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Hacking or Hatching the Skinny Label: How the Federal Circuit's Decision in GSK v. Teva Threatens Generics and Induced Infringement

Kayla McCallum

Texas A&M University School of Law (Student), kayla_mccallum@tamu.edu

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**HACKING OR HATCHING THE SKINNY LABEL: HOW THE FEDERAL CIRCUIT’S
DECISION IN *GSK v. TEVA* THREATENS GENERICS AND INDUCED
INFRINGEMENT**

Kayla McCallum[†]

Abstract

*This Note focuses on the recent precedential decision handed down by the Federal Circuit in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, which impacts “one of the greatest public health inventions of the 21st century”: generic drugs. An invention that rose to prominence when former President Ronald Reagan signed into law the Hatch-Waxman Act (“the Act”), formally known as the Drug Price Competition and Patent Term Restoration Act of 1984. The Act aimed to increase competition between brand-name and generic manufacturers while balancing two seemingly opposing interests: (1) encourage and reward innovation by pioneer drug companies and (2) increase access to low-cost alternatives. This in-depth analysis will evaluate how the Federal Circuit’s decision has jeopardized the Act’s purpose and conflicts with present U.S. policy under the Biden administration. Additionally, it will offer a critical analysis of Katherine Eban’s book, *Bottle of Lies*, which chronicles the generic drug boom that transpired after the Act’s passage. Eban’s often one-sided account fails to provide depth and context to an industry vital to public health.*

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[†] Kayla McCallum is a J.D. Candidate at Texas A&M School of Law with a graduation date of May 2023. She would like to thank her incredible parents, Anthony and Lori, and siblings, Breanna and AJ, for their love, support, and encouragement. She would also like to thank Professor Ragavan for her willingness to provide guidance and insightful feedback.

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I. INTRODUCTION

In a call to action to reverse trends that threaten “the growth and dynamism” of the United States economy, President Biden issued Executive Order (“EO”) 14036.¹ This EO, signed on July 9, 2021, sought to promote robust competition to advance the “interests of American workers, businesses, and consumers.”² Notably, the EO concentrated on the high price of prescription drugs and healthcare services compared to other countries.³ It attributed these increased costs to the consolidation of the healthcare industry and patent laws, which can and have been misused to preclude and delay competition from generic pharmaceutical manufacturers.⁴ These impediments to competition have consequently undermined access to low-cost alternatives.⁵ The Biden Administration proffered its plan of aggressive legislation to lower drug prices and increase enforcement of antitrust laws in the healthcare market, citing that the intolerance of domestic monopolization could counter the rise of “unfair competitive pressures from foreign monopolies.”⁶

To address these challenges, the EO provided instructions to Janet Woodcock, the Secretary of the Department of Health and Human Services (“HHS”), which includes the Food and Drug Administration (“FDA”) agency.⁷ It instructed Woodcock to send a letter to Andrew Hirshfeld, the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

1. Exec. Order No. 14036, 86 Fed. Reg. 36987 (2021) [<https://perma.cc/Z44Y-MLNN>].

2. *Id.*; *Fact Sheet: Executive Order on Promoting Competition in the American Economy*, WH.GOV (July 9, 2021), <https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/> [<https://perma.cc/4GHH-RN58>].

3. Exec. Order No. 14036, *supra* note 1; Fact Sheet, *supra* note 2.

4. Exec. Order No. 14036, *supra* note 1; Fact Sheet, *supra* note 2.

5. Exec. Order No. 14036, *supra* note 1; Fact Sheet, *supra* note 2.

6. Exec. Order No. 14036, *supra* note 1; Fact Sheet, *supra* note 2.

7. Exec. Order No. 14036, *supra* note 1.

(“USPTO”).⁸ The objective of the letter was to reinforce that the patent system must incentivize innovation without “unjustifiably delay[ing] generic drug and biosimilar competition.”⁹ Woodcock acknowledged that although the FDA does not have a direct role in drug pricing, it plays an indirect role “by bringing efficiencies to the drug development and review process and by promoting robust competition.”¹⁰ In fulfilling the FDA’s commitment to identifying abuses, the September 10th letter discussed three anti-competitive patent practices by brand pharmaceutical companies: (a) patent thickets, (b) evergreening, and (c) product hopping.¹¹

In recognizing these patent abuses, Woodcock discussed the practice of patent thickets or continuation patents which ensue when brand companies file several patents on different aspects of the same drug.¹² Although these continuations typically lapse simultaneously with the parent patent, the practice increases litigation and delays the approval and subsequent launches of low-cost generic drugs and biosimilar products.¹³ Evergreening or post-approval modification occurs when patents are filed on secondary features of the same drug, such as new drug formulations, concurrently with the expiration of earlier patents, which extends the drug’s exclusivity on the market.¹⁴ Within the letter, Woodcock cited a study showing that 78% of drugs for which new patents were issued from 2005–2015 were for existing drugs, not new ones.¹⁵

8. *Id.*

9. Sabrina Poulos, *FDA’s Woodcock Reviews Patents Practices as a Way to Effect Drug Pricing*, JD SUPRA (Sept. 15, 2021), <https://www.jdsupra.com/legalnews/fda-s-woodcock-reviews-patents-5332115/;%20https://www.fda.gov/media/152086/download> [<https://perma.cc/9YCN-ZFGJ>].

10. *Access to Affordable Medicine, Hearing Before the S. Spec. Comm. on Aging* (2019) (statement of Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research).

11. Poulos, *supra* note 9.

12. *Id.*; *Stop Patent Abuse and Unleash Generic and Biosimilar Price Competition*, ASSOC. FOR ACCESSIBLE MEDS., <https://accessiblemeds.org/campaign/abuse-patent-system-keeping-drug-prices-high-patients> [<https://perma.cc/U885-TDUJ>] (“[P]atent thickets chill competition by discouraging competitors from entering a market because of the exorbitant cost of litigating meritless patents.”).

13. Poulos, *supra* note 9.

14. *Id.*; *Patent “Evergreening”: Issues in Innovation and Competition*, EVERY CRS REPORT (Nov. 13, 2009), <https://www.everycrsreport.com/reports/R40917.html> [<https://perma.cc/KVJ9-MSH9>] (“The practice is abusive, impedes the introduction of generic medications, and has a negative effect upon public health in the United States.”).

15. Zoey Becker, *Amid Drug Pricing Debate, Feds Plan to Crack Down on ‘Incremental’ Patents*, FIERCE PHARMA (July 7, 2022, 3:01 PM), <https://www.fiercepharma.com/pharma/uspto-and-fda-commit-patent-reform-cracking-down-lengthy-add-patents> [<https://perma.cc/WW6S-8W5T>].

The third patent practice known as product hopping occurs when brand companies remove an approved drug near the expiration of its patent and replace it with a modified but similar drug with a later-expiring patent.¹⁶ Consequently, all three practices impede competition from generic pharmaceutical companies.¹⁷

Woodcock offered four recommendations.¹⁸ First, she suggested collaboration between the FDA and USPTO to encourage the efficiency and quality of issued patents.¹⁹ Second, the FDA invited the USPTO to share their perspective on the three patent practices and whether they intended to take preventative action.²⁰ Third, the FDA inquired whether more resources or time would assist with sensitive and complex pharmaceutical patents.²¹ Lastly, the FDA solicited data on the Patent Trial and Appeal Board (“PTAB”) to explore how the FDA could optimize the framework to support generic drug availability.²² Woodcock hoped the recommendations would assist in boosting current U.S. policy to incentivize innovation while fostering competitive drug markets, leading to affordable medical care.²³

Current U.S. policy under the Biden Administration sets the stage for this Note which will evaluate the Federal Circuit’s recent precedential decision concerning patent infringement in the case of *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.* Part II of this Note discusses the Hatch-Waxman Act, a 1984 federal law monumental in creating the modern generic pharmaceutical framework borne out of a need for affordable and accessible pharmaceuticals.²⁴ After the Act’s passage, the generic drug industry boom transpired domestically and internationally, which Katherine Eban evaluates in her book, *Bottle of Lies*. Part II will also analyze Eban’s account of the generic manufacturing industry,

16. Samantha McGrail, *Brand Drug Product Hopping Costs US \$4.7B Annually*, PHARMA NEWS INTELLIGENCE (Sept. 17, 2020), <https://pharmanewsintel.com/news/brand-drug-product-hopping-costs-us-4.7b-annually> [<https://perma.cc/DCC8-BKR8>] (“Product hopping is intended to combat generic competition and preserve monopoly profits.”).

17. Poulos, *supra* note 9.

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.*

23. *Id.*

24. Alfred Engelberg, *Unaffordable Prescription Drugs: The Real Legacy of the Hatch-Waxman Act*, STAT (Dec. 16, 2020) <https://www.statnews.com/2020/12/16/unaffordable-prescription-drugs-real-legacy-hatch-waxman-act/> [<https://perma.cc/9JUF-NLCD>].

criticizing her often one-sided narrative that fails to provide context to an industry crucial to public health.²⁵

Parts III and V discuss the case at issue, specifically, the Federal Circuit's erroneous holding, which weakened the intent and causation requirement under 35 U.S.C. § 271(b). Part IV evaluates the established law on induced infringement. Under the relevant section, an infringer is one who *actively* induces a third party to infringe. The word "actively" loses meaning when a jury verdict can be supported by evidence that could have caused a third party to infringe and a lack of sufficient evidence showing that the alleged infringer was the sole cause of such infringement. Without a clear standard, generic pharmaceutical manufacturers will be unsure of what constitutes induced infringement. Part VI focuses on policy implications.

II. THE GENERIC DRUG INDUSTRY BOOM

A. Katherine Eban's *Bottle of Lies*

Katherine Eban's *Bottle of Lies: The Inside Story of the Generic Drug Boom* serves as a scathing exposé on the generic pharmaceutical manufacturing industry, particularly overseas manufacturers in India and China.²⁶ Eban, who immerses herself in a global investigation, centers her book on the 2013 Ranbaxy scandal and Dinesh Thakur, a former senior employee and whistleblower for the FDA, who exposed the deception of what was once India's largest exporter of generic drugs.²⁷ Eban's often one-sided account heavily criticizes an overwhelmed FDA for failing to address some generic manufacturers who engage in fraudulent practices and data manipulation without offering a solution that emphasizes the necessity of generics.²⁸ Consequently, she establishes distrust without attesting to safe and effective generic drugs which offer substantial "economic and therapeutic benefits" for Americans.²⁹

Eban's investigative journey began in 2008 when Joe Graedon, an NPR radio host of "The People's Pharmacy," contacted her concerning

25. Jeremy A. Greene, *After a scandal, a one-sided warning against generic drugs*, THE WASHINGTON POST (Sept. 12, 2019), https://www.washingtonpost.com/outlook/after-a-scandal-a-one-sided-warning-against-generic-drugs/2019/09/12/6a755e48-c50a-11e9-b5e4-54aa56d5b7ce_story.html [https://perma.cc/LT69-QEW5].

26. KATHERINE EBAN, *BOTTLE OF LIES* (2019); Greene, *supra* note 25.

27. EBAN, *supra* note 26.

28. Greene, *supra* note 25.

29. Namita Kohli, *Bitter Battle*, THE WEEK (Aug. 24, 2019, 15:41 IST), <https://www.theweek.in/health/more/2019/08/20/bitter-battle.html> [https://perma.cc/J25T-8X3].

claims about generics that failed to work correctly or had adverse symptoms.³⁰ At the outset, Eban cites that the U.S. is profoundly dependent on foreign manufacturers, noting that 90% of the pharmaceutical market consists of generics, with 40% of those manufactured in India and 80% of the active ingredients in both brand and generic drugs coming from China.³¹

Eban depicts a generic industry in stark contrast with FDA regulations through anecdotes of generic companies such as Wockhardt, whose insulin vials contained metallic particles and who knowingly tried to conceal such contamination.³² Notably, Eban directs her most significant criticism to Ranbaxy Laboratories.³³ She chronicles the fall of Ranbaxy, which occurred over a decade ago, through the eyes of Thakur as he compiles a Self-Assessment Report that unearths fraud in the company's worldwide regulatory filings and production of substandard pharmaceuticals.³⁴ Ultimately, Thakur handed the Self-Assessment Report over to the FDA, which led to an eight-year criminal investigation that ended with the cessation of Ranbaxy in 2014.³⁵

Eban attributes such fraud to several FDA practices concerning foreign drug manufacturers, such as advance notice for inspections and the systematic downgrading of reports of FDA investigators.³⁶ She offers suggestions to transform the industry, including the FDA returning immediately to unannounced inspections, systematic testing of drugs to prevent data fabrication, and country of origin labeling for drug ingredients and finished doses.³⁷ She maintains that if consumers are informed about manufacturers who put profits over patient safety, not only would lives be saved, but it would incentivize drug manufacturing companies to produce a quality drug supply to compete in the global market.³⁸

However, Eban's investigation falls short by failing to "convey the other half of the socio-economic context" and seemingly shows a bias against generics produced by India and China.³⁹ Her book often seems like ammunition for brand-name pharmaceutical companies and

30. EBAN, *supra* note 26.

31. *Id.*

32. EBAN, *supra* note 26; Kohli, *supra* note 29.

33. EBAN, *supra* note 26.

34. *Id.*

35. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

39. Greene, *supra* note 25.

lobbyists.⁴⁰ The story of Ranbaxy is littered with fraud and deceit. Yet, those qualities are not limited to overseas generic pharmaceuticals.⁴¹ Eban often ignores the eagerness of the pharmaceutical industry, including European and North American brand-name manufacturers, to cut costs by promoting substandard products and engaging in fraud.⁴²

For instance, in 2010, GlaxoSmithKline (“GSK”), a British brand-name pharmaceutical company, was forced to pay \$750 million to settle a lawsuit with the Department of Justice because GSK was found guilty of producing and distributing adulterated drugs in violation of FDA rules.⁴³ Then in 2012, GSK pleaded guilty to a \$3 billion lawsuit “for promoting its best-selling antidepressants for unapproved uses and failing to report safety data about a top diabetes drug.”⁴⁴ However, GSK is not the only brand-name company engrossed in scandal. Merck, an American brand-name drug company, has as well.⁴⁵ Merck’s executives “rejected pursuing a study focused on [the painkiller] Vioxx’s cardiovascular risks” despite reason to believe that it caused heart attacks, blood clots, and strokes.⁴⁶ Unfortunately, there are numerous instances, such as these, that reinforce that unsafe manufacturing practices and widespread fraud are not limited to generic overseas manufacturers.⁴⁷

However, Eban’s book undermines public perception of generics without offering context to restore confidence.⁴⁸ Simply put, she encourages a message that foreign generics are bad and brand-name drugs are good.⁴⁹ Yet, this is an astonishing oversimplification. Much of Eban’s source of determining whether a generic is acceptable depends on the FDA’s Current Good Manufacturing Practice (“CGMP”) requirements.⁵⁰

40. *Id.*

41. *Id.*

42. *Id.*

43. Gardiner Harris & Duff Wilson, *Glaxo to Pay \$750 Million for Sale of Bad Products*, N.Y. TIMES (Oct. 26, 2010), <https://www.nytimes.com/2010/10/27/business/27drug.html> [<https://perma.cc/XW4D-Z3FB>].

44. Katie Thomas & Michael S. Schmidt, *Glaxo Agrees to Pay \$3 Billion in Fraud Settlement*, N.Y. TIMES (July 2, 2012), <https://www.nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html> [<https://perma.cc/SLM7-5HEZ>].

45. Alex Berenson, Gardiner Harris, & Barry Meier, *Despite Warnings, Drug Giant Took Long Path to Vioxx Recall*, N.Y. TIMES (Nov. 14, 2004), <https://www.nytimes.com/2004/11/14/business/despite-warnings-drug-giant-took-long-path-to-vioxx-recall.html> [<https://perma.cc/U6SP-AAR5>].

46. *Id.*

47. Greene, *supra* note 25.

48. *Id.*

49. *Id.*

50. EBAN, *supra* note 26.

Such requirements emerged from the globalization of American pharmaceutical manufacturing in nations such as China and India.⁵¹ Yet, the CGMP standards are not the global standard.⁵²

Additionally, in 2018, the FDA began conducting foreign drug inspections based on risk,⁵³ prioritizing “facilities deemed higher-risk based on specific, defined criteria,” known as the Site Selection Model (“SSM”).⁵⁴ The SSM was “designed to select facilities with the greatest potential for public health risk” by calculating a score for each facility based on six factors.⁵⁵ The factors include inherent product risk, facility type, patient exposure, inspection history, time since last inspection, and hazard signals.⁵⁶ The FDA ranks the facilities based on their score, “with the highest rank assigned for inspection regardless of location.”⁵⁷ Since the SSM intentionally selects the highest risk sites for selection, this increases the likelihood that inspections identify an issue. Eban does not establish that the CGMP is not a global standard or discuss the SSM. Therefore, she does not account for how both potentially affect her investigation.⁵⁸

Most importantly, Eban falls short of addressing the cost savings associated with overseas generic pharmaceuticals.⁵⁹ In 2020, 76 million patients within the United States took at least one prescription medicine.⁶⁰ During that year, Americans saved \$338 billion on prescriptions because many physicians and pharmacists recognized that FDA-approved generics, including those manufactured overseas, are just as safe and effective as brand-name drugs.⁶¹ “Generics represent 90% of prescriptions filled . . . accounting for only 18.1% of prescription drug

51. Srividhya Ragavan, *Taking a Myopic View of Foreign-Made Generic Drugs*, THE HINDU (July 9, 2019), <https://www.thehindu.com/opinion/op-ed/taking-a-myopic-view-of-foreign-made-generic-drugs/article28322909.ece> [<https://perma.cc/N4N9-KG66>].

52. *Id.*

53. Janet Woodcock, *Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program*, THE FDA (Dec. 10, 2019), <https://www.fda.gov/news-events/congressional-testimony/securing-us-drug-supply-chain-oversight-fdas-foreign-inspection-program-12102019> [<https://perma.cc/T6NM-LSRG>].

54. *Id.*

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*; EBAN, *supra* note 26.

59. *The U.S. Generic & Biosimilar Medicines Savings Report*, ASS'N FOR ACCESSIBLE MEDS. 3 (Dec. 9, 2019), <https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf> [<https://perma.cc/A72J-GVN5>].

60. *Id.*

61. *Id.* at 7.

spending,” and “3% of all health care spending.”⁶² This data shows how vital generics are to ensuring the accessibility and affordability of prescriptions for all Americans.⁶³

The affordability of drugs has been and remains a high priority for government officials, Republicans, and Democrats alike.⁶⁴ Without competition from generics, brand-name companies can increase costs without changing the quality of their drug.⁶⁵ For instance, multiple states have enacted or proposed laws that would cap the cost of copays for insulin in light of a 1000% increase in insulin prices over the past 25 years.⁶⁶ Much of the rise in the price of insulin is due to a lack of competition because of patent abuses, like evergreening.⁶⁷ Recently, Viatrix Inc., an American healthcare company that produces insulin, formerly known as Mylan, agreed to a \$264 million settlement in a class-action lawsuit concerning allegations that the company engaged in a scheme to delay generic competition.⁶⁸ Currently, three brand-name companies manufacture insulin, allowing the companies to hike up prices.⁶⁹

Although Eban is right to reveal instances of fraud within overseas generic drug regulatory frameworks in India and China, she often fails to offer depth and context to her investigation.⁷⁰ She does not cite notable instances of malfeasance by brand-name companies or mention that

62. *Id.* at 8.

63. *Id.* at 7, 8.

64. Jeff Bell, *Texas Senate Approves Legislation to Cap Cost of Insulin*, KVUE (Mar. 25, 2021), <https://www.kvue.com/article/news/politics/texas-legislature/texas-senate-insulin-price-bill/269-5a43c02e-fe39-4b76-bd26-a0ac9e9cafc6> [<https://perma.cc/Q737-JL6V>]; Bennet, *Warnock, Colleagues Introduce New Bill to Cap Costs of Insulin in Colorado, Across the Country*, MICHAEL BENNET U.S. SENATOR: PRESS RELEASES (Feb. 17, 2022), <https://www.bennet.senate.gov/public/index.cfm/2022/2/bennet-warnock-colleagues-introduce-new-bill-to-cap-costs-of-insulin-in-colorado-across-the-country> [<https://perma.cc/E6MS-QHNE>].

65. Bell, *supra* note 64; MICHAEL BENNET U.S. SENATOR, *supra* note 64.

66. Bell, *supra* note 64; MICHAEL BENNET U.S. SENATOR, *supra* note 64.

67. Drug Prices Team, *‘Evergreening’ Stunts Competition, Cost Consumers and Taxpayers*, ARNOLD VENTURES (Sept. 24, 2020), <https://www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers> [<https://perma.cc/642M-A4L6>] (“Because these small changes to the injector have maintained its monopoly for so long, the cost of an EpiPen package (containing two injectors) has risen from \$94 when Mylan purchased the device to between \$650 and \$700 today.”).

68. Nate Raymond, *EpiPen Antitrust Litigation Settled; Viatrix to Pay \$264 million*, REUTERS (Feb. 28, 2022, 6:12 AM), <https://www.reuters.com/business/healthcare-pharmaceuticals/viatrix-settle-epipen-antitrust-litigation-264-million-2022-02-28/> [<https://perma.cc/5XHP-CNXP>].

69. Ryan Knox, *Insulin Insulated: Barriers to Competition and Affordability in the United States Insulin Market*, 7 J. OF L. & THE BIOSCIENCES 1, 4 (2020).

70. Greene, *supra* note 25.

the Ranbaxy scandal occurred over a decade ago, or discuss the SSM.⁷¹ Generic pharmaceuticals are vital to lower drug prices; thus, public perception surrounding generic pharmaceuticals' effectiveness and safety cannot afford to be undermined with such a one-sided investigation.⁷²

B. Hatch–Waxman Act

Beginning in the late 1970s, Congress recognized the value of generics and began considering legislation to bolster generics on the market, resulting in a compromise known as the Hatch–Waxman Act.⁷³ The Act's purpose was clear: increase competition in the pharmaceutical manufacturing industry.⁷⁴ At the outset, Congress deemed this a considerable interest to combat the rapidly growing cost of health care and the burden on everyday Americans.⁷⁵ In 1979, healthcare expenditures, including prescription drugs, totaled 17.4 billion dollars.⁷⁶ Therefore, to “condone or encourage anti-competitive practices [was] to ignore [an] urgent need.”⁷⁷

Congress sought to promote innovation and access when it created the framework for generic drug development more than three decades ago in the Hatch–Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.⁷⁸ Formerly known as the Drug Price Competition and Patent Term Restoration Act of 1984, the Hatch–Waxman Act delegated authority to the FDA to regulate the manufacture, sale, and labeling of prescription drugs and created an expedited pathway for generic manufacturers to acquire FDA approval.⁷⁹ The Act was lauded as a victory for consumers because it balanced the following goals: (1) innovation

71. *Id.*

72. *Id.*

73. *What is Hatch-Waxman?*, PhRMA (June 2018), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Fact-Sheet_What-is-Hatch-Waxman_June-2018.pdf [<https://perma.cc/2H8D-8N98>].

74. *Id.*; *Competition in the Drug Industry: Hearing Before the Subcomm. On Oversight & Investigations of the Comm. On Energy and Com. H.R.*, 97th Cong. 21 (1981).

75. *Competition in the Drug Industry*, *supra* note 74.

76. *Id.*

77. *Id.* at 1.

78. *Id.*; Wendy H. Schacht & John R. Thomas, CONG. RSCH. SERV., RL 4114, THE HATCH-WAXMAN ACT: A QUARTER CENTURY LATER, (Mar. 13, 2012), https://www.everycrsreport.com/files/20120313_R41114_c3d450e3002442e4553739527f3ce5f42e6de67b.pdf [<https://perma.cc/S7Y7-DRA7>] (“Prior to the implementation of the Hatch-Waxman Act, 35% of top-selling drugs had generic competitors after patent expiration; now almost all do.”).

79. *Competition in the Drug Industry*, *supra* note 74; Schacht & Thomas, *supra* note 78.

by encouraging brand-name companies to develop new drugs and (2) affordability by increasing access to generics.⁸⁰

Prior to 1984, generics had to repeat extensive and costly clinical trials despite the brand company demonstrating the safety and effectiveness of the drug.⁸¹ Due to this, only 35% of innovator drugs faced generic competition.⁸² To pass the Act, Congress yielded to brand companies' demands and provided two considerable protections.⁸³ First, Congress granted brand-name companies periods of market exclusivity, which protected the companies from competing applications for market approval under specified conditions.⁸⁴ Second, the Act granted patent term extensions to prevent the time the drug was under regulatory review by the FDA from consuming a substantial amount of the time.⁸⁵

However, in exchange for these demands, the Act authorized Abbreviated New Drug Applications ("ANDAs"), which allowed generic companies to receive FDA approval with limited testing; requiring only a showing that the drug was bioequivalent, *i.e.*, the drug acts the same in an individual's body as the brand name drug.⁸⁶ Second, generic companies received statutory "safe harbor from patent infringement" lawsuits while preparing the ANDA.⁸⁷

To successfully file an ANDA with the FDA, a generic applicant must provide in its application a certification to each of the brand-name company's patents listed in the Approved Drug Products with Therapeutic Equivalence Evaluations.⁸⁸ Commonly known as the Orange Book, it identifies the intellectual rights of approved drug products.⁸⁹ The generic company must select from four certifications: Paragraphs I–IV.⁹⁰ Paragraphs I–III delay the marketing of the generic until the brand-name company's patent has expired.⁹¹ However, Paragraph IV certifications assert that the patents are invalid, unenforceable, or will not be infringed by the generic's proposed product.⁹²

80. Engelberg, *supra* note 24.

81. *The U.S. Generic & Biosimilar Medicines Savings Report*, *supra* note 59.

82. Dilrose Pabla, *Hatch-Waxman Act-An analysis of its impact on Generic competition*, INSTITUTE OF GOOD MANUFACTURING PRACTICES INDIA (Oct. 2, 2020), <https://www.igmpi-india.org/igmpiblog/articles.php?article=284> [<https://perma.cc/3EX7-7UQG>].

83. Schacht & Thomas, *supra* note 78 at 1.

84. *Id.* at 3.

85. *Id.*

86. *Id.* at 2.

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.*

The generic applicant submitting a Paragraph IV certification must notify the brand company of the patent challenge. This certification can expose the generic drug company to induced infringement lawsuits.⁹³ Despite this risk, Paragraph IV certifications are favorable. It rewards the first generic company for filing such certification, 180 days of market exclusivity if approved. As a result, the FDA cannot approve another generic drug's ANDA for the same drug during that time, allowing the generic to establish market share and charge a higher price.⁹⁴

In addition, under 21 U.S.C. § 355(j)(2)(A)(viii), the Act offers generic applicants another expedited pathway, known as section viii carveouts, or skinny labeling.⁹⁵ Under this section, if a brand drug is approved for multiple indications, but the brand manufacturer only obtains a patent on a subset of those, the FDA can approve generic drugs for the non-patented indications.⁹⁶ This allows the generic to enter the market before the expiration of the patented subset.⁹⁷ The FDA will approve an ANDA with a section viii statement only if (1) there is no overlap between the proposed label and the use described in the Orange Book, and (2) removing the information about the claimed method of use from the label does not make the drug less safe or effective.⁹⁸

The “ability of generic manufacturers to use skinny labeling to avoid infringement serves an important goal of the Hatch–Waxman Act, *i.e.*, enabling the sale of affordable generic drugs for unpatented uses.”⁹⁹ This protective practice, which facilitates the immediate entry of a generic on the market for unpatented uses, had its validity challenged by the Federal Circuit in the recent case of *GSK v. Teva*. This recent challenge has threatened affordable drug prices and the critical balance created by the Hatch–Waxman Act between brand-name and generic pharmaceutical companies.

93. *Id.* at 8.

94. *Id.* at 12.

95. *Id.* at 3.

96. *Id.* at 2.

97. *Id.*

98. 21 C.F.R. § 314.127(a)(7) (2021).

99. Joseph W. Arico et. al., *Skinny Labels and the Line Between Mere Information and Inducement to Infringe in ANDA Litigation*, BLOOMBERG LAW (May 7, 2018, 9:33 AM), https://www.bloomberglaw.com/bloomberglawnews/health-law-and-business/X5K528QG000000?bna_news_filter=health-law-and-business#jcite [<https://perma.cc/TNE3-NZU5>].

III. THE EMERGING THREAT TO THE HATCH–WAXMAN ACT & INDUCED
INFRINGEMENT

A. *District of Delaware*

The recent controversial ruling by the Federal Circuit in the rehearing of *GSK v. Teva* on August 5, 2021, created an emerging threat to the practice of skinny labeling and induced infringement claims.¹⁰⁰ The case, which initially appeared before a jury in the District of Delaware, rendered a verdict in favor of GSK, a brand-name pharmaceutical company, against Teva, a generic pharmaceutical company, for induced infringement.¹⁰¹ On appeal, the Federal Circuit overturned the District of Delaware’s grant of Teva’s motion of judgment as a matter of law (“JMOL”) and reinstated the jury verdict while vacating its earlier October 2020 decision.¹⁰²

In the 1980s, GSK researched the possibility of using carvedilol, a beta-blocker, to treat congestive heart failure (“CHF”); the tests yielded unexpected results and showed patients who received carvedilol remained alive while those on the placebo were dying.¹⁰³ As a result, GSK sought and received approval from the FDA to manufacture carvedilol under the brand name drug Coreg to treat hypertension, listed as U.S. Patent 4,503,067 (“the ‘067 patent”).¹⁰⁴ The ‘067 patent was set to expire in March 2007.¹⁰⁵ Then in May 1997, the FDA approved Coreg for CHF, recorded as U.S. Patent 5,760,069 (“the ‘069 patent”).¹⁰⁶ This was followed by the FDA’s approval to market Coreg for left ventricular dysfunction following a heart attack in stable patients (“post-MI-LVD”).¹⁰⁷ Ultimately, the FDA approved Coreg for three indications: hypertension, CHF, and post-MI-LVD.¹⁰⁸

In March 2002, Teva filed an Abbreviated New Drug Application (“ANDA”) No. 76-373 with the FDA seeking approval for generic carvedilol tablets.¹⁰⁹ For the ‘067 patent, Teva submitted a paragraph III

100. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1342 (Fed. Cir. 2021).

101. *Id.* at 1323.

102. *Id.*

103. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582, 591 (D. Del. 2018), *aff’d in part, vacated in part*, 7 F.4th 1320 (Fed. Cir. 2021).

104. *Id.*

105. *Id.*

106. *Id.*

107. *Id.*

108. *Id.*

109. *Id.* at 587.

certification, indicating Teva sought FDA approval of its ANDA as of the date the '067 patent expired in March 2007 to prevent infringement.¹¹⁰ Regarding the '069 patent, Teva filed a paragraph IV certification, denoting Teva maintained the patent was invalid, unenforceable, or the generic drug would not infringe it, and sent GSK notice.¹¹¹ GSK did not initiate a suit upon receipt of the notice.¹¹²

However, in 2003, GSK applied for a reissue of the '069 patent by the Patent and Trademark Office ("PTO").¹¹³ While GSK waited for approval, the FDA issued a "tentative approval" for Teva's ANDA, which included a skinny label containing only the hypertension and post-MI LVD indications.¹¹⁴ With the expiration of the original '067 patent in 2007, FDA approval became effective.¹¹⁵ Then, in 2008, the PTO issued Reissue Patent No. RE40,000 (the "000" patent), a reissue of the '069 patent set to expire in 2015.¹¹⁶ GSK notified the FDA of the '000 reissued patent, which "claim[ed] a method of decreasing mortality caused by CHF by administering carvedilol with at least one other therapeutic agent." The '000 patent was the subject of litigation.¹¹⁷

In 2011, following GSK's delisting of the '069 patent from the Orange Book, the FDA, in a letter, instructed Teva to revise its label to match GSK's.¹¹⁸ Consequently, Teva's new label also included treatment for CHF.¹¹⁹ The FDA also requested Teva's position on the reissue patent—Teva responded that it did not believe it needed to provide certification for the '000 patent because it received final ANDA approval before the patent was issued.¹²⁰

GSK sued Teva in 2014, contending that the post-MI-LVD listed on the skinny label and CHF on the full label directly infringed the '000 patent.¹²¹ More specifically, GSK claimed Teva had violated 35 U.S.C. § 271(b), which states, "whoever actively induces infringement of a patent shall be liable as an infringer."¹²² Under § 271(b), for GSK to prove

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

111. *GlaxoSmithKline LLC*, 313 F. Supp. 3d at 587.

112. *GlaxoSmithKline LLC*, 7 F.4th at 1324.

113. *GlaxoSmithKline LLC*, 313 F. Supp. 3d at 586.

114. *GlaxoSmithKline LLC*, 7 F.4th at 1324.

115. *Id.*

116. *Id.* at 1324–25.

117. *Id.* at 1324.

118. *GlaxoSmithKline LLC*, 313 F. Supp. 3d. at 587.

119. *Id.*

120. *GlaxoSmithKline LLC*, 7 F.4th at 1325.

121. *Id.* at 1325, 1327.

122. *Id.* at 1326; 35 U.S.C. § 271(b).

inducement, it was required to show that Teva, as opposed to other factors, caused the physicians to infringe the patent directly.¹²³ A jury found Teva infringed GSK's patent during the skinny and full label period.¹²⁴

In Teva's motion for judgment as a matter of law, Teva argued that alternative factors caused doctors to infringe GSK's patent.¹²⁵ Teva contended that because GSK only asserted a "class" theory of liability and failed to prove that theory, the court could not uphold the guilty verdict on the alternative theory that Teva induced "at least one" doctor to infringe GSK's patent.¹²⁶ The district court agreed with Teva concerning GSK's failure to prove that Teva's actions caused the physicians to prescribe generic carvedilol to treat CHF.¹²⁷ The district court explained its reasoning based on the two distinct periods: the skinny and full label period.¹²⁸

1. Skinny Label Period

The district court categorized the skinny label period from January 8, 2008, to April 30, 2011, when Teva's label had the post-MI-LVD and hypertension indications but not the CHF indication.¹²⁹ The court agreed it was undisputed that since the FDA disapproved Teva's generic carvedilol for CHF, it constituted an "off-label use."¹³⁰ GSK's evidence of inducement consisted principally of GSK's expert, Dr. McCullough, Teva's label, press releases, and marketing materials.¹³¹ Concerning the press releases and marketing materials that described "Teva's generic carvedilol as AB rated to Coreg" tablets, the court noted that an AB rating only signifies that the generic is bioequivalent to the brand-name drug.¹³²

The court also asserted that a reasonable juror could have found that physicians prescribed the brand name drug based on various sources in July 2007, such as the American Heart Association and American College of Cardiology guidelines.¹³³ Teva provided evidence that even with the emergence of generic carvedilol, physicians continued prescribing the

123. *GlaxoSmithKline LLC*, 313 F. Supp. 3d. at 590.

124. *Id.* at 589.

125. *Id.* at 590.

126. *Id.*

127. *Id.* at 591.

128. *Id.*

129. *Id.*

130. *Id.* at 592.

131. *Id.* at 593.

132. *Id.*

133. *Id.* at 594.

drug in the same manner based on guidelines, research, and experience, including for the treatment of CHF.¹³⁴ GSK's expert also admitted that he did not read Teva's label before writing prescriptions.¹³⁵ Neither GSK nor Teva's experts viewed the label as impacting prescribing behavior.¹³⁶ Therefore, the district court concluded that GSK failed to offer direct evidence that Teva induced physicians to infringe the '000 patent.¹³⁷

2. The Full Label Period

The full label period ran from May 1, 2011, through June 7, 2015, when Teva had all three indications on its label.¹³⁸ GSK presented evidence of Teva's full label, press releases, product catalog, marketing materials, and AB rating to prove infringement.¹³⁹ The district court held that regardless of Teva's actions, there was no evidence to support that the physicians changed their behavior, either as a class or as individuals.¹⁴⁰ GSK admitted that physicians' reasons and methods of prescribing Coreg did not change when generics entered the market.¹⁴¹ The district court explained that "[w]ithout proof of causation, which is an essential element of GSK's action, a finding of inducement cannot stand."¹⁴² Therefore, the court vacated the \$234 million judgment and granted Teva's JMOL.¹⁴³

B. *The Federal Circuit*

The Federal Circuit, which vacated the JMOL, held that substantial evidence supported that Teva actively induced infringement by marketing its generic with a label *encouraging a patented therapeutic use*.¹⁴⁴ The Federal Circuit assented to GSK's assertion that Teva encouraged physicians to infringe the '000 patent by failing to effectuate an appropriate skinny label and including the CHF indication on its full label.¹⁴⁵

134. *Id.*

135. *Id.* at 591.

136. *Id.* at 594.

137. *Id.* at 595.

138. *Id.* at 597.

139. *Id.*

140. *Id.*

141. *Id.*

142. *Id.* at 591.

143. *Id.* at 599.

144. *GlaxoSmithKline LLC*, 7 F.4th at 1326.

145. *Id.* at 1327.

The Federal Circuit focused primarily on the labels, the testimony of GSK's expert, Dr. McCullough, and Teva's promotional materials, product catalogs, and press releases.¹⁴⁶ The Federal Circuit began its analysis with testimony from Dr. McCullough that "doctors, the alleged direct infringers [in the case], receive[d] information about generic drug products from a variety of sources, including the drug's label."¹⁴⁷ Focusing on the label, the Federal Circuit emphasized Dr. McCullough's testimony that the description of the post-MI-LVD indication on Teva's label resembled the CHF indication and his explanation "that post-MI-LVD is intertwined with heart failure."¹⁴⁸ The court accepted GSK's argument that the Dosage and Administration section of the partial label relating to the post-MI-LVD indication infringes on the claims of the '000 patent because it directs the reader to Clinical Studies § 14.1.¹⁴⁹ The Federal Circuit rejected Teva's argument that GSK mischaracterized the label by "cobbling together" portions to arrive at an infringing use.¹⁵⁰ The majority also focused on Teva's Spring 2008 and 2009 Products Catalogs and 2004 and 2007 press releases that promoted its generic as an "AB-rated equivalent of Coreg" indicated for heart failure and hypertension treatment, accepting it infringed on GSK's patent.¹⁵¹

For the full label period, the Federal Circuit held that Teva encouraged physicians to use its carvedilol for infringing uses citing Teva's label which listed the CHF indication, press releases, catalogs, and marketing material.¹⁵² The Federal Circuit attempted to address concerns that its prior and current decision would upset the balance struck with skinny labels in the Hatch-Waxman Act by asserting that this case was not about such labels because Teva failed to effectuate an appropriate one.¹⁵³ The majority claimed that this was a narrow, fact-specific case that did not disturb this balance.¹⁵⁴

Chief Judge Prost wrote an ardent dissenting opinion recognizing the widespread criticism of their October decision because of the alarming implications for skinny labels.¹⁵⁵ She found it unreasonable that Teva was liable for infringement despite "play[ing] by the rules" by carving

146. *Id.* at 1328, 1338.

147. *Id.* at 1328.

148. *Id.*

149. *Id.*

150. *Id.* at 1329.

151. *Id.* at 1335.

152. *Id.* at 1337–38.

153. *Id.* at 1326.

154. *Id.*

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

out the CHF indication¹⁵⁶ noting that, unlike the majority, she believed the case was about skinny labeling since Teva had received FDA approval. She also disagreed that the language on Teva's label could support that Teva intentionally encouraged infringement.¹⁵⁷ For Chief Prost, it was irrational that the majority found that the class of doctors relied on Teva's label since each expert cardiologist admitted they did not read the label to make prescribing decisions.¹⁵⁸ Most troublesome to the dissent was that the majority was willing to find Teva guilty based on an "AB rating" listed on Teva's press release because the FDA required generic drugs to be equivalent to the brand.¹⁵⁹ The dissent emphasized that the majority's decision weakened the specific intent and causation elements needed for induced infringement and left generics in the dark about what could expose them to liability.¹⁶⁰

IV. ESTABLISHED LAW ON INDUCED INFRINGEMENT

The Federal Circuit has long-established that under 35 U.S.C. § 271(b), "[t]he plaintiff has the burden of showing that the [the defendant's actions] induced infringing acts and that [the defendant] knew or should have known that [such] actions would induce actual infringement."¹⁶¹ However, a defendant cannot violate § 271(b) by affirmative acts taken before the issuance of a patent.¹⁶² Hence, the inquiry of induced infringement requires two prima facie elements: (1) specific intent and (2) causation.¹⁶³ The patentee must prove each element by a preponderance of the evidence.¹⁶⁴

Affirming a state of mind requirement, the Supreme Court in *Metro-Goldwyn-Mayer Studios Inc. v. Grokster* stated, "the inducement rule . . . premises liability on purposeful, culpable expression and conduct."¹⁶⁵ Then in 2011, the Supreme Court, in *Global-Tech Appliances, Inc. v. SEB S.A.*, evaluated whether active inducement requires either (1) an intent to cause infringement or (2) merely intent to cause actions that

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

157. *Id.* at 1351 (Prost, J., dissenting).

158. *Id.* at 1352 (Prost, J., dissenting).

159. *Id.* at 1342-43 (Prost, J., dissenting).

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

161. *DSU Medical Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006) (quoting *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 554 (Fed. Cir. 1990)).

162. *Nat'l Presto., Inc. v. W. Bend Co.*, 76 F.3d 1185, 1196 (Fed. Cir. 1996).

163. *DSU Medical Corp.*, 471 F.3d at 1306 (citing *MEMC Elec.*, 420 F.3d 1369, 1378 (Fed. Cir. 2005)).

164. *GlaxoSmithKline LLC*, 7 F.4th at 1337.

165. *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005).

incidentally result in infringement.¹⁶⁶ Ultimately, adopting the first view of intent and causation, the Court focused on the adverb “actively,” which suggests “inducement must involve taking the affirmative steps to bring about the desired result.”¹⁶⁷

The Federal Circuit has dictated that “[t]he principles that can be distilled from [induced infringement] cases are applicable to the Hatch-Waxman Act context”¹⁶⁸ However, a case predicated on the Hatch-Waxman Act diverges from conventional induced infringement suits.¹⁶⁹ Often, the suit emerges from a generic drug company’s ANDA filing and label, which must describe the drug in great detail and often must adopt the same or nearly identical language as the FDA-approved brand label.¹⁷⁰ As a result, the evidentiary burden to establish infringement for brand companies is often high.¹⁷¹

In the 2010 case of *AstraZeneca LP v. Apotex, Inc.*, the Federal Circuit considered whether a generic drug’s label could support a finding of induced infringement.¹⁷² The district court found in favor of AstraZeneca due to Apotex’s generic label, which instructed the use of AstraZeneca’s patented titration dosages.¹⁷³ The label was used as affirmative intent to infringe in light of Apotex’s failure to draft a non-infringing label.¹⁷⁴ Affirming the district court, the Federal Circuit held that direct and circumstantial evidence could be relied upon as proof of intent, including a drug’s label.¹⁷⁵ However, when a plaintiff relies on a drug’s label, it must demonstrate that the label “encourage[d], recommend[ed] or promote[d] infringement.”¹⁷⁶ For the court, “the pertinent question [was] whether the proposed label *instructs* [or *teaches*] users to perform the patented method.”¹⁷⁷ If answered in the affirmative, the district court could properly use the label to provide evidence of affirmative intent.¹⁷⁸ However, under Federal Circuit precedent, “merely describing the

166. *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760–61 (2011).

167. *Id.* at 760.

168. *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015).

169. Gregory Bischooping, *The Analytical Framework for the Specific Intent to Induce Infringement in Hatch-Waxman Disputes*, 47 *AIPLA Q.J.* 99, 105 (2019).

170. *Id.* at 105–06.

171. *Id.* at 106; 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G).

172. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1050 (Fed. Cir. 2010).

173. *Id.* at 1049.

174. *Id.*

175. *Id.* at 1060.

176. *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015).

177. *AstraZeneca LP*, 633 F.3d at 1060.

178. *Id.*

infringing use [on a label] or knowing of the possibility of infringement will not suffice.”¹⁷⁹

The Federal Circuit has acknowledged that when “a product has substantial non-infringing uses, intent cannot be inferred even if the alleged inducer knew that some of its users might be infringing the patent.”¹⁸⁰ Non-infringing uses are substantial if “they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.”¹⁸¹ In *Takeda Pharmaceutical U.S.A., Inc. v. West-Ward Pharmaceutical Corp.*, affirming the district court’s decision that Takeda could not succeed on its infringing case, the court explained that “the mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient for inducement.”¹⁸²

V. AFFIRMATION OF THE DISTRICT COURT

To sustain an infringement action, GSK needed to bear the burden of proving that Teva’s alleged inducement alone caused physicians to infringe GSK’s patent directly.¹⁸³ The majority, in reversing the JMOL, erroneously concluded there was ample evidence to support the jury’s verdict, weakening the specific intent and causation elements.

A. *Skinny Label Period*

In holding that Teva failed to effectuate a skinny label, the Federal Circuit based its reasoning on Teva’s label, product catalogs, and press releases, none of which directly referenced the CHF indication.¹⁸⁴ Concerning the label, the majority surmised that the descriptive language regarding the post-MI-LVD indication amounted to infringement, concluding that because there was an overlap between post-MI-LVD and CHF patients, the wording on the label was broad enough to encompass the patented indication.¹⁸⁵ This seems absurd considering pursuant to federal law and FDA approval, Teva’s skinny label omitted CHF, the *only*

179. *Takeda Pharm.*, 785 F.3d at 631 (citing *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1365 (Fed. Cir. 2012)).

180. *Id.* at 636 (Newman, J., dissenting).

181. *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009).

182. *Takeda Pharm.*, 785 F.3d at 625, 631.

183. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582, 591 (D. Del. 2018), *aff’d in part, vacated in part*, 7 F.4th 1320 (Fed. Cir. 2021).

184. *Id.* at 590.

185. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1330 (Fed. Cir. 2021).

sworn patented indication that GSK reported to the FDA.¹⁸⁶ Such a broad reading of Teva's label without any exact wordage of a CHF indication obliterates the purpose of a skinny label.

In addition, under *AstraZeneca*, the Federal Circuit held that a plaintiff must prove that the label encouraged, recommended, or promoted infringement.¹⁸⁷ Unlike in *AstraZeneca*, where the defendant knew its label posed infringement issues and continued to market the drug¹⁸⁸ here, even with the court's broad reading of the language, the court finds specific intent to infringe, despite precedent that "merely describing [an] infringing use [on a label] . . . will not suffice" and offers no other sufficient evidence of culpability.¹⁸⁹

Concerning causation, the Federal Circuit fails to demonstrate that Teva's label instructed users to use the generic for the patented indication.¹⁹⁰ Furthermore, the majority omits that Dr. McCullough and two other cardiologists testified that it did not refer to Teva's label to make prescribing decisions but relied upon medical guidelines, experience, education, and knowledge about Coreg.¹⁹¹ In fact, GSK's expert, Dr. McCullough, testified he assumed Teva's generic and Coreg were the same, and he would not prescribe Teva's generic for an off-label use.¹⁹² However, the majority premises its finding of causation not on this actual testimony but on the generalization that physicians read labels supplied by GSK's expert Dr. McCullough and Teva's 2012 Monthly Prescribing Reference.¹⁹³

Shifting to Teva's Spring 2008 and 2009 Product Catalogs which touted its product as an "AB rated therapeutic equivalent to Coreg," the Federal Circuit held this amounts to active steps to induce infringement.¹⁹⁴ The court reasoned that the catalogs and press releases informed consumers that the generic was a substitute for Coreg and, therefore, could be used for all three indications.¹⁹⁵ However, under the Hatch-Waxman Act and guidelines prescribed by the FDA, the generic must be therapeutically equivalent to the brand name drug.¹⁹⁶ It seems irrational that this amounts to active steps to infringe when neither the

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

187. *Takeda Pharm.*, 785 F.3d at 631.

188. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1061 (Fed. Cir. 2010).

189. *GlaxoSmithKline LLC*, 7 F.4th at 1350-51.

190. *Id.* at 1354 (Prost, J., dissenting).

191. *Id.* at 1352.

192. *Id.*

193. *Id.*

194. *Id.* at 1335.

195. *Id.*

196. *Id.* at 1344.

product catalogs nor press releases referenced the patented indication. In fact, the jury was not allowed to consider this alone to satisfy the intent requirement.¹⁹⁷ In addition, the Federal Circuit fails to offer sufficient evidence that the statement concerning the AB rating caused prescribing physicians to change their behavior.¹⁹⁸ The actual evidence at trial proved that physicians used various resources for prescribing decisions, including the American Heart Association, England Journal of Medicine, The Lancet, etc.¹⁹⁹

Concerning the 2004 press release, the majority enlarges Teva's statement that its generic was indicated for the treatment of heart failure and hypertension, contending that physicians would understand this to mean they could prescribe the generic for CHF; notwithstanding this press release was published four years before the PTO issued the '000 patent.²⁰⁰ Under *National Presto Industries, Inc. v. West Bend Co.*, the Federal Circuit held that "as a matter of law, affirmative acts taken before a patent [is] issue[d] cannot violate § 271(b)." ²⁰¹ Even with the court's assertion that the press release remained on Teva's website beyond the issuance of the patent in 2008, the majority fails to demonstrate that this altered physicians' prescribing behavior.²⁰²

For Teva's 2007 press release, the majority fixated on Teva's claim that its generic was a "cardiovascular agent," despite that post-MI-LVD is also a cardiovascular condition, and the court acknowledged there was an overlap between the two conditions.²⁰³ The majority fails to demonstrate that the product catalogs or press releases caused physicians to alter their behavior, unlike Teva, who showed at trial that physicians continued prescribing carvedilol in the same manner when generics entered the market.²⁰⁴

B. Full Label Period

For the full label period, Teva's label included all three indications: hypertension, post-MI-LVD, and CHF.²⁰⁵ The majority held there was

197. *Id.*

198. *Id.* at 1356.

199. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582, 591 (D. Del. 2018), *aff'd in part, vacated in part*, 7 F.4th 1320 (Fed. Cir. 2021).

200. *GlaxoSmithKline LLC*, 7 F.4th at 1354.

201. *Nat'l Presto Indus., Inc. v. W. Bend Co.*, 76 F.3d 1185 (Fed. Cir. 1996).

202. *GlaxoSmithKline LLC*, 7 F.4th at 1354.

203. *Id.* at 1353.

204. *Id.* at 1356.

205. *Id.* at 1347.

substantial evidence to support the jury's verdict based on the 2004 and 2007 press releases, marketing materials, and catalogs, such as Teva's literature, which asserted a physician must read the full product label.²⁰⁶ Yet, the majority offered no evidence that physicians changed their prescribing behavior between the skinny label and full label period or even with the introduction of generics onto the market.²⁰⁷ Furthermore, GSK admitted that physicians' prescribing behaviors did not change.²⁰⁸ Without such change, there is a lack of causation—a crucial element to support a finding of induced infringement. GSK failed to offer any substantial evidence, let alone sufficient evidence to prove that Teva's actions alone caused physicians to infringe the '000 patent and, thus, could not sustain an action of induced infringement.²⁰⁹ Thus, the Federal Circuit erred in vacating the district court's grant of Teva's JMOL.²¹⁰

VI. IMPLICATIONS OF THE FEDERAL CIRCUIT'S DECISION ON PUBLIC POLICY

The implications of the Federal Circuit's decision directly conflict with the public policy goal of decreasing health care costs and increasing accessibility.²¹¹ Today, "Americans spend more than \$1,500 per person on prescription drugs"—a total much "higher than any comparable nation," with brand name drug prices "rising faster than inflation."²¹² As a result of high prescription prices, one out of four Americans experiences hardship paying for medication, and nearly one in three Americans do not take their medications as prescribed.²¹³

Presently, the exorbitant prices in the health care sector are primarily due to anti-competitive practices.²¹⁴ This emphasizes the significance of strict adherence to the purpose and balance of the Hatch-Waxman Act.²¹⁵ Table 1 illustrates data collected by GoodRx on the average price of brand-name and generic versions of carvedilol and three other

206. *Id.* at 1340.

207. *Id.* at 1356.

208. *Id.*

209. *Id.*

210. *Id.* at 1341.

211. Exec. Order No. 14036, 86 Fed. Reg. 60747 (2021) [<https://perma.cc/4E8G-YZXJ>].

212. Xavier Becerra, *Comprehensive Plan for Addressing High Drug Prices*, ASSISTANT SEC'Y FOR PLAN. & EVALUATION 2 (Sept. 9, 2021), https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf [<https://perma.cc/NGE2-7ZXQ>].

213. *Id.* at 5.

214. *Id.*

215. *Id.*

heavily prescribed drugs in the United States without insurance.²¹⁶ The price differential in Table 1 emphasizes the vital role generic drugs play in substantially reducing costs in the United States and ensuring equitable drug pricing through competition.²¹⁷

Drug	Brand Name(s)	Dosage	Brand Name Price	Generic Price
Carvedilol	Coreg	25 mg	\$350-\$375	\$4-\$37
Atorvastatin	Lipitor	40 mg	\$303-\$515	\$8-\$24
Lisinopril	Prinivil, Zestril	40 mg	\$404-\$426	\$4-\$35
Metoprolol	Toprol XL	100 mg	\$67-\$72	\$10-\$20

Table 1 Drug Prices for Brand-name and Generic Drugs²¹⁸

In the United States, generic drug competition continues to generate billions in savings each year, and “[t]he U.S. health care system has saved nearly \$2.4 trillion in the last 10 years due to the availability of affordable generics.”²¹⁹ In 2020, “on average, states saved \$6.6 billion” with larger states such as Texas, California, and Florida realizing a savings of over \$20 billion.²²⁰ Generics “are one of the most effective mechanisms to control drug costs.”²²¹ With over 90% of the pharmaceuticals dispensed being generics and the substantial price savings that attach to such products, decisions that erect a considerable barrier to the entrance of generics will severely disrupt the pharmaceutical landscape.²²²

In response to President Biden’s EO 14036, which sought to increase competition in the American economy, the Comprehensive Plan for Addressing High Drug Prices was created.²²³ It identified three guiding principles for drug reform: (1) “make drugs prices more affordable and equitable for all consumers and throughout the health care system;” (2)

216. *Prices for some common brand-name medications and their generic versions (without insurance)*, UPTODATE (Nov. 15, 2021), <https://www.uptodate.com/contents/image?imageKey=PC%2F90835> [<https://perma.cc/KH48-439F>].

217. *Id.*

218. *Id.*

219. *The U.S. Generic & Biosimilar Medicines Savings Report*, *supra* note 59, at 8.

220. *Id.* at 11.

221. *Id.*

222. *Id.* at 6.

223. Becerra, *supra* note 212, at 2.

“improve and promote competition throughout the prescription drug industry;” and (3) “foster scientific innovation.”²²⁴ The plan recognized ways to effectuate the principle such as “support[ing] drug price negotiation, strengthen supply chains, and support public and private research for valuable and accessible new treatments.” The main goal of the plan was to “keep Americans healthier and more financially secure.”²²⁵

Within the plan, published a month after the Federal Circuit’s decision in *GSK v. Teva*, the administration addressed recent litigation which has raised questions about skinny labeling— affirming that the administration was committed to taking appropriate steps to ensure the critical practice remains available for generic drugs and biosimilars.²²⁶ The Federal Circuit’s holding of induced infringement is in direct contention with current U.S. policy under the Biden Administration and the intention of the Hatch–Waxman Act.²²⁷ Former representative Henry Waxman, the original sponsor of the bill, filed an amicus brief on Teva’s behalf contending that the majority’s decision “[was] flatly inconsistent with the language of the Act and congressional intent.”²²⁸

VII. CONCLUSION

By asserting that *GSK v. Teva* was a narrow, fact-specific case that should not be viewed as upsetting the balance struck by the Hatch–Waxman Act, the Federal Circuit underestimates their holding.²²⁹ Under § 271(b), the word actively loses meaning when a brand-name company can offer evidence that fails to demonstrate that culpable conduct by the generic was the sole cause of such infringement, thus, weakening the specific intent and causation elements. Generics will now be forced to heavily dissect and narrowly tailor all aspects of its label, promotional materials, and external communications.²³⁰ By allowing GSK to prevail

224. *Id.*

225. *Id.* at 3.

226. *Id.* at 21.

227. *Id.* at 23.

228. Tina W. McKeon & April A. Isaacson, *GSK v. Teva: The Skinny on Induced Infringement and Label Carve-Outs*, KILPATRICK TOWNSEND (Jan. 13, 2021), <https://kilpatricktownsend.com/en/Blog/MEMO/2021/1/GSK-v-Teva---The-Skinny-On-Induced-Infringement-And-Label-Carve-Outs> [<https://perma.cc/4F5L-79DH>] (quoting Brief of Amicus Curiae Former Congressman Henry A. Waxman in Support of Petition for Rehearing En Banc [Corrected] at 1–2, *GlaxoSmithKline LLC*, Nos. 18-1976, 18-2023 (Fed. Cir. Dec. 30, 2020)).

229. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1326 (Fed. Cir. 2021).

230. *GSK v. Teva: Federal Circuit Opinion After Rehearing Confirms Induced Infringement Liability Despite Skinny Label*, COOLEY, <https://www.cooley.com/news/ins>

on a weakened standard of specific intent and causation, the decision raises crucial questions about what Teva did wrong and, more broadly, how generics can protect themselves from patent infringement suits.²³¹ In addition, the Federal Circuit's decision utterly defeats congressional intent by enforcing that skinny labels "do not safeguard generic applicants from liability from patent infringement."²³² This creates uncertainty for generic drug manufacturers and will potentially lead to a decrease in such carve-outs and delay the introduction of generics on the market. As a result, this uncertainty will increase pharmaceutical prices, consequently failing to ensure Americans are healthier and financially secure.

ight/2021/2021-08-17-gsk-v-teva-federal-circuit-opinion-rehearing-induced-infringement-liability-skinny-label [https://perma.cc/UX7D-LA67].

231. Kevin Dunleavy, *GSK Again Scores \$235 in 'Skinny Label' Case, but Court Admits it's Unclear What Teva Even Did Wrong*, FIERCE PHARMA (Aug. 6, 2021), https://www.fiercepharma.com/pharma/court-reaffirms-235m-judgement-for-gsk-against-generic-manufacturer-teva-skinny-label-case [https://perma.cc/Y9V5-9H8M].

232. *What GSK v. Teva Means for ANDA Skinny Labels*, PHARM. LAW GROUP (Aug. 10, 2021), https://www.pharmalawgrp.com/blog/15/what-gsk-v-teva-means-for-anda-skinny-labels/ [https://perma.cc/UUT8-XFB5].