

GENERIC DRUGS AND THE FUTURE OF “SKINNY LABELS”

*Jonathan A. Bell**

TABLE OF CONTENTS

I. INTRODUCTION.....	660
II. PHARMACEUTICALS AND PATENT LAW	661
<i>A. The Patent Bargain</i>	661
<i>B. The Hatch-Waxman Act’s Dual Purposes</i>	663
<i>C. Skinny Labels</i>	665
III. CARVEDILOL, THE PATENTS-IN-SUIT, AND TEVA’S SKINNY LABELS	667
<i>A. Carvedilol</i>	667
<i>B. Patents-in-Suit</i>	668
<i>C. Teva’s Skinny Labels</i>	669
IV. <i>GSK v. TEVA</i> AT THE FEDERAL CIRCUIT	670
<i>A. The Majority Decision</i>	671
1. Induced Infringement	671
2. Causation.....	674
<i>B. Judge Prost’s Dissent</i>	674
1. Lack of Induced Infringement.....	675
2. A Dire Warning.....	676
V. SKINNY LABELS “GONE AWRY”	677
<i>A. Conflict with Dual Purposes of Hatch-Waxman</i>	677
<i>B. A Shift in Precedent</i>	679
<i>C. Going Forward</i>	682
1. The FDA’s Role in Induced Infringement.....	682
2. A Surprising Solution.....	683
VI. CONCLUSION	687

* William & Mary Law School, Candidate for J.D., 2022; University of Pennsylvania, M.S., Chemistry, 2016; University of Pennsylvania, B.A., Biochemistry, 2016. I would like to thank Professor Sarah R. Wasserman Rajec for her encouragement and invaluable feedback through multiple iterations of this Note when it was an independent project. This Note would not be possible without the diligent and thoughtful work of Julianne Orr and the other student editors of *JOLT*.

I. INTRODUCTION

In July 2014, international pharmaceutical giant GlaxoSmithKline (GSK) sued the generics company Teva Pharmaceuticals (Teva) for induced infringement of patents related to the congestive heart failure drug carvedilol.¹ Following a seven-day trial, a jury found Teva had willfully induced infringement of GSK's carvedilol patent by encouraging doctors to prescribe generic carvedilol for a patented off-label use — that is, the use still covered by GSK's remaining patent.² The district court disagreed and found for Teva as a matter of law.³ On appeal, the Federal Circuit reversed in a 2-1 decision.⁴ However, the opinion was met with sharp backlash, including media criticism,⁵ several amicus briefs,⁶ and ultimately a petition for rehearing.⁷

On rehearing, the same Federal Circuit panel once again found for GSK, but issued a new decision aimed at tempering the backlash the original received.⁸ The majority panel was unsuccessful in their endeavor to calm concerns.⁹ Amici, legal commentators, and academics decried the new opinion as an existential threat to the entire generic pharmaceutical market.¹⁰ Despite these concerns, a majority of the

1. Complaint for Patent Infringement at 1, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582 (D. Del. 2018) (No. 14-cv-00878).

2. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582, 584–85, 589 (D. Del. 2018).

3. *Id.* at 599.

4. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347 (Fed. Cir. 2020), *vacated-in-part*, 7 F.4th 1320 (Fed. Cir. 2021), *denial of reh'g en banc*, 25 F.4th 949 (Fed. Cir. 2022).

5. *E.g.*, Beth Snyder Bulik, 'Skinny Labeling' Under Fire: GSK, Teva Federal Court Decision Undermines Common Practice, *FIERCE PHARMA* (Jan. 22, 2021, 7:30 PM), <https://www.fiercepharma.com/marketing/skinny-labeling-under-fire-gsk-teva-federal-court-decision-undermines-common-practice> [<https://perma.cc/A4DV-PJQ6>].

6. *E.g.*, Corrected Brief of Amici Curiae Fifty-Seven Law, Economics, Business, Health, & Medicine Professors in Support of Cross-Applicant's Petition for Rehearing En Banc, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021) (No. 18-1976), 2020 WL 7867875.

7. Order on Petition for Rehearing at 2, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021) (No. 18-1976), ECF No. 181 ("Oral argument shall be limited to the following issue raised in Teva Pharmaceuticals USA, Inc.'s petition for en banc rehearing: whether there is substantial evidence to support the jury's verdict of induced infringement during the time period from January 8, 2008 through April 30, 2011. We find all other issues to be sufficiently briefed.")

8. *See* *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1323–26 (Fed. Cir. 2021).

9. *See, e.g.*, *GlaxoSmithKline*, 7 F.4th at 1342 (Prost, J., dissenting).

10. *See* Kevin Dunleavy, *GSK Again Scores \$235M in 'Skinny Label' Case, but Court Admits It's 'Unclear What Teva Even Did Wrong'*, *FIERCE PHARMA* (Aug. 6, 2021, 9:35 AM), <https://www.fiercepharma.com/pharma/court-reaffirms-235m-judgement-for-gsk-against-generic-manufacturer-teva-skinny-label-case> [<https://perma.cc/U7KG-CC3A>].

Federal Circuit denied Teva’s petition for rehearing en banc.¹¹ The case is currently on remand to the District of Delaware.¹² The district court must decide a pending equitable estoppel defense — a theory of the case the majority of the Federal Circuit appears to view favorably.¹³

This Note seeks to explore this revised decision and its implications for the continued existence of the generics pharmaceutical market in the United States. Part II of this paper overviews the Hatch-Waxman Act and previews the concept of “skinny labeling.” Part III overviews the factual background of the case, including the patenting, labeling, and marketing of carvedilol. Part IV then details the rationale of the Federal Circuit panel, as well as the dissenting opinion of Judge Prost. Finally, Part V argues that this decision, despite the alarm it produced, is the inevitable result of a subtle but consistent shift in Federal Circuit jurisprudence over the past decade. Part V then proposes a new “carve-out” to induced infringement liability for generic pharmaceuticals more aligned with the dual purposes of the Hatch-Waxman Act.

II. PHARMACEUTICALS AND PATENT LAW

A. The Patent Bargain

Any inventor who “invents or discovers any new and useful process”¹⁴ that satisfies statutory requirements of patentable subject matter,¹⁵ utility,¹⁶ novelty,¹⁷ nonobviousness,¹⁸ and who enables “any person skilled in the art to which it pertains” to understand their patent,¹⁹ is granted “the right to exclude others from making, using, or selling the invention throughout the United States” for a period of 20 years.²⁰ This exchange — exclusivity for disclosure — embodies the “carefully crafted bargain” of patent law.²¹

11. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 25 F.4th 949, 950 (Fed. Cir. 2022).

12. *Id.* at 952.

13. *Id.* at 953 (“[E]quitable estoppel [is] the natural vehicle to address the concerns the dissents express over GSK’s representations to the FDA We should not grant Teva’s en banc petition to consider altering our settled inducement law standards based on fairness concerns that are central to the equitable estoppel defense not yet addressed.”).

14. 35 U.S.C. § 101.

15. *Id.*

16. *Id.*

17. 35 U.S.C. § 102.

18. 35 U.S.C. § 103.

19. 35 U.S.C. § 112.

20. 35 U.S.C. § 154.

21. SARAH BURSTEIN, SARAH R. WASSERMAN RAJEC & ANDRES SAWICKI, *PATENT LAW: AN OPEN-ACCESS CASEBOOK* 23 (2021).

The pharmaceutical industry as we know it would not exist without this patent bargain.²² “Due to the high costs of researching diseases, developing treatments, and traversing the FDA approval process, patents are thought to be necessary to encourage pharmaceutical companies to develop and commercialize new therapies.”²³ Patent protections following these research, development, and regulatory costs are arguably necessary incentives for pharmaceutical companies to bring a drug to market and disclose their inventions to the public.²⁴ The belief that patent incentives drive innovation is inherent to patent law itself.²⁵ The monopoly granted by the patent is thought to provide the motivation for an inventor to invent in the first place.

Due to “[l]engthy development times, extensive clinical trials and regulatory requirements, and the low probability of success,” pharmaceutical companies regard patent protection as a necessary and proper tool for recuperating research and development costs within the industry.²⁶ Thus, pharmaceutical companies must be profit-motivated in order to deliver life-saving medication.²⁷ However, these high costs and patent-granted monopolies create a conflict with the consumer/patient: while drugs may be available for consumption, they are often

22. See, e.g., 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.”); Kevin Outterson, *Fair Followers: Expanding Access to Generic Pharmaceuticals for Low- and Middle-Income Populations*, in *THE POWER OF PILLS: SOCIAL, ETHICAL & LEGAL ISSUES IN DRUG DEVELOPMENT, MARKETING & PRICING* 164, 166 (Jillian Clare Cohen et al. eds., 2006) (“[T]he analogy between tangible and intangible property breaks down [for the pharmaceutical industry] Tangible goods are rivalrous. They suffer from exhaustion and congestion. But most intangibles are non-rivalrous, including the biomedical knowledge which forms the basis of the pharmaceutical industry.”).

23. Sachs, *supra* note 22, at 503.

24. See *id.*

25. See U.S. CONST., art. I, § 8, cl. 8 (“To promote the Progress of Science and useful Arts”). But see Mark Eccleston-Turner, *The Economic Theory of Patent Protection and Pandemic Influenza Vaccines: Do Patents Really Incentivize Innovation in the Field?*, 42 AM. J.L. & MED. 572, 572–73 (2016).

26. Kristina M. Lybecker, *Social, Ethical, and Legal Issues in Drug Development, Marketing, and Pricing Policies: Setting Priorities Pharmaceuticals as Private Organizations and the Duty to Make Money/Maximize Profits*, in *THE POWER OF PILLS*, *supra* note 22, at 25, 27 (“Given the ease of replicating chemical and pharmaceutical innovations, [intellectual property rights] protection, through product and process patents, ensures that the research is able to appropriate the returns to R&D.”). Widely cited cost estimates of bringing a new drug to market — including research, development, clinical studies, and regulatory approval — calculate a necessary investment of \$802 million. Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 151 (2003).

27. See Joel Lexchin, *The Pharmaceutical Industry and the Pursuit of Profit*, in *THE POWER OF PILLS*, *supra* note 22, at 11, 12 (“[B]ut the caveat has always been that there is no contradiction between profit-seeking behavior and delivering medications that satisfy healthcare needs.”).

inaccessible due to price.²⁸ This problem is particularly pronounced in the United States, where brand-name drug prices are often 30–40% higher than in other developed countries.²⁹ This problem is only compounded when considering Americans’ lower rate of drug insurance.³⁰ To help rebalance this conflict between innovation and access, Congress enacted the Hatch-Waxman Act.³¹

B. The Hatch-Waxman Act’s Dual Purposes

The Drug Price Competition and Patent Term Restoration Act of 1984,³² commonly known as the Hatch-Waxman 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.”³³ The Act specifically sought to strike that balance “at the close of a patent term,” thus ensuring a branded drug enjoys the full length of its patent term while allowing a generic drug to quickly enter the market upon that patent’s expiration.³⁴ To strike this balance, the Act created an expedited pathway for generic drug approval, a statutory “safe harbor” to shield generic drug manufacturers from allegations of patent infringement, and patent term extensions for pioneer drugs.³⁵

The Hatch-Waxman Act established the Abbreviated New Drug Application (ANDA), a new process for seeking market approval for a drug.³⁶ A generic pharmaceutical company may file an ANDA for a generic drug if the active ingredient of the drug is “bioequivalent” to the listed or reference product.³⁷ Further, “[a]n ANDA allows a generic drug manufacturer to rely on safety and efficacy data developed by the original manufacturer” when obtaining its approval.³⁸

28. See Michael J. Selgelid & Eline M. Sepers, *Patents, Profits, and the Price of Pills: Implications for Access and Availability*, in *THE POWER OF PILLS*, *supra* note 22, at 153.

29. Lexchin, *supra* note 27, at 15 (“Nearly all developed countries, with the exception of the U.S., exercise some control over drug prices. In the absence of price controls, pharmaceutical manufactures set U.S. prices for brand-name products at levels that are, in general 30–40 per cent higher than those in Canada and Europe . . .”).

30. *Id.*

31. See *infra* notes 32–35 and accompanying text.

32. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271).

33. *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

34. *Novo Nordisk v. Caraco Pharm. Lab’ys, Ltd.*, 601 F.3d 1359, 1360 (Fed. Cir. 2010).

35. JOHN R. THOMAS, CONG. RSCH. SERV., R44643, *THE HATCH-WAXMAN ACT: A PRIMER* 5 (2016).

36. *Id.* at 6.

37. *Id.*

38. *Id.*; see also *infra* Sections II.B, III.C, V.C.1.

In an ANDA, a generic manufacturer must make one of four certifications to the Food and Drug Administration (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.”³⁹ These certifications are referred to as paragraph I, II, III, and IV certifications, respectively.⁴⁰

The filing of an ANDA with a paragraph IV certification constitutes a “somewhat artificial” act of patent infringement.⁴¹ The Hatch-Waxman Act specifically requires the generic manufacturer to notify the branded patent owner of the patents that are the subject of a paragraph IV certification.⁴² The patent owner may then sue an ANDA applicant for infringement in a federal district court.⁴³ This process is aimed at providing “sufficient time [for the parties] to resolve their patent dispute before the ANDA applicant introduce[s] its generic product to the market.”⁴⁴

Alternatively, an ANDA applicant may seek approval through a section viii “carve-out” statement.⁴⁵ Through ANDA, a generic drug applicant may seek a limited approval of some methods of use that are not patent-protected — and are not listed in the “Orange Book.”⁴⁶ The Orange Book is the name commonly used to refer to the FDA’s list of approved drugs, published as *Approved Drug Products with Therapeutic Equivalence Evaluations*.⁴⁷ The Orange Book, in theory, should list

39. 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV).

40. Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 189 (1999).

41. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990); accord THOMAS, *supra* note 35, at 7.

42. 21 U.S.C. § 355(j)(2)(B)(i).

43. 35 U.S.C. § 271(e)(2). If this infringement litigation is brought within forty-five days of the ANDA notice, the FDA must suspend approval of the ANDA until one of the following occurs: (1) the district court decides that the listed drug’s patent is either invalid or not infringed; (2) the listed drug’s patent expires, if the court finds the listed drug’s patent was infringed; or (3) after thirty months have passed from the date the owner of the listed drug’s patent received notice of the paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iii).

44. THOMAS, *supra* note 35, at 8.

45. 21 U.S.C. § 355(j)(2)(A)(viii) (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”).

46. See *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582, 586 n.4 (D. Del. 2018).

47. See *id.*; 21 U.S.C. § 355(b)(1)(A)(viii) (“Such persons shall submit to the Secretary as part of the application . . . the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person . . . engaged in the manufacture, use, or sale of the drug.”); 21 C.F.R. § 314.3(b) (“Listed drug status is evidenced by the drug product’s identification in the current edition of [the Orange Book] . . . as an

all patents related to an approved drug, including both composition⁴⁸ and method of use patents.⁴⁹

Essentially, section viii statements allow a generic ANDA applicant to remove or “carve out” specified, patent-protected indications for a new drug.⁵⁰ A section viii statement will explain that the ANDA applicant does not seek approval for a patent-protected use and that the uses for which it does seek approval are not currently protected by a patent.⁵¹ After still-patented uses are “carved out,” what remains is a skinny label.⁵² Together patent term extensions and multiple paths to an ANDA satisfy the dual purposes of the Hatch-Waxman Act: patent extensions incentivize brand-name pharmaceuticals to develop and pioneer new drug discoveries, and ANDA pathways incentivize generic pharmaceutical companies to bring cheap alternative drugs to market.⁵³

C. Skinny Labels

Briefly, before discussing the principal case, an explanation of “skinny labels” is necessary. Drug labels constitute the printed information packaged with any drug product and are highly regulated by the FDA.⁵⁴ A drug label includes a description of the drug, its indications (approved uses), warnings, adverse events, dosage and administration information, clinical safety data, and more.⁵⁵ Method patents often, but not always, protect the indications listed on a drug label following clinical development by a brand-name pharmaceutical company.⁵⁶ When that method patent expires, a generic company will often begin the

approved drug. A drug product is deemed to be a listed drug on the date of approval for the NDA or ANDA for that drug product.”).

48. 21 C.F.R. § 314.53(b)(1) (“For patents that claim the drug substance, the applicant must submit information only on those patents that claim the drug substance . . . or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending [application].”).

49. *Id.* (“For patents that claim a method of use, the applicant must submit information only on those patents that claim indications or other conditions of use for which approval is sought or has been granted in the [application].”).

50. *See* THOMAS, *supra* note 35, at 7. It is normally the case that the patent has expired but sometimes the intended method of use was never patented to begin with. *See, e.g.*, Glaxo-SmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320, 1323 (Fed. Cir. 2021).

51. *See* THOMAS, *supra* note 35, at 7.

52. *See id.*

53. *See id.* at 5.

54. *What’s in a Drug Product Label?*, U.S. FOOD & DRUG ADMIN. (May 6, 2016), <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-whats-drug-product-label> [<https://perma.cc/CZ4H-P3D2>].

55. *See id.*

56. *See* ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET 103 (2017). *But see* GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 313 F. Supp. 3d 582, 588 (D. Del. 2018).

process of bringing a generic drug equivalent to market, and in the process create a skinny label.⁵⁷ This borrowed hypothetical is illustrative:

Suppose a hypothetical brand-name drug is used to treat both allergy symptoms and back pain. However, the brand-name drug company that discovered this drug only possesses a method patent for use of this drug to treat back pain. In this hypothetical, a generic company may bring a generic drug to market by declaring their generic drug will only be sold to treat allergies. The protected use (back pain) will be “carved out” of the label, excluding any description of the patented use from the prescribing information. What remains is a “skinny label,” specifying only the non-patented indication (allergy symptoms).⁵⁸

Through skinny labeling, generic manufacturers can bring generic drugs to market sooner.⁵⁹ Instead of waiting for all method patents associated with a branded drug to expire,⁶⁰ a generic manufacturer may manufacture and sell the drug for non-patented indications — expired or otherwise.⁶¹ When a generic manufacturer applies for an ANDA, they must provide the FDA with “information to show that the labeling proposed for the new drug *is the same as* the labeling approved for the listed drug”⁶² The FDA only allows changes to the label that show the new drug “has a different active ingredient[,] . . . route of administration, dosage form, or strength differ[ent] from that of a listed drug;”⁶³ that reflect a change in manufacturer;⁶⁴ or for a section viii carve-out.⁶⁵ In total, a skinny label must be the same as a branded label, except that it may not mention any still-patented indications.

Together, ANDA, paragraph IV litigation, section viii carve-outs, skinny labels, and patent term extensions attempt to strike a balance between encouraging innovation of new brand-name drugs and

57. FELDMAN & FRONDORF, *supra* note 56, at 103.

58. *Id.* at 102–03.

59. See Arti Rai, *Use Patents, Carve-Outs, and Incentives — A New Battle in the Drug-Patent Wars*, 367 NEW ENG. J. MED. 491, 491 (2012) (“If the FDA finds this narrower labeling acceptable from the standpoint of safety and efficacy, the generic version has a potential path to market.”).

60. This is a long and fraught process. See generally Robin Feldman, *May Your Drug Prices Be Evergreen*, 5 J.L. & BIOSCIENCES 590 (2018).

61. See, e.g., *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1343–44 (Fed. Cir. 2021) (discussing generic approval for indications that were never patented).

62. 21 U.S.C. § 355(j)(2)(A)(v) (emphasis added); see also 21 C.F.R. § 314.53(b)(1).

63. 21 U.S.C. § 355(j)(2)(C).

64. 21 U.S.C. § 355(j)(2)(A)(v).

65. 21 U.S.C. § 355(j)(2)(A)(viii).

reducing the cost of generic drugs after a branded patent has expired.⁶⁶ In other words, the Hatch-Waxman Act constitutes a rebalancing of the patent bargain. And overall, the Act has been widely successful in striking this balance.⁶⁷

III. CARVEDILOL, THE PATENTS-IN-SUIT, AND TEVA’S SKINNY LABELS

The development of carvedilol, GSK’s numerous and successive patents for carvedilol and its associated methods, and Teva’s multiple skinny labels offer a complicated history of facts in the principal case.

A. Carvedilol

Carvedilol, sold under the name Coreg⁶⁸ by GSK, is a beta-blocker used to treat a series of cardiovascular conditions.⁶⁹ Initially approved in 1995 for congestive heart failure (CHF), the branded drug is now approved for mild to severe heart failure, left ventricular dysfunction (LVD) following a heart attack, and hypertension.⁷⁰

Carvedilol is a widely successful drug. In 2019 alone, estimates show that over 4.5 million patients in the United States were prescribed the drug, with over 20 million individual prescriptions filled.⁷¹ This made carvedilol the 33rd most prescribed drug in the United States.⁷² Additionally, carvedilol is a relatively inexpensive drug: the average

66. See THOMAS, *supra* note 35, at 5.

67. See, e.g., Lybecker, *supra* note 26, at 28–29 (“Since the [Hatch-Waxman Act] was passed, the generic industry’s share of the U.S. prescription drug market has grown from 19% to 47%. Prior to 1984, generic entry occurred three to five years following patent expiry. Many generic products now enter the market as soon as the innovator’s patent expires.”); see also FELDMAN & FRONDORF, *supra* note 56, at 20 (“Today, almost 90 percent of all prescriptions in the United States are filled using generic medications When a generic is introduced into a market previously monopolized by a brand-name drug, the generic drug normally enters at a 20 percent discount from the branded medication . . . and the price falls quickly from that point.”).

68. Throughout this Note, both GSK’s Coreg and Teva’s generic drug will be referred to individually and collectively as “carvedilol.” When necessary, this Note will distinguish between versions of carvedilol by using its brand name, Coreg, or the term “generic carvedilol.”

69. GlaxoSmithKline, Coreg (carvedilol phosphate) U.S. Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/022012s010s0131bl.pdf [https://perma.cc/22YN-2D7S].

70. *Id.*

71. *Carvedilol*, CLINICALC (2021), <https://clincalc.com/DrugStats/Drugs/Carvedilol> [https://perma.cc/3VWG-KMTK].

72. *Id.*

cost of a prescription is \$30.34.⁷³ This price amounts to an average out-of-pocket cost for patients of only \$0.09 per day.⁷⁴

B. Patents-in-Suit

Carvedilol was first patented on March 5, 1985.⁷⁵ This first patent (“the ’067 patent”) claimed only the underlying composition of matter for carvedilol.⁷⁶ In the early 1990s, GSK researchers discovered that, in addition to treating high blood pressure, carvedilol was effective at treating CHF.⁷⁷ As a result of this research, the FDA approved the drug for treatment of CHF in May 1997, leading to the launch of Coreg.⁷⁸ In February 1998, under the Hatch-Waxman Act, the United States Patent and Trademark Office (USPTO) extended the ’067 composition of matter patent term by five years until March 5, 2007 — meaning it is now expired.⁷⁹ Then, in June 1998, the USPTO issued a method patent covering the same research (“the ’069 patent”).⁸⁰ Following further research, GSK eventually obtained FDA approval for carvedilol for three indications: (1) mild- to severe- CHF, (2) LVD following a heart attack in clinically stable patients, and (3) high blood pressure.⁸¹ GSK later decided to correct what it viewed as errors in the ’069 patent, culminating in a reissued patent in January 2008 (“the ’000 patent”).⁸²

73. *Id.*

74. *See id.* However, it should be noted that carvedilol has not always been this inexpensive. While historic data on carvedilol prior to Teva entering the generic market is unavailable, for a brief period in 2014 (following the initiation of the underlying litigation) the average cost of carvedilol doubled to \$59.42. Out-of-pocket costs peaked at \$10.06. *Id.*

75. *See* U.S. Patent No. 4,503,067 (filed Mar. 5, 1985).

76. *See id.*; 35 U.S.C. § 101 (“Whoever invents or discovers any new . . . composition of matter . . . may obtain a patent therefor.”).

77. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582, 586 (D. Del. 2018).

78. *Id.*

79. *See id.*; 35 U.S.C. § 156 (“The term of a patent which claims a product . . . shall be extended . . . by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued . . .”).

80. Method of treatment for decreasing mortality resulting from congestive heart failure, U.S. Patent No. 5,760,069 (issued June 2, 1998). The ’069 patent claimed “[a] method of decreasing mortality caused by [CHF] in a patient in need thereof which comprises administering a therapeutically acceptable amount of carvedilol in conjunction with one or more other therapeutic agents, . . . consisting of an angiotensin converting enzyme inhibitor (ACE), a diuretic, and digoxin.” *Id.* at col. 8 ll. 27–33.

81. Coreg (carvedilol phosphate) U.S. Prescribing Information, *supra* note 69, at 1; *see also GlaxoSmithKline*, 313 F. Supp. 3d at 586.

82. *See GlaxoSmithKline*, 313 F. Supp. 3d at 586; *see also* U.S. Patent No. RE40,000 (issued Jan. 8, 2008). The ’000 patent reissued the same independent claim as the ’069 patent, but added the following after “digoxin”: “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.” ’000 Patent, at col. 8 ll. 36–40. The eight remaining dependent claims in the ’000

C. Teva’s Skinny Labels

Despite its FDA approval for multiple indications, GSK only marketed carvedilol for CHF.⁸³ As such, the FDA published the ’069 patent, and subsequently the ’000 patent, in the Orange Book,⁸⁴ only under use code U-233, “decreasing mortality caused by congestive heart failure.”⁸⁵ This limited Orange Book listing directly impacted Teva’s approach to its generic carvedilol skinny label. In March 2002, after the ’069 patent had been issued but before it was reissued as the ’000 patent, Teva filed an ANDA⁸⁶ seeking permission to market generic carvedilol tablets.⁸⁷ As part of its ANDA, Teva submitted a paragraph IV certification⁸⁸ asserting that the ’069 patent was invalid.⁸⁹ Teva further requested its ANDA not be given final approval until a second Orange Book-listed patent (the ’067 patent concerning carvedilol’s composition of matter) expired in March 2007.⁹⁰

After the ’067 patent expired, Teva sought to label its generic carvedilol for post-heart attack LVD and hypertension, “carving out” the CHF indication.⁹¹ GSK’s patents only claimed a method for using carvedilol to treat CHF; as such, the other FDA-approved indications were available for generic use.⁹² When the ’067 composition of matter patent expired in 2007, fourteen generic companies began to market and sell carvedilol, including Teva.⁹³ On September 5, 2007, Teva received

patent involve dosage limitations for carvedilol and various combinations with other heart medications, including ACE inhibitors. *Id.* at col. 8 ll. 41–65.

83. *GlaxoSmithKline*, 313 F. Supp. 3d at 588.

84. *See supra* notes 46–49 and accompanying text.

85. *GlaxoSmithKline*, 313 F. Supp. 3d at 586, 587.

86. *See supra* Section II.B. A generic manufacturer must establish that the generic drug is “bioequivalent” to the listed drug to obtain approval. 21 U.S.C. § 355(j)(2)(A)(iv). Not only must the ANDA show the generic drug has the same active ingredient as the listed drug, 21 U.S.C. § 355(j)(2)(A)(ii), but the route of administration, dosage form, and strength must also be equivalent, 21 U.S.C. § 355(j)(2)(A)(iii). The generic drug must also have the same labeling as the listed drug, 21 U.S.C. § 355(j)(2)(A)(v), except it may omit infringing uses (i.e., the generic manufacturer may print a skinny label). 21 U.S.C. § 355(j)(2)(A)(viii); 21 C.F.R. § 314.127(a)(7) (“[T]he labeling proposed for the [new] drug is the same as the labeling approved for the listed drug referred to in the ANDA except for changes required because . . . the listed drug’s labeling are protected by patent.”).

87. *GlaxoSmithKline*, 313 F. Supp. 3d at 587.

88. Paragraph IV certifications refer to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Under paragraph IV, an ANDA applicant must submit a certification that, to the best of their knowledge, “each patent which claims the listed drug . . . or which claims a use for such listed drug . . . is *invalid or will not be infringed* by the manufacture, use, or sale of the new drug for which the application is submitted . . .” 21 U.S.C. § 355(j)(2)(A)(vii) (emphasis added).

89. *GlaxoSmithKline*, 313 F. Supp. 3d at 587.

90. *Id.*

91. *See id.*

92. *Id.*

93. *Id.*

FDA approval for its generic tablets and its skinny label — which listed all carvedilol uses but CHF.⁹⁴

IV. *GSK v. TEVA* AT THE FEDERAL CIRCUIT

In July 2014, GSK sued Teva for induced infringement of its method patents related to the use of carvedilol for CHF.⁹⁵ After a jury verdict in favor of GSK, the district court found that substantial evidence did not support the finding of induced infringement as a matter of law.⁹⁶ On appeal in a 2-1 decision, the Federal Circuit reversed, upholding the jury verdict.⁹⁷ Following backlash and petition for rehearing, the same panel once again found for GSK but issued a new decision hoping to temper the criticism the original decision received.⁹⁸ As made clear by the dissent, the majority was not successful in doing so: “This new opinion does little to assuage, and even exacerbates, concerns raised by the original.”⁹⁹ Generic pharmaceutical manufacturers, patent law scholars, Congressman Waxman himself, and Judge Prost in her dissent all sounded the alarm — with this current decision, the generics market and the practice of skinny labels may be eliminated.¹⁰⁰ Following this precedent, “it’s unclear what Teva even did wrong — or, put another way, what another generic in its shoes should do differently.”¹⁰¹ More to the point, “this case signals that our law on this issue has gone awry.”¹⁰²

94. *Id.*

95. Complaint for Patent Infringement at 1, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582 (D. Del. 2018) (No. 14-cv-00878).

96. *GlaxoSmithKline*, 313 F. Supp. 3d at 597, 599.

97. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347, 1357 (Fed. Cir. 2020).

98. *See GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1323 (Fed. Cir. 2021). The Federal Circuit panel acknowledged this backlash and the need for rehearing: “*Amici* were concerned that our prior decision could be read to upset the careful balance struck with section viii carve-outs . . . [W]e agreed to rehear this case to make clear how the facts of this case place it clearly outside the boundaries of the concerns expressed by *amici*.” *Id.* at 1326 (citations omitted); *see also* Corrected Brief for *GlaxoSmithKline*, *supra* note 6; Dunleavy, *supra* note 10.

99. *GlaxoSmithKline*, 7 F.4th at 1361 (Prost, J., dissenting).

100. *Teva Pharmaceutical’s Petition for Rehearing En Banc at 1, GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1323 (Fed. Cir. 2021) (No. 18-1976) (“Judge Prost’s dissent and a host of critics — generic and brand manufacturers, law professors, and Congressman Waxman himself — all recognized that the decision placed every skinny-labeled generic at risk.”).

101. *GlaxoSmithKline*, 7 F.4th at 1360 (Prost, J., dissenting).

102. *Id.* at 1343 (majority opinion).

A. The Majority Decision

The majority opinion included consideration of the following questions: (1) did Teva’s skinny label induce infringement of GSK’s patent, and (2) was there sufficient causation between Teva’s actions and the infringement?¹⁰³

1. Induced Infringement

To infringe a patent, one does not need to infringe it directly; “[w]hoever actively *induces* infringement of a patent shall be liable as an infringer” as well.¹⁰⁴ Induced infringement is a particularly attractive theory of liability for pharmaceutical patentees: while generic drugs with skinny labels carve out patented uses in order to be noninfringing, physicians and patients may nevertheless prescribe and use the generic drug for still-patented uses (or off-skinny-label uses).¹⁰⁵ By suing generic competitors for inducement, brand-name pharmaceuticals avoid the ill-advised strategy of suing one’s customer base (here either physicians or patients) for the infringing activity. Instead, a generic manufacturer that distributes marketing materials or a skinny label that teaches an infringing use “can be found liable for distributing instructions on using goods according to a patented method.”¹⁰⁶

While direct infringement is usually considered a strict liability tort with no intent requirement,¹⁰⁷ to show a defendant induced infringement of a third party, the plaintiff must show that the defendant “possessed specific intent to encourage another’s infringement and ha[d] taken ‘affirmative steps to bring about [that] desired result.’”¹⁰⁸ The specific intent of induced infringers is not usually at issue in generic pharmaceutical litigation such as the principal case; through ANDA, the generic manufacturer must be explicitly aware of any existing

103. *Id.* at 1326–40.

104. 35 U.S.C. § 271(b) (emphasis added).

105. This litigation strategy becomes even more attractive when generic manufacturers market the drug for off-skinny-label uses or distribute labels with information that could lead to even inadvertent off-skinny-label use. See Sarah R. Wasserman Rajec, *Infringement, Unbound*, 32 HARV. J.L. & TECH. 117, 152 (2018) (“Induced infringement is an attractive theory to rights holders who are unable to enforce their patents through contributory infringement, often because there are substantial noninfringing uses for the distributed goods. In these circumstances, the alleged inducer can be found liable for distributing instructions on using goods according to a patented method.” (footnote omitted)).

106. *Id.*

107. See, e.g., Saurabh Vishnubhakat, *An Intentional Tort Theory of Patents*, 68 FLA. L. REV. 571, 573 (2016).

108. *GlaxoSmithKline*, 7 F.4th at 1349 (Prost, J., dissenting) (quoting *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006)) (alteration in original); see also Rajec, *supra* note 105, at 152 (“The intent requirement for indirect infringement . . . focuses explicitly on the alleged infringer’s state of mind . . .”).

brand-name patents and certify that said patents are invalid or otherwise that their generic drug will not infringe them.¹⁰⁹ Within the pharmaceutical space, there is a clear standard for induced infringement by generic manufacturers: “When a plaintiff relies on a drug’s label accompanying the marketing of a drug to prove intent, [t]he label must encourage, recommend, or promote infringement.”¹¹⁰

While Teva used a skinny label¹¹¹ and provided the FDA with a section viii certification carving out patented uses of carvedilol, GSK argued on appeal that Teva encouraged and induced infringing use of the drug through the skinny label’s description of the post-heart attack LVD indication, as well as Teva’s marketing materials.¹¹² Teva’s skinny label for post-heart attack LVD states: “Carvedilol is indicated to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of $\leq 40\%$ (with or without symptomatic heart failure)”¹¹³

As the majority opinion explains, experts for both GSK and Teva agreed that patients with “a left ventricular ejection fraction of less than or equal to 40% with symptomatic heart failure . . . would be diagnosed as suffering from congestive heart failure.”¹¹⁴ The majority opinion also found clinical studies cited in the partial skinny label disclosed information related to the dependent claims of the ’000 patent.¹¹⁵ Namely, clinical studies cited in the skinny label included data on patients taking carvedilol who had previously received ACE inhibitors and diuretics.¹¹⁶ Citing precedent, the Federal Circuit panel found that referencing this section essentially “direct[ed] the reader to that section for elaboration of the class of patients for whom the drug is indicated

109. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (establishing Paragraph IV certifications); 21 U.S.C. § 355(j)(2)(A)(viii) (establishing Section viii carve-outs); *see supra* Section II.B.

110. *GlaxoSmithKline*, 7 F.4th at 1327 (majority opinion) (citing *Takeda Pharm. USA, Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015)).

111. The district court and Federal Circuit deal with two distinct skinny labels during two time periods: a “partial label” that indicated generic carvedilol for post-heart attack LVD and hypertension but not CHF, and a “full label” that included the CHF indication. *Id.* at 1325. The “full label” was used during a time while the ’000 patent was still valid, and therefore induced infringement. *See id.* at 1339. Teva did not dispute that its full label contained all of the claim limitations. *Id.* at 1338. This Note is primarily concerned with the “partial label” period and will refer exclusively to that skinny label.

112. *Id.* at 1325–26, 1338.

113. *Id.* at 1328.

114. *Id.*

115. ’000 Patent col. 8 ll. 33–36 (issued Jan. 8, 2008) (claiming “carvedilol in conjunction with one or more other therapeutic agents, said agents being selected from the group consisting of an [ACE inhibitor], a diuretic, and digoxin”).

116. *GlaxoSmithKline*, 7 F.4th at 1328. GSK and its experts argue this satisfies language in claim 1 of the ’000 patent: “therapeutically acceptable amount of carvedilol in conjunction with one or more other therapeutic agents.” ’000 Patent col. 8 ll.32–34. The majority panel agreed. *GlaxoSmithKline*, 7 F.4th at 1328.

to achieve the stated objective.”¹¹⁷ The majority panel held that Teva’s skinny label did not sufficiently carve out all patented uses of carvedilol, resulting in an induced infringing use:

All of the claim limitations were contained in the Indication section (which amounted to a single sentence), the Clinical Study section (to which doctors were directly referred by the Indication section), and the Dosage and Administration section (which immediately follows the Indication section and which says how much and how often to give the carvedilol).¹¹⁸

Teva’s partial skinny label included an indication for post-heart attack LVD; that indication referred to the Clinical Study section; the Clinical Study section cited the CAPRICORN¹¹⁹ clinical trial.¹²⁰ Papers summarizing this clinical trial, in turn, referenced the success of the drug in patients with a history of CHF.¹²¹ Judge Prost later characterized this connection as a “‘cobb[ing] together’ of disparate portions of the partial label.”¹²²

The majority panel also relied some of on Teva’s marketing materials to support a finding of induced infringement.¹²³ First were product catalogs from 2008 and 2009, in which Teva described its generic carvedilol as “an AB rated therapeutic equivalent to Coreg.”¹²⁴ Second was a series of Teva press releases.¹²⁵ In one press release, following Teva’s tentative ANDA approval in 2004, Teva announced that its “[c]arvedilol Tablets are the AB rated generic equivalent of Glaxo-SmithKline’s Coreg[] Tablets and are indicated for *treatment of heart failure* and hypertension.”¹²⁶ The “heart failure” referenced did not

117. *GlaxoSmithKline*, 7 F.4th at 1328–29 (internal quotation mark omitted) (quoting *Sanofi v. Watson Lab’ys Inc.*, 875 F.3d 636, 645 (Fed. Cir. 2017)).

118. *Id.* at 1329.

119. The CAPRICORN study, or the “carvedilol post-infarct survival controlled evaluation trial” (stylized as CArvedilol Post-infaRct survival COntRolled evaluationN) was a placebo-controlled clinical trial designed to test the long-term efficacy of carvedilol on morbidity and mortality in patients with post-heart attack LVD. The Capricorn Investigators, *Effect of Carvedilol on Outcome After Myocardial Infarction in Patients with Left-Ventricular Dysfunction: The CAPRICORN Randomised Trial*, 357 LANCET 1385, 1385 (2001). The trial included patients with a history of chronic heart failure. *Id.* at 1386. The trial was coordinated by GSK and Roche Pharmaceuticals. *Id.* at 1389.

120. Teva, Carvedilol Tablet U.S. Prescribing Information, at 18, <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=68c275e8-992a-4520-8065-ab6d615d89cc> [<https://perma.cc/3P2Z-3B69>].

121. See The Capricorn Investigators, *supra* note 119, at 1385, 1389 nn.4–7.

122. *GlaxoSmithKline*, 7 F.4th at 1329.

123. *Id.* at 1335–38.

124. *Id.* at 1335.

125. *Id.*

126. *Id.* at 1335–36 (quoting the Joint Appendix at 6347) (emphasis added).

differentiate between CHF or post-heart attack LVD.¹²⁷ In 2007, Teva announced via press release that “its Generic version of Glaxo-SmithKline’s *cardiovascular agent* Coreg (Carvedilol) Tablets” had received final approval from the FDA.¹²⁸ By leaving “cardiovascular agent” undefined in the press release, the majority found that Teva left the world to “wonder about [generic carvedilol’s] uses.”¹²⁹

2. Causation

After demonstrating an inducing infringer possessed specific intent to encourage another’s infringement and took affirmative steps to bring about that infringement, the patent holder must show the inducing infringer’s actions actually *caused* the infringement it sought to bring about.¹³⁰ Here, Teva argued that they did not cause doctors to prescribe generic carvedilol for all of Coreg’s branded indications,¹³¹ pointing to extensive medical literature, treatment guidelines from the American Heart Association, and GSK’s own years of successful marketing for Coreg to argue that these information sources are what “made physicians aware of all the benefits of carvedilol for heart failure patients.”¹³² While the district court accepted this argument, the majority panel disagreed.¹³³ Believing this was a question properly presented to the jury and supported by substantial evidence, the majority reinstated the prior verdict.¹³⁴

B. Judge Prost’s Dissent

In an impassioned dissent, Judge Prost strongly disagreed with the majority panel’s finding of induced infringement and causation, describing the evidence for both as “thin to nonexistent.”¹³⁵ Instead, Judge Prost characterized the majority’s reasoning as “sometimes labored . . . [and] sometimes opaque” in order to “prop up a jury verdict that is unsupportable.”¹³⁶ As Judge Prost argued, the majority opinion found that Teva “intentionally encouraged” infringement of GSK’s Coreg, despite carving out everything GSK identified as an infringing

127. *Id.* at 1336.

128. *Id.* (emphasis added).

129. *Id.* at 1337.

130. *Id.* at 1349 (Prost, J., dissenting).

131. *Id.* at 1339 (majority opinion).

132. *Id.*

133. *Id.*

134. *Id.* at 1340.

135. *Id.* at 1342 (Prost, J., dissenting).

136. *Id.*

use — as required by ANDA procedure.¹³⁷ In dissent, Judge Prost argues the majority then inferred that doctors, writ large, “relied” on Teva’s skinny label to infringe GSK’s patent.¹³⁸ This is despite evidence presented at trial that cardiologists do not “even read the label to make prescribing decisions.”¹³⁹ Further, and “most troubling,” Judge Prost cautioned that “the majority is willing to see culpable intent behind a generic’s describing its product as the ‘equivalent’ of a brand drug — in a system that *requires* generic drugs to be equivalent, and in which everyone understands that generic drugs are equivalent.”¹⁴⁰ Judge Prost warned that the facts of this case and of this holding signal “our law on this issue has gone awry.”¹⁴¹

1. Lack of Induced Infringement

Most importantly, for Judge Prost, Teva demonstrated intent *not to* infringe by actively seeking a carved-out label.¹⁴² Judge Prost argued that no reasonable jury could have found the skinny label induced infringement; instead, at most the label “described the infringing use” and only “if pieced together just right.”¹⁴³ Judge Prost held that “describing [the infringing use] is not enough.”¹⁴⁴ Instead, for a skinny label “to induce [infringement], [it] must ‘encourage, recommend, or promote infringement’ ‘Merely describing an infringing use’ in a label ‘will not suffice.’”¹⁴⁵

Judge Prost expanded on this contention and argued that a finding of induced infringement should be impossible under these facts given the skinny labeling approval process.¹⁴⁶ Teva followed the procedures established by ANDA and section viii: “Teva took out the only indication GSK said was patented”¹⁴⁷ Judge Prost argued that all of this demonstrates Teva’s lack of intent — a required element of induced

137. *Id.* (emphasis omitted).

138. *Id.* (emphasis omitted).

139. *Id.* (emphasis omitted).

140. *Id.* at 1343.

141. *Id.*

142. *Id.* at 1342.

143. *Id.* at 1351 (emphasis omitted).

144. *Id.*

145. *Id.* at 1350–51 (internal citations omitted) (first quoting Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp., 785 F.3d 625, 631 (Fed. Cir. 2015); then quoting HZNP Meds. LLC v. Actavis Lab’ys UT, Inc., 940 F.3d 680, 702 (Fed. Cir. 2019)).

146. *See id.*

147. *Id.* at 1351.

infringement.¹⁴⁸ Judge Prost repeated this argument in her dissent to the denial of rehearing en banc.¹⁴⁹

Judge Prost further objected to the majority’s handling of the press releases:

[T]he majority holds that a generic can be deemed liable for inducement for saying that its product is a “generic version” or “generic equivalent” of a brand drug. This is a drastic holding. And it makes little sense. Essentially *all* ANDA generics are the “generic version” or “generic equivalent” of a brand drug; *the law requires them to be*. To come to market, such a generic must demonstrate that its product is bioequivalent to a brand drug.¹⁵⁰

Judge Prost was sounding an alarm: under this new standard, describing a generic product as a “generic” of a known, branded, listed drug opens a generic manufacturer up to liability for induced infringement, despite the legal requirement that the drug be “bioequivalent” to the listed drug.¹⁵¹ The law requires this equivalence, yet describing the drugs as such publicly now constitutes evidence of intent to induce infringement.¹⁵² The law was not originally designed to support this finding.¹⁵³

2. A Dire Warning

Judge Prost presented a warning to generics manufacturers: “[I]t’s unclear what Teva even did wrong — or, put another way, what another generic in its shoes should do differently.”¹⁵⁴ The facts in this case are seemingly no different from any other case concerning skinny labels: generic drugs will present as “bioequivalent” to the listed brand drug, as they are legally required to do; the generic company will rely on the brand company’s clinical trial data for safety and efficacy metrics; the generic company will use the “same” label as the brand;¹⁵⁵ the generic

148. *Id.*

149. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 25 F.4th 949, 954 (Fed. Cir. 2022) (Prost, J., dissenting) (“Regulations require the brand to identify exactly what label language corresponds to its patented uses, thus eliminating any guesswork as to what needs omitting to avoid infringement Teva, the generic here, followed that pathway.”).

150. *GlaxoSmithKline*, 7 F.4th at 1353 (emphasis added).

151. *See id.*

152. *See id.*

153. *GlaxoSmithKline*, 25 F.4th at 955 (Prost, J., dissenting) (“The system can’t work like this. Congress enacted the skinny-label provisions as a way for generics to avoid inducement liability — and thus litigation itself.”).

154. *GlaxoSmithKline*, 7 F.4th at 1360.

155. *See supra* notes 62–65 and accompanying text.

company will release press statements about the generic drug’s approval; doctors will make assumptions about the generic product based on their history with the brand product; pharmacies will make generic substitutions; and generic companies can reasonably suspect that some off-label (or off-skinny-label) use will occur, whether they induce that use or not.¹⁵⁶

Before this decision, a generic company that wanted to avoid infringing brand-name patents had the ability to omit the patented uses from its skinny label. Similarly, if a branded company wanted to block a skinny label from containing a patented use, it only had to include that use in its FDA patent declaration.¹⁵⁷ It appears “[t]hat equilibrium is no more.”¹⁵⁸

V. SKINNY LABELS “GONE AWRY”

The holding in this case conflicts with the dual purposes of the Hatch-Waxman Act but did not occur in a vacuum. Instead, this holding is the natural progression of a sequence of decisions from the Federal Circuit in this area. Going forward, if generic pharmaceutical companies are not careful, they may find themselves liable for induced infringement for the simple act of following FDA regulations. Instead, reevaluating the FDA’s role in the skinny labeling process and the congressional intent behind the Hatch-Waxman Act may be necessary to restore the balance between generic and branded pharmaceutical interests.

A. Conflict with Dual Purposes of Hatch-Waxman

When Congress enacted the Hatch-Waxman Act, it created a “complex statutory framework to balance generic and brand interests.”¹⁵⁹ With an ANDA, a generic manufacturer does not have to “rehash” the branded drug’s safety and efficacy data; instead, the generic must only show it is “bioequivalent” to the brand drug.¹⁶⁰ Once a generic company establishes bioequivalence, the generic drug’s proposed labeling must “essentially copy” the branded drug’s — omitting only the still-

156. See *supra* notes 62–65 and accompanying text.

157. *GlaxoSmithKline*, 7 F.4th at 1361.

158. *Id.*

159. *Id.* at 1343 (Prost, J., dissenting); see also *supra* Section II.B.

160. *GlaxoSmithKline*, 7 F.4th at 1353; 21 U.S.C. §§ 355(j)(2)(A)(iv), (j)(4)(F); 21 C.F.R. § 314.94(a)(7)(i). “Bioequivalence” is “the absence of a significant difference in the rate and extent to which the active ingredient . . . becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed [bioequivalence] study.” 21 C.F.R. § 314.3(b).

patented uses from the Indications section.¹⁶¹ This process follows Congress's intent "that a single drug could have more than one indication and yet that an ANDA applicant could seek approval for less than all of those indications."¹⁶² Essentially, Congress intended skinny labels to be a common practice. For skinny labels, the usual rule is "that a generic drug must bear the same label" as the branded reference product — except for section viii carve-outs.¹⁶³

This is exactly what happened here. At primary issue in the majority decision is the skinny label's description of generic carvedilol's use for post-heart attack LVD. The two descriptions are identical.¹⁶⁴ Importantly, the use described for post-heart attack LVD was never patented by GSK.¹⁶⁵ Teva carved out the specific indication for CHF by removing CHF from the "Indications" section of its skinny label.¹⁶⁶ However, limited language in the "Dosage and Administration" section of Teva's partial skinny label is now sufficient to show evidence of induced infringement.¹⁶⁷ This "Dosage and Administration" information was also reproduced from GSK's original label for Coreg, as required by the FDA regulations.¹⁶⁸

All of this culminates in a confounding yet inevitable result. When following specified FDA regulations under ANDA, including section viii carve-outs for skinny labels, any language that could drive a physician or pharmacist to find information on the branded drug's (other) patented uses may now constitute an act of induced infringement. Further, complying with the statutory and regulatory processes for creating skinny labels will help establish the intent requirement for inducing infringement by another. This situation could not be what Congress intended in enacting the Hatch-Waxman Act. Under this new standard, section viii carve-outs are effectively nullified; a skinny label can never

161. That is, a skinny label may have a section viii carve-out. *GlaxoSmithKline*, 7 F.4th at 1344 n.4 (Prost, J., dissenting) (citing 21 U.S.C. §§ 355(j)(2)(A)(i), (v), (j)(4)(G)); *see also* 21 U.S.C. § 355(j)(2)(A)(viii).

162. *GlaxoSmithKline*, 7 F.4th at 1344 (quoting *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406 (2012)).

163. *Id.*; *see also supra* notes 62–65.

164. As they should be. *Compare* Carvedilol Tablet U.S. Prescribing Information, *supra* note 120 ("Carvedilol tablets are indicated to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of less than or equal to 40% (with or without symptomatic heart failure) [*see Clinical Studies (14.2)*]."), with Coreg (carvedilol phosphate) U.S. Prescribing Information, *supra* note 69 ("COREG is indicated to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of less than or equal to 40% (with or without symptomatic heart failure) [*see Clinical Studies (14.2)*].").

165. *See supra* Section III.B.

166. *See* Carvedilol Tablet U.S. Prescribing Information, *supra* note 120.

167. *See supra* Section IV.A.

168. *See* Carvedilol Tablet U.S. Prescribing Information, *supra* note 120.

be skinny enough to avoid liability. The careful equilibrium struck by the Hatch-Waxman Act has thus been upended. The brand dictates the contents of its label, the FDA dictates that the generic label must be the same, and as a result, the generic label must infringe. This cannot be what Congress intended. The law “has gone awry.”¹⁶⁹

B. A Shift in Precedent

Prior cases from the Federal Circuit demonstrate how this decision may not be as surprising as its critics declare. Instead, it is the result of the gradual evolution of the Federal Circuit’s thinking in this area of law. This evolution began, at the latest, in 2010 with *AstraZeneca LP v. Apotex, Inc.*¹⁷⁰ Apotex’s drug budesonide, the generic form of AstraZeneca’s “Pulmicort Respules,” is an anti-inflammatory corticosteroid used for the treatment of asthma.¹⁷¹ In relevant part, AstraZeneca’s method patent claimed, “a new method of treating respiratory diseases such as asthma that involves administering a budesonide composition with a nebulizer *not more than once per day*.”¹⁷² The FDA-approved label for AstraZeneca’s branded drug allowed for the drug to be administered once or twice daily — meaning the twice-daily indication was not protected by AstraZeneca’s patent.¹⁷³ Apotex, as part of its ANDA, submitted a section viii statement asserting that it did not seek approval for the claimed, once-daily method.¹⁷⁴ However, Apotex’s proposed (and FDA-approved) generic label copied language from AstraZeneca’s “Dosage and Administration” section — as it was required to do.¹⁷⁵ The skinny label warned patients to “downward-titrate to the lowest effective dose once asthma stability is achieved.”¹⁷⁶ This statement was not infringing in itself. However, when combined with the smallest recommended starting dosage, the district court concluded, and the Federal Circuit affirmed, that this skinny label language “would lead many users to directly infringe the asserted method claims because titrating down . . . would necessarily lead to once-daily usage.”¹⁷⁷ “Even if . . . the downward titration language may be applied to other [non-infringing] dosing regimens, the language . . . would inevitably

169. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1343 (Fed. Cir. 2021) (Prost, J., dissenting).

170. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042 (Fed. Cir. 2010).

171. *Id.* at 1046.

172. *Id.* (emphasis added).

173. *See id.* at 1047.

174. *Id.*

175. *Id.*

176. *Id.*

177. *Id.* at 1049, 1059.

lead some consumers to practice the claimed method.”¹⁷⁸ This was enough. Language copied directly from the branded label — as was required — and “cobbl[ed] together”¹⁷⁹ with other information necessary for the safe administration of the drug constituted sufficient evidence to support a finding of induced infringement.¹⁸⁰

A case from 2017, *Sanofi v. Watson Laboratories Inc.*, demonstrates the next step in precedent that led to the result in *GlaxoSmithKline*.¹⁸¹ In *Sanofi*, defendant Watson Laboratories sought to market a generic version of Sanofi’s drug Multaq (generic dronedarone), a different heart medication.¹⁸² Like in *GlaxoSmithKline*, Watson sought to use the same language as the branded drug in its skinny label.¹⁸³ Similar to *GlaxoSmithKline*, Watson’s proposed skinny label also cited to a Clinical Studies section.¹⁸⁴ However, unlike *GlaxoSmithKline*, the “Clinical Studies” section in the proposed skinny label only defined one population of patients that qualified for the generic drug.¹⁸⁵ The clinical trial cited in the skinny label was designed to treat the exact patients described in Sanofi’s patent.¹⁸⁶ Or rather, Sanofi’s patent was written to describe the exact method discovered in the trial.¹⁸⁷ This was Watson’s critical error. The underlying patent at issue was expressly written to “meet[] conditions mirroring those stated in the . . . [clinical] trial.”¹⁸⁸ To cite to the trial was to describe, in detail, the patients that qualified for treatment and to teach the method claimed by Sanofi’s patent.¹⁸⁹

178. *Id.* at 1060.

179. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1329 (Fed. Cir. 2021) (quoting defendant brief).

180. *AstraZeneca*, 633 F.3d at 1059–60.

181. *Sanofi v. Watson Lab’s Inc.*, 875 F.3d 636 (Fed. Cir. 2017); *GlaxoSmithKline*, 7 F.4th at 1341.

182. *Sanofi*, 875 F.3d at 639.

183. *Id.* at 642–43; *GlaxoSmithKline*, 7 F.4th at 1324–25.

184. *Sanofi*, 875 F.3d at 643; *GlaxoSmithKline*, 7 F.4th at 1328.

185. *Sanofi*, 875 F.3d at 643; *GlaxoSmithKline*, 7 F.4th at 1325, 1330.

186. *Compare* The Capricorn Investigators, *supra* note 119, at 1385 (“We designed the . . . [CAPRICORN] study to test the hypothesis that the addition of carvedilol to standard modern management of acute myocardial infarction in patients with left ventricular dysfunction *with or without* heart failure.” (emphasis added)), *with* Stefan H. Hohnloser et al., *Effect of Dronedrone on Cardiovascular Events in Atrial Fibrillation*, 360 NEW ENG. J. MED. 668, 669 (2009) (“ATHENA . . . was designed to determine whether dronedarone would reduce the rate of the composite outcome of hospitalization due to cardiovascular events or death in patients with atrial fibrillation.”), *and* *Sanofi*, 875 F.3d at 642 (“A method of decreasing a risk of cardiovascular hospitalization in a patient, said method comprising administering to said patient an effective amount of dronedarone . . . wherein said patient has a history of, or current, paroxysmal or persistent non-permanent atrial fibrillation or flutter.” (quoting the patent-in-suit)).

187. *See Sanofi*, 875 F.3d at 642.

188. *Id.* at 642. *See generally* Hohnloser et al., *supra* note 186, at 668.

189. *See Sanofi*, 875 F.3d at 642.

In *GlaxoSmithKline*, the CAPRICORN trial¹⁹⁰ included some patients with CHF, allowing doctors to infer using carvedilol for an infringing use.¹⁹¹ In *Sanofi*, the clinical trial more directly described patients for whom the use would be infringing.¹⁹² The Federal Circuit merely expanded its induced infringement standard one minor step further.¹⁹³ Watson’s skinny label in *Sanofi* duplicated a “Clinical Studies” section.¹⁹⁴ That section included a study that described a patient population eligible for the drug.¹⁹⁵ Prescribing that drug to that patient population resulted in an infringing use.¹⁹⁶ Likewise, Teva’s skinny label in *GlaxoSmithKline* duplicated a “Clinical Studies” section.¹⁹⁷ That section included a study that described multiple patient populations.¹⁹⁸ Prescribing that drug to one of those patient populations resulted an infringing use.¹⁹⁹

The Federal Circuit’s induced liability doctrine stretched to allow for the combination (or cobbling together) of multiple sections of a skinny label — including sections that must be copied under FDA regulations.²⁰⁰ A physician, patient, or the court is free to combine language from the “Indication” section of the skinny label with the “Dosage” section²⁰¹ — or the “Clinical Studies” section.²⁰² If a clinical trial mentioned in the “Clinical Studies” section describes a patient population, that information may also be combined with the skinny label.²⁰³ Whether the trial describes one patient population or multiple makes little difference if infringing conduct occurs.²⁰⁴ The majority of the Federal Circuit made this explicit when it denied Teva’s petition for rehearing en banc: “[T]he cobbling together argument is a nonstarter.

190. See *supra* notes 119–22 and accompanying text.

191. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1328 (Fed. Cir. 2021).

192. *Sanofi*, 875 F.3d at 645.

193. *Compare id.* (“The reference to the Clinical Studies section (14) of the label expressly directs the reader to that section for elaboration of the class of patients for whom the drug is indicated to achieve the stated objective, *i.e.*, reduced hospitalization.”), with *GlaxoSmithKline*, 7 F.4th at 1328 (“The Clinical Studies . . . showed that patients taking carvedilol in the study had background treatment of ACE inhibitors and diuretics . . . [including patients with] symptoms of heart failure.”).

194. *Sanofi*, 875 F.3d at 645.

195. *Id.*

196. See *id.* at 646.

197. *GlaxoSmithKline*, 7 F.4th at 1328.

198. *Id.*

199. *Id.* at 1330.

200. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1048 (Fed. Cir. 2010).

201. *Id.* at 1058.

202. *Sanofi v. Watson Lab’s Inc.*, 875 F.3d 636, 645 (Fed. Cir. 2017).

203. *Id.*

204. See *GlaxoSmithKline*, 7 F.4th at 1328.

We regularly allow claim elements to be found in different portions of a label.”²⁰⁵

Along the way the generic company has no control of this label information.²⁰⁶ The generic company does not dictate the design of a clinical trial that leads to FDA approval; these choices belong to the brand-name manufacturer. The generic company does not dictate which “Clinical Safety” data must be included in their skinny label. And the generic company cannot dictate how a physician may combine these different sources of information together.

C. Going Forward

As it stands, this holding — that skinny labels referencing a “bio-equivalent” brand drug or merely duplicating the “Clinical Studies” section of a brand label incur liability for induced infringement — may have a devastating impact on the generic market.²⁰⁷

1. The FDA’s Role in Induced Infringement

The FDA shares responsibility here. As Judge Prost noted, “it’s unclear what Teva even did wrong,” primarily because they expressly followed FDA regulations.²⁰⁸ A skinny label for a generic drug must be “the same as the labeling approved for the listed drug.”²⁰⁹ The only significant change a skinny label may make is to exclude still-patented indications.²¹⁰

Along with these ANDA requirements, generic manufacturers must also comply with FDA regulations for all drug labels, including indication and usage statements,²¹¹ dosage and administration information,²¹² drug interactions,²¹³ and so on. Importantly, the FDA also requires the identification of relevant clinical studies that led to the drug’s approval.²¹⁴ The “Clinical Studies” section “must discuss those

205. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 25 F.4th 949, 951 n.2 (Fed. Cir. 2022) (citing *Sanofi v. Watson Lab’ys Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017)).

206. *See supra* notes 62–65 and accompanying text.

207. *GlaxoSmithKline*, 7 F.4th at 1360–61 (Prost, J., dissenting).

208. *Id.*

209. 21 U.S.C. § 355(j)(2)(A)(v); *see also supra* notes 62–65 and accompanying text.

210. *See supra* notes 62–65 and accompanying text.

211. 21 C.F.R. § 201.57(c)(2) (“This section must state that the drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition . . .”).

212. 21 C.F.R. § 201.57(c)(3) (“This section must state the recommended dose and, as appropriate: (A) The dosage range . . .”).

213. 21 C.F.R. § 201.57(c)(12).

214. 21 C.F.R. § 201.57(c)(15).

clinical studies that facilitate an understanding of how to use the drug safely and effectively.”²¹⁵

For generic drugs, that means the skinny label must always include references to the original clinical trial for which the branded drug gained approval. FDA regulations required Teva’s skinny label to reference the CAPRICORN trial.²¹⁶ By following the explicit requirements of the FDA, Teva was found liable for induced infringement. On the denial of Teva’s petition for rehearing en banc, three different dissents²¹⁷ noted this inherent conflict. It is unclear what Teva “should do differently.”²¹⁸ Under this holding, FDA requirements, and federal law, all skinny labels necessarily plagiarize branded drug labels, include reference to branded drug studies, and therefore induce infringement.²¹⁹ This paradox of law goes against the heart of the Hatch-Waxman Act’s dual purposes.²²⁰

2. A Surprising Solution

This conflict between intellectual property law and the Hatch-Waxman Act’s goals is not the first, nor is it likely to be the last. In 2000, in a case involving familiar players, a misapplication of intellectual property law to skinny labels threatened to foreclose the entire generics market.²²¹ In *SmithKline v. Watson*, the plaintiffs were the manufacturer of a high-strength prescription-only nicotine gum,

215. *Id.* (“Ordinarily, this section will describe the studies that support effectiveness for the labeled indication(s), including discussion of study design, population, endpoints, and results, but must not include an encyclopedic listing of all, or even most, studies performed as part of the product’s clinical development program.”).

216. The CAPRICORN trial was discussed in the GSK-label’s Clinical Studies section; Teva was required to duplicate this information. Coreg (carvedilol phosphate) U.S. Prescribing Information, *supra* note 69, at 28–29; *see also supra* notes 62–65 and accompanying text.

217. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 25 F.4th 949, 955 (Fed. Cir. 2022) (Prost, J., dissenting) (“When a generic plays by the skinny-label rules, the FDA-required label can’t be evidence of intent. Even if remaining label language might be pieced together to ‘meet’ the elements of a patent claim . . . it can’t meaningfully separate the liable from the lawful.”); *id.* at 959 (Dyk, J., dissenting) (“The FDA provided Teva with a redline for its skinny label, carving out the patented indication for congestive heart failure from GSK’s branded label and keeping the remaining uses in the label Thus, Teva was obligated to use the label at issue.”); *id.* at 960 (Reyna, J., dissenting) (“I am concerned that, if left untouched, the majority’s opinion may reasonably be read to mean that companies like Teva may be held liable for induced infringement despite demonstrated compliance with the statutory and regulatory requirements.”).

218. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1360 (Fed. Cir. 2021) (Prost, J., dissenting).

219. *See supra* Sections IV.A, IV.B.

220. *See supra* Section V.A.

221. *See SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 28 (2d Cir. 2000) (“The purposes of the Hatch-Waxman Amendments would be severely undermined if copyright concerns were to shape the FDA’s application of the ‘same’ labeling requirement.”).

Nicorette.²²² Defendants, Watson Laboratories, sought approval of a generic version of the gum under ANDA.²²³ To obtain FDA approval, Watson complied with all labeling requirements for the generic drug, including the requirement the proposed label “[be] the same as” the plaintiffs’ branded label.²²⁴ However, before Watson could bring its generic gum to market, SmithKline brought a copyright infringement suit, alleging Watson’s generic label willfully infringed its prescribing information.²²⁵ This would mean that, had SmithKline’s copyright claim been meritorious, it would be impossible for Watson to use the ANDA process to sell its generic nicotine gum because “it will either have to change the label and lose FDA approval or be enjoined from using a label that infringes SmithKline’s copyright.”²²⁶

While Watson responded with plausible fair use²²⁷ and implied license defenses, neither was necessary for the court to resolve the case.²²⁸ Instead, the court viewed the issue as “straightforward,” stating:

[T]he Hatch-Waxman Amendments to the [Federal Food, Drug, and Cosmetic Act] not only permit but require producers of generic drugs to use the same labeling as was approved for, and is used in, the sale of the pioneer drug, even if that label has been copyrighted. Because those Amendments were designed to facilitate rather than impede the approval and [over-the-counter] sale of generic drugs, *the FDA’s requirement that Watson use much of SmithKline’s label precludes a copyright infringement action by SmithKline.*²²⁹

As such, SmithKline’s copyright claim was “meritless.”²³⁰

In reaching this conclusion, the court resolved the inherent conflict between the Hatch-Waxman Act and the Copyright Act.²³¹ This

222. *Id.* at 23.

223. *Id.*

224. *Id.* (quoting 21 U.S.C. § 355(j)(2)(A)(v)) (alteration in original).

225. *Id.* at 23–24.

226. *Id.* at 27.

227. *Id.* at 25; *see also* 17 U.S.C. § 107.

228. *SmithKline*, 211 F.3d at 25. Watson and amici argued that by “submitting its copyrighted materials for FDA approval, SmithKline gave the FDA an implied, nonexclusive license to permit or require generic drug applicants to copy the user’s guide and audiotape in their own nicotine gum packaging.” *Id.*

229. *Id.* (emphasis added).

230. *Id.*

231. *Id.* at 27; *see also* 17 U.S.C. § 101 et seq.

conflict was resolved by considering the purposes of each act in turn.²³² If SmithKline had prevailed in this suit, “[t]he purposes of the Hatch-Waxman Amendments would be severely undermined if copyright concerns were to shape the FDA’s application of the ‘same’ labeling requirement.”²³³ After all, Congress designed the Hatch-Waxman Act to facilitate the introduction of generic competitors “by allowing the generic producer to piggyback upon the pioneer producer’s successful FDA application.”²³⁴ The court found that the goals of the Hatch-Waxman Act clearly outweighed those of the Copyright Act; the potential administrative cost that copyright compliance would place on the FDA review process — not to mention the issues that would arise with multiple, iterative generic companies attempting to produce unique, non-infringing labels for the same branded drug — was too high a burden.²³⁵ The court was clear such a requirement would defeat the purpose of the Hatch-Waxman Act:

Avoiding such infringement would also delay the introduction of the generic product without advancing public health and safety to any perceptible degree. For that reason, Congress left no room for such redundant proceedings and adopted the ‘same’ labeling requirement. The FDA cannot be faithful to that requirement, however, without requiring labels that will often violate copyrights. If copyright law were to prevail, producers of generic drugs will always be delayed in — and quite often prohibited from — marketing the generic product, results at great odds with the purposes of the Hatch-Waxman Amendments.²³⁶

In this rare instance of patent infringement, the law demands the same result. In *GlaxoSmithKline*, liability under a current intellectual property law regime was due to a generic manufacturer’s compliance with established FDA regulations. A Congressional and administrative requirement that “the labeling proposed for the new [generic] drug is the same as the labeling approved for the listed [reference] drug”²³⁷ would be “severely undermined” if that fact alone led to liability for

232. *SmithKline*, 211 F.3d at 27–28.

233. *Id.* at 28.

234. *Id.*

235. *Id.* (“If labels that were ‘substantially similar’ to copyrighted labels on pioneer drugs had to be avoided, the administrative process of approving a new label would . . . drain the resources of the FDA and generic producer — not to mention the problem of successive generic producers avoiding infringement of multiple copyrighted labels.”).

236. *Id.*

237. 21 U.S.C. § 355(j)(2)(A)(v).

induced infringement.²³⁸ Neither Congress nor the Court required the FDA to ensure copyright differentiability between branded and generic labels; nor should they require the FDA assess if a generic label enables induced infringement — a likely more administratively burdensome task.²³⁹ Congress was well aware of the FDA’s labeling requirements at the time that it enacted the Hatch-Waxman Act; it is illogical to assume Congress then intended for generics to be liable for induced infringement by complying with established law.²⁴⁰

To ensure the continued balance of the dual goals of the Hatch-Waxman Act, and the prevention of copycat litigation strategies by other brand-name pharmaceutical companies,²⁴¹ a “carve-out” to induced infringement law is necessary. Further, “the profit [incentives] sought by the creator of the pioneer drug” would not be substantially impacted by this carve-out.²⁴² In exchange for exclusivity periods and patent term extensions granted to pioneer companies, the Hatch-Waxman Act granted safe harbors and the streamlined ANDA process to generic companies, especially “at the close of a patent term.”²⁴³ Congress explicitly struck this balance and created the ANDA process, including the “same” label requirement, to accelerate the entry of generic drugs. Eliminating induced infringement liability under these very specific facts — when a generic manufacturer’s only inducing act is

238. *SmithKline*, 211 F.3d at 28.

239. *See id.* at 28; *see also* *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1061 (Fed. Cir. 2010) (“[W]e lack expertise in patent matters. An administrative process for reviewing patents, assessing patent challenges, and de-listing patents would involve patent law issues that are outside both our expertise and our authority.” (quoting statement by the FDA) (alteration in original)).

240. *See* *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 25 F.4th 949, 959 (Fed. Cir. 2022) (Dyk, J., dissenting) (“Canons of statutory construction demonstrate that the more specific and later-enacted provisions of the Hatch-Waxman Act override the general infringement provisions of the Patent Act.”); *accord* *SmithKline*, 211 F.3d at 29 (“Congress would have provided explicitly that the Hatch-Waxman Amendments trump the copyright laws had it foreseen the statutory conflict exposed by the present action . . .”).

241. *E.g.*, Brief for the Association for Accessible Medicines as Amicus Curiae Supporting Defendants, *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, No. 20-cv-01630, (D. Del. Aug. 20, 2021); *see also* Ian Lopez, *Amarin Drug-Label Case Imperils Low-Cost Competition, Group Says*, BLOOMBERG LAW (Aug. 20, 2021, 4:20 PM), <https://www.bloomberglaw.com/bloomberglawnews/health-law-and-business/XCM2T7QC000000> [<https://perma.cc/8DKT-YNX9>] (“Although the very intent of the skinny label regime is to allow generics to come to market as quickly as possible, the Report concludes that Amarin has stated a claim for inducement largely on the basis of allegations that Hikma did what the law requires.”). *But see* *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, No. CV 20-1630, 2022 WL 605734, at *2 (D. Del. Jan. 4, 2022) (“GSK is a ‘narrow, case-specific review.’” (quoting *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1326 (Fed. Cir. 2021))).

242. *SmithKline*, 211 F.3d at 29.

243. *Novo Nordisk A/S v. Caraco Pharm. Lab’ys, Ltd.*, 601 F.3d 1359, 1360 (Fed. Cir. 2010); *see also supra* Section II.B.

creating a skinny label that is “the same as”²⁴⁴ the brand label — does not invalidate or diminish the value of the brand company’s otherwise valid patent.²⁴⁵ The brand company may bring patent infringement claims, including induced infringement claims, “against potential infringers in other circumstances.”²⁴⁶ For example, if a generic company advertises its generic drug for still-patented indications, or distributes press releases that reference the branded drug’s full label, the generic company may be found liable for induced infringement. In this same scenario, a generic company that uses label-specific language in its advertisements, might also be liable for copyright infringement.²⁴⁷ However, if the only place the label language appears is in the label itself, this fact alone should be insufficient to support a finding for induced infringement.

VI. CONCLUSION

The recent holding in *GlaxoSmithKline v. Teva* has been labeled a threat to the generic pharmaceutical market as it currently exists in the United States. While the Hatch-Waxman Act created a careful balance between generic and brand-name pharmaceutical manufacturers, the scales are no longer balanced. By complying with FDA regulations for labeling and ANDA approvals, generic manufacturers can be liable as infringers, regardless of their underlying intent. This permissive finding of induced infringement by the Federal Circuit, while the natural evolution of recent case law, is incongruent with the congressional intent underlying the Hatch-Waxman Act. Instead, federal courts should allow a specified exception to induced infringement liability to correct this error, rebalance competing interests, and ensure the continued future of skinny labels. Just as skinny labels carve out still-patented drug uses, federal courts must carve out this exception to induced infringement liability. By following FDA regulations, generic companies are complying with the law. The courts should treat them as such.

244. 21 U.S.C. § 355(j)(2)(A)(v).

245. *Accord SmithKline*, 211 F.3d at 29 (“Even though such an owner cannot enforce its copyright against generic drug manufacturers who are required by the Hatch-Waxman Amendments to copy labeling and who do no more than that, it still retains a copyright, if otherwise valid, in the label and might well pursue copyright claims against potential infringers in other circumstances . . .”).

246. *Id.*

247. *See id.*