial label and full label periods separately.¹⁰⁰

1. *Partial Label Period*

The majority explained that there were many sources from which a reasonably jury could find Teva intended to encourage, recommend, or promote infringement.¹⁰¹ These sources included the partial label itself, “expert testimony, Teva’s product catalog, Teva’s advertising and promotional activities, Teva’s Monthly Prescribing References for doctors, and testimony from Teva’s own company witnesses.”¹⁰²

To assert inducement of infringement, the majority cited expert testimony from Dr. McCullough, GSK’s cardiology expert, on Teva’s label and its infringement of the ‘000 patent.¹⁰³ The court concluded that three portions of the label resulted in a finding of infringement of the ‘000 patent. First, both Teva and GSK medical experts agreed that Teva’s post-MI LVD indication, “satisfied the ‘decreasing mortality caused by CHF in a patient’ limitation” on the ‘000 patent because both experts agreed that someone with a “left ventricular ejection fraction $\leq 40\%$. . . as indicated on Teva’s label) would be diagnosed with congestive heart failure.”¹⁰⁴ Second, the post-MI LVD indication “explicitly directs the reader to Clinical Study § 14.1” which “showed that patients taking carvedilol in the study had background treatment of ACE inhibitors and diuretics”.¹⁰⁵ Third, a figure within Clinical Study § 14.1 showed treatment for more than six months, satisfying the “maintenance period is greater than six months” limitation.¹⁰⁶ From this, the majority suggested that the jury could use these sections *in conjunction with one another* to conclude that Teva’s partial label “explicitly instructs [physicians to] adminis[ter] carvedilol for the claimed use of decreasing mortality caused by CHF.”¹⁰⁷ So, the majority held that Teva’s skinny label did not effectively carve out all uses of carvedilol indicated in the ‘000 patent.¹⁰⁸

The majority then discussed that the FDA “has no expertise in patent law” and “made clear that use codes in the Orange Book ‘are not meant to substitute for the [ANDA] applicant’s review of the patent and the approved labeling.”¹⁰⁹

⁹⁸ *Id.* at 1333 (“The issues before us are the issues that were tried to the jury and decided in the district court.”).

⁹⁹ *Id.* at 1340.

¹⁰⁰ *GlaxoSmithKline*, 7 F.4th at 1327.

¹⁰¹ *Id.* at 1333; *see Takeda Pharm. USA, Inc.*, 785 F.3d at 631.

¹⁰² *GlaxoSmithKline*, 7 F.4th at 1333.

¹⁰³ *Id.* at 1328-29.

¹⁰⁴ *GlaxoSmithKline*, 7 F.4th at 1328 (“Carvedilol is indicated to reduce cardiovascular mortality in clinically stable patients who have survived acute phase of a myocardial infarction and have a left ventricular ejection fraction of $\leq 40\%$ (with or without symptomatic heart failure.”).

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* at 1329.

¹⁰⁷ *Id.* at 1330.

¹⁰⁸ *Id.* at 1335.

¹⁰⁹ *GlaxoSmithKline*, 7 F.4th at 1331-32 (quoting Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676; 36,683 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314)).

The majority discussed other evidence of infringement in Teva's marketing and advertising, specifically, the two press releases, the first in 2004 and the second in 2007.¹¹⁰ The 2004 press release indicated that Teva was granted tentative approval by the FDA, noting that the "[c]arvedilol tablets are the AB-rated generic equivalent" of GSK's Coreg tablets and "are indicated for *treatment of heart failure* and hypertension."¹¹¹ Since Teva did not distinguish between congestive heart failure and post-MI LVD, and because it used the indication of heart failure, the majority said that this press release was Teva's way of "telling the world that its generic is a substitute . . . to treat congestive heart failure in the same manner as Coreg (which is a method that infringed the '000 patent)."¹¹²

In the second press release in 2007, Teva stated it received approval "to market its Generic version of GlaxoSmithKline's *cardiovascular agent* Coreg {Carvedilol} Tablets."¹¹³ By using the phrase "cardiovascular agent" in conjunction with its indication as the generic equivalent of GSK's version, the majority held it was reasonable for a jury to conclude that Teva encouraged use of its generic version "for all indications', including heart failure."¹¹⁴

2. Full Label Period

After the addition of the "Heart Failure" indication was added to Teva's label in 2011, the majority contended, and Teva did not dispute, that substantial evidence supports a jury finding that Teva's full label contained all of the claim limitations.¹¹⁵ The majority also cited Teva's Monthly Prescribing Reference to show that these materials are "clearly telling doctors they should read the label [for prescribing information]."¹¹⁶ The majority concluded there was substantial evidence to support a jury finding that Teva intended to encourage, recommend, or promote the use of Carvedilol by physicians in an infringing manner during the full label period.¹¹⁷

¹¹⁰ *Id.* at 1335-36.

¹¹¹ *Id.* (emphasis added).

¹¹² *Id.* at 1336.

¹¹³ *Id.* (emphasis added).

¹¹⁴ *GlaxoSmithKline*, 7 F.4th at 1336.

¹¹⁵ *Id.* at 1338. Teva's label contained the 'Heart Failure' indication. Specifically, it added the following indication: Heart Failure. Carvedilol tablets are indicated for the treatment of mild-to-severe chronic heart failure of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitors, and digitalis, to increase survival, and, also, to reduce the risk of hospitalization [see Drug Interactions (7.4) and Clinical Studies (14.1)].

¹¹⁶ *Id.* at 1338 ("Monthly Prescribing References . . . were 'intended solely for use by the medical professional,' [and] explained that '[t]he clinician must be familiar with the full product labeling provided by the manufacturer or distributor of the drug, of every product he or she prescribes, as well as the relevant medical literature'. [Dr. McCullough] testified that the 2012 MPR was telling doctors to 'verify any questions against the labeling or contact the company marketing the drug,' that the label 'provides the base information that flows to the doctors.'").

¹¹⁷ *Id.* at 1339.

3. Causation

After showing that Teva possessed the intent to induce infringement, the majority explained how Teva's actions *caused* physician infringement of the '000 patent.¹¹⁸ Teva argued that they "did not cause doctors to actually prescribe generic carvedilol," citing medical guidelines, textbooks, and other literature to show that "this *information*, not [Teva's] actions, made physicians aware of the benefits of carvedilol for heart failure patents."¹¹⁹ However, the majority disagreed.¹²⁰ The majority found there was sufficient circumstantial evidence (the "labels, marketing materials, catalogs, press releases, and expert testimony") such that the jury could infer that when Teva distributed and marketed their generic with labels encouraging an infringing use, it "succeeded in influencing doctors to prescribe carvedilol for the infringing use."¹²¹

C. Prost's Dissent

Judge Prost wrote a moving dissent in which she discussed the legal pitfalls of the majority's opinion and her concerns as to the future ramifications of drug manufacturing.¹²² Unlike the majority, Prost saw this as a clear case of a "skinny-label."¹²³ Prost found the reasoning of the majority opinion to be "sometimes opaque" while "strain[ing] to prop up a jury verdict that is unsupportable."¹²⁴ She voiced her concern for the future of generic drugs following this decision because "it's unclear what Teva even did wrong—or, put another way, what another generic in its shoes should do differently."¹²⁵

Prost discussed the lack of evidence of inducement during either the partial label period or the full label period.¹²⁶ While the majority found that Teva encouraged infringement, Prost reasoned there was no culpable intent by Teva or causation because Teva was intentionally "trying to *avoid* having its label encourage infringement" by carving out possible infringing indication from GSK's label.¹²⁷ Prost found difficulty in the majority's finding of culpable intent behind a generic calling its product "equivalent" to its brand name counterpart when this correlation is an FDA

¹¹⁸ *Id.* at 1339-40.

¹¹⁹ *GlaxoSmithKline*, 7 F.4th at 1339 ("Teva points to guidelines from the American College of Cardiology (ACC), the American Heart Association (AHA), medical textbooks, and treatises to argue doctors already knew to treat CHF using carvedilol long before Teva launched its generic . . . The district court accepted Teva's argument as sufficient to overcome the jury verdict in GSK's favor.") (emphasis added).

¹²⁰ *Id.* at 1339 ("The district court accepted Teva's argument as sufficient to overcome the jury's verdict in GSK's favor. [The majority panel] do[es] not agree.").

¹²¹ *Id.* at 1340.

¹²² *Id.* at 1342 (Prost, S., dissenting).

¹²³ *Id.* at 1348.

¹²⁴ *GlaxoSmithKline*, 7 F.4th at 1342.

¹²⁵ *Id.* at 1360 (Judge Prost continues, "[s]o where did Teva go wrong in this case? Should it not have followed the brand's sworn representations as to what was patented? The majority offers no principled division between this and what it suggests would be a true skinny label").

¹²⁶ *Id.* at 1349-56.

¹²⁷ *Id.* at 1342.

requirement for generic drug production.¹²⁸ Prost took issue with the two main conclusions of the majority's opinion. First, Prost contended that "the 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."¹²⁹ This is an important distinction because while encouragement "provides evidence of intent, [describing] does not."¹³⁰ Second, Prost asserted that the majority failed to show the causation required for inducement.¹³¹

Judge Prost proposed that the majority only "relie[d] on three key pieces of evidence" to show evidence of infringement in the partial label period: "the skinny label itself . . . and two press releases," one from 2007, and another from 2004, both "distributed before the '000 patent issued."¹³² From these three pieces of evidence, Prost said "alone or combined, no reasonable jury could have found (1) culpable intent to encourage infringement or (2) causation, much less both."¹³³

On Prost's first point, she argued that the majority's use the GSK's expert testimony to show infringement did not illustrate an attempt to "encourage, recommend or promote infringement."¹³⁴ Instead, Prost explained that Dr. McCullough "'merely *describ[ed]* an infringing use' in [the] label, [which] 'will not suffice.'"¹³⁵ Prost was hesitant to accept that Dr. McCullough's testimony established inducement because although he testified that in certain portions of the label, "limitations were 'met' (or 'mentioned') a reasonable jury could only find that the label merely *described* the infringing use, but that would only happen if the sections of the label were "pieced together just right."¹³⁶

Further, in response to the majority's explanation of the evidence of infringement shown by the 2007 press release, Judge Prost did not see culpable intent in Teva describing its product as a "generic version' of a 'cardiovascular' brand drug."¹³⁷ Accordingly, Prost did not see how using the word "cardiovascular" to describe a heart-related drug could "*reasonably* be viewed as evidencing culpable intent to encourage practicing the specific claimed CHF method in particular here—or how this adjective does anything beyond what 'generic version' or 'generic equivalent' do in terms of intent."¹³⁸ Prost mentioned that the majority failed to show causation with respect to

¹²⁸ See 21 U.S.C. § 355(j)(2)(A)(iv) (2022).

¹²⁹ *GlaxoSmithKline*, 7 F.4th at 1343 (emphasis added).

¹³⁰ *Id.* at 1357.

¹³¹ *Id.* at 1358 ("[T]o prove causation, GSK had to show that Teva's conduct (apart from simply being on the market) was a substantial factor in causing doctors to prescribe its carvedilol in an infringing way. A mere possibility wouldn't do; rather, a reasonable jury must have been able to find that it was more likely than not. Here it could not.").

¹³² *Id.* at 1349.

¹³³ *Id.*

¹³⁴ *GlaxoSmithKline*, 7 F.4th at 1350-51; see *Takeda Pharm. USA, Inc.*, 785 F.3d at 631.

¹³⁵ *GlaxoSmithKline*, 7 F.4th at 1350-51 (quoting *HZNP Meds LLC v. Actavis Labs. UT, Inc.* 940 F.3d 680, 702 (Fed. Cir. 2019)).

¹³⁶ *Id.* at 1351 ("[S]ome limitations were met . . . in the Indications and Usage section, others in the Dosage and Administration section, and still others in the Clinical Studies section.").

¹³⁷ *Id.* at 1353 (Judge Prost indicates that "cardiovascular" is a well-known adjective that means "relating to the heart").

¹³⁸ *Id.* at 1353 (emphasis in original).

the press release, outside of the testimony that doctors receive the press release and “that it’s ‘possible’ doctors read them.”¹³⁹

Last, Judge Prost rejected the majority’s conclusion that the 2004 press release provided evidence of intent to infringe.¹⁴⁰ She did not understand how “the majority [was] willing to see culpable intent behind a generic’s describing its product as ‘equivalent’ of a brand drug—in a system that *requires* generic drugs to be equivalent.”¹⁴¹ In Prost’s view, this is a concerning finding because Congress did not intend “to make generics liable for simply stating what the law requires” when it enacted the Hatch-Waxman Act.¹⁴² Prost concluded her opinion with the thought that “the background facts here will seemingly persist in most skinny-label cases[,]” creating significant uncertainty as to how generic companies can comply with the Hatch-Waxman Act and avoid patent infringement lawsuits.¹⁴³

IV. ANALYSIS

A. No Inducement of Patent Infringement by Teva

As Judge Prost explained in her dissent, Teva did not induce infringement of GSK’s ‘000 patent.¹⁴⁴ The majority’s conclusions rest on mere speculation and inferences in an effort to uphold a jury verdict that was founded on thin evidence to begin with.¹⁴⁵

The majority relinquished any distinction between direct infringement and inducement because the majority “never meaningfully engage[d] with the legal distinction between encouraging, recommending, or promoting an infringing use and describing it.”¹⁴⁶ However, a large part of GSK’s evidence rested on the testimony of Dr. McCullough, and the fragmented logic which would take the various sections of Teva’s label “pieced together just right” to reach merely the describing of the infringing

¹³⁹ *Id.* at 1353.

¹⁴⁰ *GlaxoSmithKline*, 7 F.4th at 1354.

¹⁴¹ *Id.* at 1343; see 21 U.S.C. § 355(j)(2)(A)(iv) (2022); Corrected Brief for Former Congressman Henry A. Waxman as Amicus Curiae in Support of Petition for Rehearing En Banc, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, No. 1:14-cv-00878-LPS-CJB (Fed. Cir. 2021), 2021 WL 5050353, at 5-6, <https://fedcircuitblog.com/wp-content/uploads/2021/10/Brief-of-Amicus-Curiae-Former-Congressman-Henry-Waxman-18-1976.pdf> (“Congress was aware that the approval of a generic drug as therapeutically equivalent to the brand drug means that it may be safely substituted for all uses, including those that are carved out of the labeling”); *Takeda Pharm. USA, Inc.*, 785 F.3d at 631.

¹⁴² *GlaxoSmithKline*, 7 F.4th at 1353.

¹⁴³ *Id.* at 1360.

¹⁴⁴ *Id.* at 1342.

¹⁴⁵ *Id.* (considering the industry-changing conclusions that the majority reached, one would hope that those conclusions were grounded in solid evidence of inducement).

¹⁴⁶ *Id.* at 1357; *GlaxoSmithKline v. Teva*, 7 F.4th 1320 (Fed. Cir. 2021), *petition for cert. filed*, No. 22-37, 2022 WL 2757522 (U.S. Jul. 11, 2022) at 28, https://www.supremecourt.gov/DocketPDF/22/22-37/229830/20220711182924194_cert%20petition.pdf (quoting *GlaxoSmithKline*, 7 F.4th at 1343) (“effectively eliminat[es] the demarcation between describing an infringing use and encouraging that use—a demarcation that is not just essential to the inducement framework, but also necessary for Hatch-Waxman to function.”).

use.¹⁴⁷ The question of encouragement is not, “whether a user following the instructions may end up using the device in an infringing way,” however, GSK seemed to rely on the contrary, and the majority panel agreed.¹⁴⁸

In *HZNP v. Actavis*, the Federal Circuit found that Actavis’s (generic) label did not encourage infringement of the HZNP’s brand name label.¹⁴⁹ HZNP’s label contained instructions that “the user must: (1) apply the . . . formulation, (2) wait for the area to dry, and (3) apply sunscreen, insect repellent, or a second topical medication.”¹⁵⁰ The issue of inducement centered around a warning contained in Actavis’s label that a patient “wait until area is completely dry before covering with clothing or applying sunscreen . . . or other substances.”¹⁵¹ However, the court reasoned that the instructions in Actavis’s label, “only require the first step . . . nothing else.”¹⁵² The court explained that HZNP’s patent was for three distinct steps, and that the warning on Actavis’s label was much broader than the HZNP label.¹⁵³ So, the court found no inducement of infringement.¹⁵⁴ Instead, the label merely *suggested* to patients that they should wait for the treatment to dry if they were going to apply anything on top.¹⁵⁵ The court concluded that although “some users might infringe [.] [t]he evidence[] does not establish that ‘the proposed label instructs users to perform the patented method.’”¹⁵⁶

While Teva’s label is not entirely missing pieces of GSK’s label, as the court found with Actavis’s label in *HZNP*, it is difficult to see how containing disjointed pieces describing how carvedilol should be used can be seen as inducement of infringement.¹⁵⁷ The disjointed sections of Teva’s label could merely be seen as *suggestions of use* such that the label did not infringe.¹⁵⁸ Although the sections reference one another, one would have to parse through the label to surgically sew the instructions together to

¹⁴⁷ *GlaxoSmithKline*, 7 F.4th at 1351.

¹⁴⁸ *Id.* at 1351; see *Vita-Mix Corp.*, 581 F.3d at 1329.

¹⁴⁹ *HZNP*, 940 F.3d at 702.

¹⁵⁰ *GlaxoSmithKline*, 7 F.4th at 682.

¹⁵¹ *Id.* at 700.

¹⁵² *Id.* at 702.

¹⁵³ *Id.* (“For example, beyond warning the user about waiting for the treated area to be completely dry before covering it with sunscreen, insect repellent, or another topical medication, Actavis’s label also warns about clothing, cosmetics, lotion, water, moisturizer, and other substances.”).

¹⁵⁴ *HZNP*, 940 F.3d at 702 (the court explained that Actavis’s label worked in an “if/then manner: if the user wants to cover the treated area with clothing or apply another substance over it, then the patient should wait until the area is dry”).

¹⁵⁵ *Id.*

¹⁵⁶ *Id.* (quoting *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010)).

¹⁵⁷ Brief for Apotex Inc. as Amicus Curiae in Support of the Petition for Rehearing En Banc, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, No. 1:14-cv-00878-LPS-CJB (Fed. Cir. 2021), 2021 WL 5003029, at 3, <https://fedcircuitblog.com/wp-content/uploads/2021/10/Brief-of-Amicus-Curiae-Apotex-Inc-in-Support-of-Defendent-Cross-Appellants-Petiton-for-Rehearing-En-Banc.pdf> (explaining that it was improper for the “panel majority [to rely] on testimony from GSK’s expert . . . to recast these disjointed references to certain claim elements in Teva’s label as encouragement, recommendation, or promotion of the claimed methods . . . [instead,] courts should undertake an objective inquiry into whether the generic’s label actually encourages, recommends, or promotes infringement as a matter of law”).

¹⁵⁸ See *HZNP*, 940 F.3d at 702.

create an inducement.¹⁵⁹ As this Court previously held, the “common knowledge” that “physicians routinely prescribe approved drugs for purposes other than those listed on the drugs' labels,” or that pharmacies often fill prescriptions for patented uses with generic substitutes, did not show an affirmative step to “encourage doctors to infringe.”¹⁶⁰

However, should some of the blame also be placed on the FDA? Of course, “the FDA is not the arbiter of patent infringement issues” and “has no expertise in patent law” because “a court is the appropriate forum for determining the scope of patent rights.”¹⁶¹ However, but for the FDA asking Teva to change their label to *match* GSK's, this lawsuit would not have occurred. By statute, “a generic drug must bear the same label as the brand-name drug.”¹⁶² So, if a generic plays by the skinny-label rules, it is hard to see how an FDA-required label can be evidence of intent to infringe.¹⁶³ Although the language that remains on the label after the carve-out *might* be pieced together to “meet” the elements of a patent claim, it becomes difficult to “meaningfully separate the liable from the lawful.”¹⁶⁴ This is especially true given that it's the brand who dictates what label language is omitted—and thus what language remains.¹⁶⁵

Teva filed a petition for writ of certiorari, and explained the impact on future suits, specifically how easily but unfairly, generics can be found to have infringed.¹⁶⁶ Teva contends that “needing only to find claim elements ‘mentioned’ in portions of [generic's] label that speak to *unpatented* uses, brands will regularly find *something* in the skinny label that can serve as the basis for an inducement complaint years (and hundreds of millions of dollars) after generic launch.”¹⁶⁷ The majority's decision sets a precedent that means description of an infringing use combined with expert testimony and a

¹⁵⁹ *GlaxoSmithKline*, 7 F.4th at 1351-52 (“GSK also . . . had to prove that doctors would have read the skinny label, then pieced together the disparate portions . . . then viewed that pieced-together description as an encouragement to prescribe carvedilol for CHF according to the specific limitations of the claimed method, and then relied on that pieced-together message to make that prescribing decision.”).

¹⁶⁰ Corrected Brief for Mylan Pharmaceuticals Inc. as *Amicus Curiae* in Support of Petition for Rehearing En Banc, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, No. 1:14-cv-00878 (Fed. Cir. 2021), at 3-4, <https://fedcircuitblog.com/wp-content/uploads/2021/10/Corrected-Brief-for-Mylan-Pharma-as-Amicus-Curiae-18-1976.pdf> (quoting *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003)).

¹⁶¹ *GlaxoSmithKline*, 7 F.4th at 1360 (quoting *AstraZeneca*, 633 F.3d at 1061).

¹⁶² *Caraco Pharm. Lab'ys, Ltd.*, 566 U.S. at 406 (citing 21 U.S.C. §§ 355(j)(2)(A)(v), (j)(4)(G) (2022)).

¹⁶³ *GlaxoSmithKline*, 7 F.4th at 1342.

¹⁶⁴ *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 25 F.4th 949, 955 (Fed. Cir. 2022) (“[T]he extent to which [labels might be pieced together] is an unreliable gauge of a generic's ‘intent’ in this highly regulated area.”).

¹⁶⁵ *GlaxoSmithKline*, 7 F.4th at 1345. (“In determining whether an ANDA applicant can ‘carve out’ the method of use, . . . [the FDA] will rely on the description of the approved use provided by the NDA holder or patent owner in the patent declaration and listed in the Orange Book”); *see* 68 Fed. Reg. at 36,682.

¹⁶⁶ Petition for Writ of Certiorari, *supra* note 146, at 33.

¹⁶⁷ *GlaxoSmithKline*, 7 F.4th at 1345; *see* Corrected Brief for Former Congressman Henry A. Waxman, *supra* note 141 at 10 (commenting that the majority decision “incentivizes brand [drug] companies to develop labels with an eye toward future infringement actions, wait for years to sue—as happened here— then hire experts willing to cherry-pick parts of skinny labels to show infringement”).

press release would always suffice to infer inducement.¹⁶⁸ This conclusion applied to future cases will have long-lasting effects on future pharmaceutical companies and consumers.

B. Healthcare and Economic Effects

1. Public Pushback

The majority decision in *GlaxoSmithKline* has been met with much pushback from law professors to pharmaceutical companies, to Congressman Henry Waxman himself.¹⁶⁹ Each of these critics wrote amicus briefs in support of Teva's petition for rehearing from October 2020 (after the panel majority released their first opinion).¹⁷⁰ These briefs echo much of Judge Prost's concerns about the ramifications of the majority's decision, including the clear conflict with legislative intent and the uncertain future of generic drug manufactures.¹⁷¹

Frustration of Congressional Purpose

One concern among amici was that *GlaxoSmithKline* contradicts the intent of Congress in enacting the Hatch-Waxman Act in the first place.¹⁷² It is well-known that the Act created a regulatory scheme that "provides a clear roadmap for generics to avoid infringement."¹⁷³ Congressman Waxman, one of the named legislators who proposed the Hatch-Waxman Act, points out that the majority's holding "effectively

¹⁶⁸ *GlaxoSmithKline*, 7 F.4th at 1341-42.

¹⁶⁹ See Corrected Brief for Former Congressman Henry A. Waxman, *supra* note 141; Corrected Brief of 14 Professors of Law as Amici Curiae in Support of the Petition for Rehearing En Banc, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, (Nos. 2018-1976, 2018-2023) (Fed. Cir. 2021) 2021 WL 5079132, <https://fedcircuitblog.com/wp-content/uploads/2021/10/Corrected-Brief-of-14-Professors-of-Law-as-Amici-Curiae-18-1976.pdf>; Brief for the Association for Accessible Medicines as Amicus Curiae in Support of the Petition for Rehearing En Banc, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, No. 1:14-cv-00878-LPS-CJB (Fed. Cir. 2021), 2021 WL 5003030, <https://fedcircuitblog.com/wp-content/uploads/2021/10/Brief-For-the-Association-for-Accessible-Medicines-as-Amicus-Curiae-in-Support-of-Rehearing-En-Banc.pdf>; see Corrected Brief for Mylan Pharmaceuticals, *supra* note 160; see Brief for Apotex Inc. *supra* note 157; Corrected Brief for Fifty-Seven Law, Economics, Business, Health, and Medicine Professors as Amici Curiae in Support Petition for Rehearing En Banc, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, No. 1:14-cv-00878-LPS-CJB (Fed. Cir. 2020), 2020 WL 7867875, https://fedcircuitblog.com/wp-content/uploads/2020/07/Glaxo_Amicus4.pdf.

¹⁷⁰ *GlaxoSmithKline*, 25 F.4th at 955 (Some of those critics revised their briefs to be in accordance with the majority's second opinion in August 2021).

¹⁷¹ See Corrected Brief for Former Congressman Henry A. Waxman, *supra* note 141, at 1 ("[T]he Majority's decision in this case is flatly inconsistent with the language of the Act and congressional intent"); Brief for Apotex Inc. *supra* note 157, at 3 ("The ramifications for the generic drug industry and consumers are enormous.").

¹⁷² Corrected Brief for Former Congressman Henry A. Waxman, *supra* note 141, at 1.

¹⁷³ *Id.* at 11; see Corrected Brief of 14 Professors of Law, *supra* note 169, at 4 ("The purpose of the section viii carve-out, then, is to ensure that generic manufacturers can efficiently deal with inducement of infringement during the ANDA approval process, consistent with Hatch-Waxman being 'designed to speed the introduction of low-cost generic drugs to market.'"); *Caraco Pharm. Lab'ys, Ltd.*, 566 U.S. at 405 (citing *Eli Lilly & Co.*, 496 U.S. at 676).

rescinds the protection Congress intended the section viii statement to confer when a generic ‘play[s] by the rules’ and ‘carve[s] out exactly what [the brand] said would infringe,’ as Teva did here.”¹⁷⁴ Before the Act, there was no streamline process for generics to get into the market.¹⁷⁵ So, “[t]he purpose of the section viii carve-out . . . is to ensure that generic manufacturers can efficiently deal with inducement of infringement during the ANDA approval process, consistent with Hatch-Waxman being ‘designed to speed the introduction of low-cost generic drugs to market.’”¹⁷⁶ Further, the majority’s holding essentially held the Act inapplicable by saying this is not a skinny-label case.

Issues also arose out of the majority’s creation of a direct conflict between patent law and the Hatch-Waxman Act.¹⁷⁷ The Act requires a generic to use the same labeling as its equivalent brand-name product with only limited exceptions, as part of the carve-out procedure that deals specifically with inducement.¹⁷⁸ This system ensured generics a speedy entry into the market with the guarantee that the generic will be equivalent in quality to the brand-name version.¹⁷⁹ However, this purpose becomes *frustrated* when brand name manufacturers are allowed to design their own labels in a way that pushes out generics from the market.¹⁸⁰ Additionally, the Association for Accessible Medicines found that the majority’s decision “[i]f allowed to stand . . . ‘would confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to confer,’ by allowing single method-of-use patents accounting for a small fraction of all uses of a drug to stifle the launch of generics.”¹⁸¹

Drug Manufacturing Concerns

¹⁷⁴ Corrected Brief for Former Congressman Henry A. Waxman, *supra* note 141, at 12 (quoting *GlaxoSmithKline*, 7 F.4th at 1342, 1357 (Prost, J., dissenting)).

¹⁷⁵ Frederick, *supra* note 41, at 2. Ralph Neas, president and CEO of the Generic Pharmaceutical Association stated:

The Hatch-Waxman Act is more than the cornerstone of the modern generic pharmaceutical industry; it is nothing short of a remarkable bipartisan legislative triumph. [The law] . . . demonstrates that good policy that embraces compromise can benefit all Americans. Brand drug makers have profited from a reasonable extension of patent protections, and generic manufacturers have benefited, as well, growing into a thriving industry that has produced approximately 12,000 safe, more affordable versions of brand drugs.

¹⁷⁶ Corrected Brief of 14 Professors of Law, *supra* note 169, at 5 (citing *Caraco Pharm. Lab'ys, Ltd.*, 566 U.S. at 405); see *Eli Lilly & Co.*, 496 U.S. at 676.

¹⁷⁷ Corrected Brief of 14 Professors of Law, *supra* note 169, at 1 (a brief was written by “14 professors of law, economics, business, health, and medicine” whose “sole interest in this case is to ensure that patent law develops in a way that serves the public interest and public health by promoting competition”).

¹⁷⁸ See Corrected Brief of 14 Professors of Law, *supra* note 169, at 1 (“By requiring ANDA applicants to make scattered revisions throughout their labels lest they induce infringement despite FDA approval of the label otherwise, the panel decision conflicts with this aspect of Hatch-Waxman.”).

¹⁷⁹ See *Caraco Pharm. Lab'ys, Ltd.*, 566 U.S. at 405.

¹⁸⁰ Corrected Brief of 14 Professors of Law, *supra* note 169, at 2 (“[T]he decision does not merely create dual tracks of liability that ANDA applicants must navigate; it creates a tension between the laws themselves insofar as one threatens to frustrate the other.”).

¹⁸¹ Brief for the Association for Accessible Medicines, *supra* note 169, at 11 (quoting *Warner-Lambert*, 316 F.3d at 1359).

In congruence with the frustration of Congressional intent, the briefs were concerned with the future of the pharmaceutical industry and the fate of generic drug manufacturers.¹⁸² Consequently, the outcome of *GlaxoSmithKline* puts generic manufacturers in an impossible position. On the one hand, they must stray from inserting much information on their label (as to avoid accusations of infringement). On the other hand, if they do not insert enough information, the FDA may be unsure whether they should grant the ANDA. The briefs find that the majority found statements of inducement in Teva's label not even in a “contiguous block, but in sentences embedded in three separate sections of the label.”¹⁸³ They further consider that “[a]voidance of inducement by excising snippets of text across the label--including text on dosing and administration--would likely prompt the FDA to question whether the drug remains safe and effective with that whittled-down label.”¹⁸⁴ The Department of Health and Human Services predicts the majority decision will “discourage the use of carve-outs and thus delay the approval of some generic drugs.”¹⁸⁵

As a result, similarly situated generics who apply for an ANDA will run the risk of rejection due to proactive efforts to protect themselves from infringement. For example, Apotex, a generic drug manufacturer, “who routinely file ANDAs and carve out patented uses from their drug labels,” weighed in on the controversy.¹⁸⁶ Apotex agreed that “[t]he ramifications for the generic drug industry and consumers are enormous-- many generic drug companies, like Apotex, will now forgo filing ANDAs for off-patent drugs that carve out patented indications and only seek approval for off-patent uses.”¹⁸⁷ This means that generic manufacturers will likely have to tread lightly when considering whether it is *even worth the burden* of going through the ANDA and Section viii carveout.

To that end, we may be looking at a future where some prescription drugs will cease to have a generic counterpart, setting the U.S. pharmaceutical industry back almost forty years. Generics drug manufacturers like Apotex need this decision to be reheard “to restore this Court's longstanding inducement jurisprudence.”¹⁸⁸

Future Infringements Suits

Multiple amici have asserted that because most skinny labels contain language that (with clever expert testimony) could be pieced together to satisfy a patent claim,

¹⁸² See, e.g., Corrected Brief of 14 Professors of Law, *supra* note 169; Brief for Apotex Inc. *supra* note 157.

¹⁸³ Corrected Brief of 14 Professors of Law, *supra* note 169, at 4 (emphasis added).

¹⁸⁴ Corrected Brief of 14 Professors of Law, *supra* note 169, at 4; see *ANDA Submissions--Refuse-to-Receive Standards: Guidance for Industry*, Food and Drug Admin.: Ctr. for Drug Evaluation & Rsch. (2016), <https://www.fda.gov/media/86660/download> (describing alterations to dosing regimens as reason for FDA to reject an ANDA).

¹⁸⁵ Corrected Brief for Mylan Pharmaceuticals, *supra* note 160, at 1 (quoting Xavier Becerra, *Comprehensive Plan for Addressing High Drug Prices*, U.S. Dep't of Health & Human Servs. (2021), https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf at 21).

¹⁸⁶ Brief for Apotex Inc *supra* note 157, at 3.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

essentially all these cases will now go to trial.¹⁸⁹ Future litigation is bound to pit prescription drugs against their generic counterparts more than ever, resulting in costly suits.¹⁹⁰ These suits will essentially consist of a battle of the experts, arguing to what degree the labels encourage infringement, and leaving the jury to decide who is most convincing.

Congressman Waxman was particularly concerned that generic pharmaceutical companies will be looking to this decision with concern as to the “uncertainty caused for ANDA applicants relying on Section viii—namely, that a generic manufacturer could later be found liable for infringing methods of use that were omitted from their labels under Section viii.”¹⁹¹ Further, he asserted that the majority did not lend any guidance to generic manufacturers as to how they can avoid infringement with their skinny label.¹⁹² It is not enough for the majority to merely say that there was substantial evidence of infringement, because as many have said, where does this leave future generics?

As the expiration of a prescription drug patent approaches, “major pharmaceutical companies have significant financial incentive to delay the inevitable competition that will result.”¹⁹³ In preparation for expiration, these companies “fil[e] . . . hundreds of patents” extending their “monopoly power far beyond the 20 years of patent protection intended under the law.”¹⁹⁴ Although drugmakers market [this practice] as incremental innovation and improvements,” it is an “abusive practice known as ‘evergreening.’”¹⁹⁵ This practice can be seen in a 2022 report from I-MAK, focusing on the top 10 drugs by 2021 U.S. sales. On average, there were “74 granted patents on each of these drugs,” providing a substantial advantage to these manufacturers to “keep generic and biosimilar competitors off the market.”¹⁹⁶ Evergreening makes it easy for brand manufacturers “to maintain its exclusivity merely by regularly filing a new patent application claiming a narrow method of use not covered by its original

¹⁸⁹ See, e.g., Brief for Apotex Inc., *supra* note 157 at 7 (asserting that brands will always “be able to present expert testimony at trial showing that physicians will subjectively ‘understand’ the generic’s label to ‘show’ or ‘meet’ elements of the claimed methods”); Corrected Brief for Mylan Pharmaceuticals, *supra* note 160, at 1 (noting that, under the panel majority’s “‘Where’s Waldo?’ approach to reading labels . . . [g]enerics cannot know if their labels are ‘true’ carve-outs until the jury speaks—years into litigation, itself filed years after the product launched”).

¹⁹⁰ Corrected Brief for Former Congressman Henry A. Waxman, *supra* note 141, at 6 (“If the panel’s decision stands, however, section viii products will face unwarranted litigation, and many will never launch. Indeed, brands are already invoking the majority’s reasoning”); see *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 2021 WL 3396199, (D. Del. Aug. 3, 2021).

¹⁹¹ Corrected Brief for Former Congressman Henry A. Waxman, *supra* note 141, at 4.

¹⁹² See *GlaxoSmithKline*, 7 F.4th at 1360 (Prost, J., dissenting) (“[I]t’s unclear what Teva even did wrong—or, put another way, what another generic in its shoes should do differently”); see Brief for Association for Accessible Medicines, *supra* note 169, at 3 (noting that “it would be difficult for any generic manufacturer to risk using a skinny label if the panel decision is allowed to stand”).

¹⁹³ INITIATIVE FOR MEDS., ACCESS & KNOWLEDGE (I-MAK), *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving up Drug Prices* (2022), <https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf> at 2.

¹⁹⁴ *Id.* at 2.

¹⁹⁵ *Id.* at 5.

¹⁹⁶ *Id.* at 2 (these manufacturers filed “more than 140 patent applications on average per drug” and “on average 66% of [these] applications were filed after the FDA approved the drug to be on the market”).

patent.”¹⁹⁷ These manufacturers can “use the threat of infringement actions as a sword against any competitor’s [application] seeking approval to market an off-patent drug for an approved use not covered by the patent.”¹⁹⁸

“The pharmaceutical industry is unique in the extent to which the regulatory regime explicitly recognizes the roles of innovation and competition.”¹⁹⁹ However, this highly regulated and “carefully crafted regime cannot work if the provisions fostering generic entry are undermined.”²⁰⁰ *GlaxoSmithKline* threatens to diminish generic competition, by giving brand-name manufacturers unfair advantages in generic ANDAs and the power to threaten generics with costly litigation.

2. Negative Consumer Impacts

The decision in *GlaxoSmithKline* threatens to bring in a new era of the perpetuation of brand name drug monopolies in a market where generic drugs are an economic and healthcare cornerstone.²⁰¹ There will be large downstream effects of this decision, and the “ultimate losers will be consumers who urgently need affordable medicine but will be forced to wait until every method-of-use patent has expired--a result directly contrary to Congress's goal in passing Hatch-Waxman.”²⁰²

Since the enactment of Hatch-Waxman, skinny labels have played an integral role in saving American consumers billions of dollars by using the generic version of their brand name, and more expensive, counterpart.²⁰³ The FDA reported that generic drugs approved in 2018 yield annual savings of \$17.8 billion, \$24.8 billion in 2019, and \$10.7 billion in 2020.²⁰⁴ Although generics are typically lower in price than the brand name version, the cost of prescription drugs rose 3% year-over-year from December 2018 to 2019.²⁰⁵ However, in 2018, one in four families reported difficulty in paying for their prescriptions, and a staggering nineteen million Americans (or eight percent of the

¹⁹⁷ Corrected Brief for Former Congressman Henry A. Waxman, *supra* note 141, at 15 (quoting *Warner-Lambert*, 316 F.3d at 1359 (internal quotes omitted)).

¹⁹⁸ *Id.*

¹⁹⁹ Corrected Brief for Fifty-Seven Law, Economics, Business, Health, and Medicine, *supra* note 169, at 2.

²⁰⁰ *Id.*

²⁰¹ INITIATIVE FOR MEDS., ACCESS & KNOWLEDGE (I-MAK), *supra* note 193, at 4.

²⁰² Corrected Brief for Mylan Pharmaceuticals, *supra* note 160, at 2; see *GlaxoSmithKline LLC*, 25 F.4th at 955 (“[The panel majority’s decision] gives brands a powerful tactic: neglect to identify language as patent-covered, then sue a generic for including that very language.”).

²⁰³ ASS’N FOR ACCESSIBLE MEDS., *Securing Our Access & Savings: 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report* (2020), <https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf>, at 16; see Corrected Brief for Fifty-Seven Law, Economics, Business, Health, and Medicine Professors, *supra* note 169, at 2-3 (“skinny-labeling plays an indispensable role in expediting generic entry and bringing more affordable medicines to consumers. The panel decision threatens this balance by allowing brand companies to improperly block the marketing of generic drugs for indications no longer covered by patents, thus reducing generic competition.”).

²⁰⁴ Ryan Conrad, et. al, *Estimating Cost Savings from New Generic Drug Approvals in 2018, 2019, and 2020*, FDA (2022), <https://www.fda.gov/media/161540/download>, at 3.

²⁰⁵ U.S. BUREAU OF LABOR STATISTICS, *Consumer Price Index: 2019 in review* (Jan. 16, 2020), <https://www.bls.gov/opub/ted/2020/consumer-price-index-2019-in-review.htm>.

population) were purchasing their medicines overseas due to high drug prices.²⁰⁶ No family should have to go out of their way to seek access to much-needed medicines. Although Hatch-Waxman has allowed generics to come into the market more seamlessly, saving Americans money, there are still accessibility issues.²⁰⁷ This problem will certainly not be fixed by discouraging generics or subjecting them to costly infringement suits.

Allowing more generics into the market fuels generic competition, which ultimately lowers costs.²⁰⁸ In a 2017 poll, lowering prescription drug prices was cited as the most critical issue by voters.²⁰⁹ This is important to voters because as prices start to skyrocket, accessibility to those vital prescriptions begins to plummet for most Americans.²¹⁰ In another survey, out of a list of actions that would keep prescription drug prices down, 88% of adults favored making it easier for generic drugs to come into the market.²¹¹ Voters understand that generics equate to lower drug costs, which increases accessibility.²¹²

Loss of access to pharmaceuticals will take a toll on vulnerable populations like those with low income and those suffering from long-term conditions. Those suffering from conditions which need to be maintained through prescriptions, such as seizure disorders or heart disease, will not be able to stabilize their condition because they cannot afford their medication.²¹³ As a result, they will not be able to work, and thus will not be able to make the money to afford their prescription. More than 13% of American adults, or about 34 million people, reported knowing of at least one friend or family member in the past five years who died after not receiving needed medical treatment because they were unable to pay for it.²¹⁴ This is unacceptable. It should not be the case that patients are dying because they cannot afford treatment. This is especially true where there is a cheaper version of a brand name drug that is just as effective.

²⁰⁶ Ashley Kirzinger, et. al., *Kaiser Health Tracking Poll: November 2016*, THE HENRY J. KAISER FAM. FOUND. (Dec. 1, 2016), <https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-november-2016/>.

²⁰⁷ *Id.*

²⁰⁸ Conrad, *supra* note 204, at 3.

²⁰⁹ POLITICO-HARVARD T.H. CHAN SCHOOL OF PUB. HEALTH, *The Public's Views of Tax Reform and Other Domestic Issues* (2017), <https://www.politico.com/f/?id=0000015e-a4d7-d873-adfe-bdd740140000>, at 3.

²¹⁰ Dan Witters, *Millions in U.S. Lost Someone Who Couldn't Afford Treatment*, GALLUP (November 12, 2019), <https://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx> (“[M]ost respondents agree that U.S. consumers are paying too much for prescription drugs.”).

²¹¹ Liz Hamel, et al., *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAM. FOUND. (Oct. 20, 2022), <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>.

²¹² See INITIATIVE FOR MEDS., ACCESS & KNOWLEDGE (I-MAK), *supra* note 193, at 2.

²¹³ Thomas Goetz, MPH, MA, *Health Insurance Aside, Americans Still Struggle to Pay for Their Medications*, GOOD RX HEALTH (Nov. 25, 2018), <https://www.goodrx.com/healthcare-access/drug-cost-and-savings/health-insurance-aside-americans-still-struggle-to-pay-for-their-medications> (29% of Americans failed to take their medications as prescribed because of the cost, with about 19% of respondents saying they did not fill the prescription and 12% saying they cut pills in half or skipped a dose).

²¹⁴ Witters, *supra* note 210, at 1.

The Hatch-Waxman Act’s generic drug program has saved patients, the federal government, and other payers trillions of dollars.²¹⁵ Although the majority insisted that its decision is a “narrow, case-specific review of substantial evidence [that] does not upset the careful balance struck by the Hatch-Waxman Act regarding section viii carve-outs, the impact of [*GlaxoSmithKline*] is unfortunately not so limited.”²¹⁶ The majority’s decision will reach far beyond the walls of the courtroom, and extend into pharmacies, boardrooms, and importantly, the homes of millions of Americans.²¹⁷ *GlaxoSmithKline* has not only setback the little progress that has been made towards making drugs more affordable, but it has crushed the hope that drug monopolies will be stopped any time soon.²¹⁸

V. CONCLUSION

It is hard to see how Teva, who followed the FDA’s rules and described its drug as the equivalent of GSK’s drug, could have induced infringement.²¹⁹ The decision in *GlaxoSmithKline* threatens to contradict the purpose of both the Hatch-Waxman Act and the patent system itself.²²⁰ The Hatch Waxman Act was enacted to ensure generics a speedy entry into the market with the guarantee of equivalent quality as the brand-

²¹⁵ ASS’N FOR ACCESSIBLE MEDS, *supra* note 203, at 16; Corrected Brief for Fifty-Seven Law, Economics, Business, Health, and Medicine, *supra* note 169, at 4 (“Generic competition would save consumer, as well as the federal and state governments, millions of dollars each year”); Brief for Association for Accessible Medicines, *supra* note 169, at 5 (“Since 1984, patients (and the taxpayers who fund public health programs like Medicare) have saved billions of dollars by using generic versions of expensive drugs for unpatented uses.”).

²¹⁶ Corrected Brief for Former Congressman Henry A. Waxman, *supra* note 141, at 14 (quoting *GlaxoSmithKline LLC*, 7 F.4th at 1326) (internal quotations omitted).

²¹⁷ *See, e.g.*, Brief for Association for Accessible Medicines, *supra* note 169, at 10-11 (quoting *GlaxoSmithKline LLC*, 7 F.4th at 1360 (Prost, J., dissenting)) (commenting that “The panel’s attack on Hatch-Waxman will harm the millions of American patients who benefit from cost-effective generic drugs. The decision continues to provide a roadmap for bringing inducement claims that will chill generic availability—even for manufacturers such as Teva that were “about as faithful as it gets” in adhering to Congress’s skinny label framework”).

²¹⁸ *See* Brief for Mylan Pharmaceuticals, *supra* note 160 (quoting *Warner-Lambert*, 316 F.3d at 1359) (“If the panel’s decision stands, however, section viii products will face unwarranted litigation, and many will never launch. Indeed, brands are already invoking the majority’s reasoning, hoping to monopolize every use of their drugs ‘merely by regularly filing a new patent application claiming a narrow method of use.’”).

²¹⁹ *GlaxoSmithKline*, 7 F.4th at 1343 (“[t]he majority is willing to see culpable intent behind a generic’s describing its product as ‘equivalent’ of a brand drug—in a system that *requires* generic drugs to be equivalent”); *see also* 21 U.S.C. § 355(j)(2)(A)(iv) (2022); *see* Brief for Former Congressman Henry A. Waxman, *supra* note 141, at 7 (quoting *GlaxoSmithKline*, 7 F.4th at 1342, 1357 (Prost, J., dissenting)) (commenting that the majority opinion “effectively rescinds the protection Congress intended the section viii statement to confer when a generic ‘play[s] by the rules’ and ‘carve[s] out exactly what [the brand] said would infringe’”).

²²⁰ Brief of 14 Professors of Law, *supra* note 169, at 1 (“[T]he panel’s treatment of inducement opens up a direct conflict between patent law and the Hatch–Waxman Act amendments to the Federal Food, Drug, and Cosmetic Act”); *see* Brief for Former Congressman Henry A. Waxman, *supra* note 141, at 6-7.

name version.²²¹ The patent system was built on the idea of promoting progress of science and the useful arts, seeing that innovation and “refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.”²²²

The majority’s decision gained the attention of policymakers, drug manufacturers, and health organizations.²²³ Those who wrote amicus briefs come from different areas of expertise but unify based on the negative impacts which this decision imparts on their respective industries.²²⁴ As Judge Prost stated in her dissent and the many amici briefs indicate, while the majority insisted that its “narrow, case-specific review of substantial evidence [that] does not upset the careful balance struck by the Hatch-Waxman Act regarding section viii carve-outs, the impact of [*GlaxoSmithKline*] is unfortunately not so limited.”²²⁵

The decision itself gives courts in future cases much to consider when looking at inducement of infringement, especially with regards to “the demarcation between describing an infringing use and encouraging that use.”²²⁶ This distinction, or lack thereof, could cause problems for generics who want to bring their generic version to market.²²⁷ When deciding future cases, courts should consider the negative impacts of

²²¹ See *Caraco Pharm. Lab’ys, Ltd.*, 566 U.S. at 405; Brief for Former Congressman Henry A. Waxman, *supra* note 141, at 2 (“For decades the Hatch-Waxman Act has been instrumental in maintaining the availability of less expensive but equally safe and effective generic medicines”); Brief of 14 Professors of Law, *supra* note 169, at 2 (commenting that the majority “relies on product advertisements and government submissions that a product is ‘equivalent’ to another to find inducement of a method-of-use patent” and that this practice is “problematic insofar as it denies basic comparative product information to consumers. That problem is especially concerning given that statements of product equivalence are found in a range of industries beyond generic drugs, such as biosimilars, mechanical repair parts, and information and communication technology”).

²²² *Bonito Boats, Inc.*, 489 U.S. at 146; U.S. CONST. art. I, § 8, cl. 8.

²²³ See, e.g., Brief of 14 Professors of Law, *supra* note 169, at 2 (“[T]he decision does not merely create dual tracks of liability that ANDA applicants must navigate; it creates a tension between the laws themselves insofar as one threatens to frustrate the other”); Brief for Former Congressman Henry A. Waxman, *supra* note 141, at 3 (explaining that through the Hatch-Waxman Act, “Congress attempted to foresee and close loopholes and in so doing anticipated the very scenario at issue in this case and addressed it[,] [but] [t]he Majority decision ignore[d] the legislative text and undermine[d] Congress’s careful and considered ‘legislative plan’”).

²²⁴ See Brief for Apotex Inc., *supra* note 157, at 8 (“[*GlaxoSmithKline*] has provided brands with a blueprint for securing crippling damages awards against generics who carve out patented methods to avoid Hatch-Waxman litigation. Brands can simply lie in wait to sue on their method patents, as GSK did”); Brief for Mylan Pharmaceuticals, *supra* note 160, at 1 (“This case remains exceptionally important—to patent law, to the pharmaceutical industry, and to those needing affordable medicine . . . By effectively nullifying section viii and upending induced infringement law, the decision promises both to generate unnecessary litigation and to stifle the launch of affordable drugs, all to consumers’ detriment”).

²²⁵ Brief for Former Congressman Henry A. Waxman, *supra* note 141, at 14 (quoting *GlaxoSmithKline*, 7 F.4th at 1326) (internal quotations omitted).

²²⁶ Brief for the Association for Accessible Medicines, *supra* note 169, at 4; see *Takeda Pharm. USA, Inc.*, 785 F.3d at 631 (“When the alleged inducement relies on a drug label’s instructions, [t]he question is not just whether [those] instructions describ[e] the infringing mode . . . but whether the instructions teach an infringing use such that we are willing to infer from those instructions an affirmative intent to infringe the patent. The label must encourage, recommend, or promote infringement.”).

²²⁷ See, e.g., Brief for Apotex Inc., *supra* note 157, at 8-9 (“[T]he panel majority disregarded the statutory and regulatory structure of Hatch-Waxman and the carve out statute, in particular, to hold

GlaxoSmithKline on drug manufacturing, such as discouraging generics in the marketplace and the unfair advantage given to brand name manufacturers.²²⁸ Beyond these crucial impacts, there are detrimental downstream effects on the healthcare industry, and courts need to consider the ultimate impacts on patients and consumers who need access to affordable medical treatment.²²⁹

that what GSK told [the] FDA in a sworn declaration about what the '000 patent claims covered in the brand label . . . did not negate Teva's specific intent to induce infringement. This renders the carve out statute nearly impossible for generics to comply with.”)

²²⁸ See *GlaxoSmithKline*, 7 F.4th at 1361 (“The only clear thing now is that no generic can know until hit with the bill whether it's staying within the confines of the law”); See Brief for Apotex Inc., *supra* note 157, at 3 (“many generic drug companies . . . will now forgo filing ANDAs for off-patent drugs that carve out patented indications and only seek approval for off-patent uses.”).

²²⁹ See Brief for Mylan Pharmaceuticals Inc., *supra* note 160, at 2 (noting the “ultimate losers will be consumers who urgently need affordable medicine but will be forced to wait until every method-of-use patent has expired--a result directly contrary to Congress's goal in passing Hatch-Waxman”); Brief for Association for Accessible Medicines, *supra* note 169, at 4 (“[T]he losers will be American patients, who will be deprived of low-cost, high-quality generic and biosimilar alternatives that are non-infringing.”).