GLAXOSMITHKLINE V. TEVA PHARMACEUTICALS: WHAT THE "NEW" LAW OF INDUCED INFRINGEMENT MEANS FOR MANUFACTURERS OF GENERIC DRUGS

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I. INTRODUCTION

In July 2014, pharmaceutical company GlaxoSmithKline (GSK) sued generic drug manufacturer Teva Pharmaceuticals (Teva) for infringing United States Patent No. RE40,000 ('000 Patent), which discloses the use of GSK's drug carvedilol, marketed as COREG®, in the treatment of congestive heart failure.[1] GSK alleged that Teva actively induced others to infringe the '000 patent by marketing its generic carvedilol tablets as bioequivalent and "fully substitutable" for GSK's COREG® and encouraging the use of Teva's generic tablets for the long-term treatment of congestive heart failure.[2] After a seven-day trial, a jury returned a verdict for GSK, finding Teva willfully induced infringement of the '000 patent, and awarded damages exceeding $235 million.[3]

Despite the jury's findings, the court granted Teva's renewed motion for judgment as a matter of law (JMOL), citing insufficient evidence to support a finding of induced infringement.[4] The Federal Circuit reversed the JMOL on appeal and reinstated the jury verdict and damages award.[5] The Federal Circuit cited various pieces of evidence that supported the jury's finding including the generic label, expert testimony, and various marketing and promotional materials.[6] Teva, in a petition that garnered much support from amici curiae,[7] sought review by the United States Supreme Court shortly thereafter.[8]

Many saw the Federal Circuit's decision to uphold the jury's verdict of induced infringement as a dangerous change for generic drugs.[9] Amici warned of harm to generics competition, rising costs for Americans, and even loss of human life.[10] However, the verdict against Teva is not the

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1. Second Amended Complaint for Patent Infringement at 1, GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 313 F. Supp. 3d 582 (D. Del. 2018) (No. 14-877-LPS-CJB).

2. *Id.* at 18–19.

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

4. *Id.* at 590.

5. GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320, 1341–42 (Fed. Cir. 2021).

6. *Id.* at 1333.

7. *See generally* Brief of 42 Professors of Law, Economics, Business, and Medicine as Amici Curiae in Support of the Petition, Teva Pharms. USA, Inc. v. GlaxoSmithKline LLC, et al., 2022 U.S. S. CT. BRIEFS LEXIS 2529 (2022) (No. 22-37).

8. Petition for Writ of Certiorari at 1, Teva Pharms. USA, Inc. v. GlaxoSmithKline LLC, et al., 2022 U.S. S. CT. BRIEFS LEXIS 2193 (2022) (No. 22-37).

9. *See* Matthew Lane, *Federal Circuit Should Restore Generics 'Skinny Label'*, BLOOMBERG L. (Jan. 12, 2021, 3:01 AM), https://news.bloomberglaw.com/business-and-practice/federal-circuit-should-restore-generics-skinny-label-process; *see also* Amy L. Baker et al., *The Wide-Ranging Effects of the Federal Circuit's Assault on Skinny Labels*, The NAT'L L. REV. (Dec. 4, 2020), https://www.natlawreview.com/article/wide-ranging-effects-federal-circuit-s-assault-skinny-labels.

10. Brief of 42 Professors, *supra* note 7, at *4 ("[T]he Federal Circuit's decision . . . could be leveraged to stymie generic competition for years to come, greatly raising costs for American patients . . . ."); Brief of 42 Professors, *supra* note 7, at *14 ("Saddling the lion's share of future

first of its kind. In fact, Teva is not the first defendant to unsuccessfully use FDA approval as a shield against complaints of induced infringement.[11] The Federal Circuit, in its opinion vacating the grant of JMOL, described the decision as a "narrow, case-specific review" which does not disturb the existing law on patent infringement and generic drug labels.[12] Nevertheless, the decision alarmed many in the industry who foresee dire consequences to the generics drug market.[13]

Specifically, opponents of the decision claim that Teva complied with all relevant FDA labeling requirements for its "skinny label,"[14] and that to hold a compliant generic drug manufacturer nevertheless liable for induced infringement destroys the economic incentives for generic manufacturers wishing to enter the market.[15] The reality of a $235 million verdict juxtaposed with only $74 million in sales during the same period[16] presents serious business risks for generics manufacturers. Even though the Federal Circuit's decision in *GSK v. Teva* itself does not purport to represent a material change to induced infringement jurisprudence, it will nevertheless have a significant impact on the generic drug market.

This article analyzes the Federal Circuit's decision against its established patent infringement jurisprudence and explores the potential business consequences of the ruling, including how a generics manufacturer may change its practices to reduce the risk of infringement liability. Part II of this article provides relevant background, including the foundations and purposes of patent law, an overview of the Hatch-Waxman scheme and the relevance of so-called "skinny labels" for generic drugs, and a brief history of the law of induced infringement leading up to *GSK v. Teva*. Next, Part III of this article provides the facts of the *GSK v. Teva* case, including the patent-in-suit, infringing product, and infringing activity. Lastly, Part IV of this article provides an analysis of the Federal Circuit's decision, exploring if and how the law of induced infringement has changed, and how the *GSK v. Teva* ruling changes the risk analysis for a generic drug manufacturer bringing a product to market.

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generic entrants with this litigation, indeed likely deterring them from entering markets at all, will have costs measured not just in billions of dollars but also in human lives.").

11. *See, e.g.*, AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1061 (Fed. Cir. 2010) (affirming grant of preliminary injunction to prevent generic manufacturer from launching FDA-approved generic drug).

12. *GlaxoSmithKline*, 7 F.4th at 1326.

13. *See, e.g.*, Brief for Mylan Pharmaceuticals Inc. as *Amicus Curiae* In Support of Petitioner at 1–3, Teva Pharms. USA, Inc., v. GlaxoSmithKline LLC, et al., 2022 U.S. S. CT. BRIEFS LEXIS 2546, (2022) (No. 22-37).

14. *See, e.g.*, Brief of the Association For Accessible Medicines as *Amicus Curiae* In Support of Petitioner at 3, Teva Pharms. USA, Inc. v. GlaxoSmithKline LLC, et al., 2022 U.S. S. CT. BRIEFS LEXIS 2545, (2022) (No. 22-37).

15. *Id.* at *7 ("No generic manufacturer would dare risk coming to market with a skinny label if it could face enormous liability for using a label the law required it to use.").

16. Lane, *supra* note 9.

II. BACKGROUND

A. Patent Law & The Pharmaceutical Industry

To understand the legal and business implications of this case, one must first understand the basics of patent law and its role within the pharmaceutical industry. The United States Constitution grants Congress the authority to establish the patent system by instructing Congress to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[17] Patent laws throughout U.S. history have reflected this constitutional ambition of incentivizing innovation while appropriately limiting the monopolies given to inventors.[18] From the first Patent Act of 1790, Congress has placed requirements on what may be patented and what is required from those seeking a patent.[19] Today's patent statute[20] "embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of [20] years."[21]

Without the protection of the patent system, today's pharmaceuticals industry likely would not exist.[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] The cost to develop and bring a new drug to market can be well into the billions.[24] It requires a lengthy, risky process.[25] On average, the time from inception to FDA approval takes twelve to sixteen years, with many drugs failing to ever reach the market.[26] Plus, once on the market, most drugs are relatively easy to replicate.[27] If required to compete under these conditions without patent protection, those investing in a new drug may not be able to recoup their costs, and thus

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17. U.S. CONST. art. I, § 8, cl. 8.
18. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146–48 (1989).
19. *Id.*
20. *Bonito Boats* refers to the patent statute from before the America Invents Act of 2011. However, the requirements of novelty, utility, and nonobviousness remain in the current statute. *Id.* at 141; *see* 35 U.S.C. §§ 101–103.
21. *Bonito Boats*, 489 U.S. at 150–51; *see also* 35 U.S.C. § 154(a)(2) (stating that the patent term is 20 years from the date of filing).
22. Jonathan A. Bell, *Generic Drugs and the Future of "Skinny Labels",* 35 HARV. J. L. & TECH. 659, 662 (2022).
23. Rachel E. Sachs, *The Uneasy Case for Patent Law*, 117 MICH. L. REV. 499, 503 (2018).
24. *Id.* at 506.
25. *Id.*
26. *Id.*
27. *Id.*

may not be motivated to enter the market in the first place.[28] The patent monopoly provides the necessary economic incentive to induce progress and innovation in the pharmaceutical industry.[29]

However, the monopolies that the patent system creates for pharmaceutical inventors are not without societal harm.[30] A patent-granted monopoly allows an inventor to charge higher prices.[31] While the ability to charge higher prices is necessary to the economic incentives created by the patent system, higher prices can make accessing a patented product difficult for consumers.[32] The problem of access is particularly concerning in the context of pharmaceuticals where the patented products are necessary, even life-saving, medications.[33] Many consumers rely on generic drugs,[34] especially in the United States, where brand-name drug prices are 30-40% higher than in other developed countries.[35] In order to address this tension between innovation and access, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act.[36]

B. The Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984 attempted to strike "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."[37] In part, the Hatch-Waxman Act accomplished this by creating "an expedited pathway" for generic manufacturers to obtain FDA-approval for their generic products.[38]

Under the Hatch-Waxman Act, a generic manufacturer may seek FDA approval of a generic version of a brand-name drug through an

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28. *See* Bell, *supra* note 22, at 662 ("The monopoly granted by the patent is thought to provide the motivation for an inventor to invent in the first place. . .[P]harmaceutical companies regard patent protection as a necessary and proper tool for recuperating research and development costs within the industry.").

29. Sachs, *supra* note 23, at 507.

30. *See* Bell, *supra* note 22, at 662–63.

31. Sachs, *supra* note 23, at 505 ("[T]he inventor's right to exclude enables them to charge higher prices . . . .").

32. Bell, *supra* note 22, at 662–63.

33. Jane F. Djung, *Insufficient Mechanisms for Orange Book Corrections and the FDA's Ministerial Role: A Need for Reform*, 47 CONN. L. REV. 229, 233 (2014) (discussing examples of pharmaceutical innovations).

34. *Id.* at 231 ("American healthcare consumers have increasingly relied on [prescription generic drug] safety and effectiveness.").

35. Bell, *supra* note 22, at 663.

36. *Id.*; Drug Price Competition and Patent Term Restoration Act of 1984, 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).

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

38. John R. Thomas, Cong. Rsch. Serv., R244643, The Hatch-Waxman Act: A Primer (2016).

Abbreviated New Drug Application (ANDA).[39] To use this expedited pathway to approval, a generic manufacturer must demonstrate that their proposed generic drug contains the same active ingredient(s)[40] and is "bioequivalent" to the brand-name drug,[41] also referred to as the listed drug (LD).[42] A generic drug will be deemed bioequivalent to a LD when it delivers the same concentration of the same active ingredient into the patient's bloodstream, or other action site, over the same period of time.[43] Because the generic drug is bioequivalent to the LD, a generic manufacturer may "piggy-back[]" on already obtained safety and efficacy data from the LD instead of obtaining its own.[44] This allows generics manufacturers to save considerable time and money that would otherwise be required for FDA approval.[45]

Under the Hatch-Waxman Act, an ANDA applicant has multiple avenues for pursuing FDA approval depending on the patented status of the LD.[46] In its ANDA, an applicant may make one of four certifications.[47] An applicant may make a "paragraph I certification" and therefore assert that, at the time of its application, there is no relevant patent on the LD.[48] A "paragraph II certification" asserts that the relevant patent(s) is expired.[49] A "paragraph III certification" asserts that the relevant patent(s) will expire before requested approval.[50] Finally, an applicant may make a "paragraph IV certification" and therefore assert that the relevant patent is "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."[51]

Despite the applicant's assertion of invalidity or noninfringement, submitting a paragraph IV certification is technically an act of statutory patent infringement.[52] Luckily, the Hatch-Waxman scheme provides for how a patent owner may remedy its rights for this act of infringement.[53] If an applicant elects to make a paragraph IV certification, it must notify

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39. 21 U.S.C. § 355(j).
40. *Id.* § 355(j)(2)(A)(ii).
41. *Id.* § 355(j)(2)(A)(iv).
42. *Id.* § 355(j)(2)(A)(i) ("hereinafter in this subsection referred to as a 'listed drug'").
43. Lisa B. Pensabene & Dennis Gregory, *Hatch-Waxman Act: Overview*, WESTLAW (database updated Sept. 2023) ("Generally, a drug is bioequivalent when it delivers the same amount of active ingredient in a patient's bloodstream over the same amount of time as the [LD].").
44. Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 405 (2012).
45. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990) ("ANDAs . . . permit an applicant seeking approval of a generic drug to avoid the costly and time-consuming studies required for a pioneer drug.").
46. *See* 21 U.S.C. § 355(b)(2)(A)(i)–(iv).
47. *Id.*
48. *See id.*
49. *Id.* § 355(b)(2)(A)(i)–(iv).
50. *Id.* § 355(b)(2)(A)(iii).
51. *Id.* § 355(b)(2)(A)(iv).
52. 35 U.S.C. § 271(e)(2).
53. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

the brand-name drug company[54] within twenty days of when the FDA accepts the ANDA.[55] The brand-name company then has forty-five days to initiate an infringement suit against the applicant, at which time ANDA approval is stayed pending litigation.[56]

However, a paragraph IV certification is not the only available mechanism for a generics manufacturer who is faced with a patented brand-name drug.[57] Whether an applicant elects to make a paragraph IV certification or use another route to FDA approval will likely depend on the types of patents covering the LD.[58] When a new drug is invented, there are typically two types of patents that can be granted: a composition patent and a method-of-use patent.[59] A composition patent gives the patentee the right to exclude others from making, using, or selling the drug compound itself.[60] A method-of-use patent only gives the patentee the right to exclude others from using the drug in the patented method of treatment.[61] The brand-name manufacturer will often be the owner of both types of patents for a given drug, with the composition patent expiring before the method-of-use patent.[62] This allows a strategic brand-name manufacturer who obtains a method-of-use patent as their composition patent approaches expiration to effectively extend their patent monopoly by excluding others for two consecutive patent terms. Once the composition patent expires, but before the method-of-use patent expires, a generic manufacturer looking to enter the market may pursue a "section viii statement."[63]

Unlike a paragraph IV certification, a section viii statement does not require an act of statutory infringement.[64] With a section viii statement, the generics manufacturer avoids the patented method of treatment by promoting and labeling the generic drug only for the uses not covered by the method-of-use patent.[65] While a section viii statement does not come with the same statutory incentives as a

54. *See* 21 U.S.C § 355(b)(2)(A)(iv). An applicant . . . shall give notice to each "owner of the patent that is the subject of the certification" and "the holder of the approved [New Drug Application] for the drug that is claimed by the patent." 21 U.S.C. § 355(b)(3)(C).

55. *Id.* § 355(b)(3)(B)(i).

56. *Id.* § 355(j)(5)(B)(iii).

57. *See id.* § 355(j)(2)(A)(viii).

58. Djung, *supra* note 33, at 240; *see Caraco Pharm.*, 566 U.S. at 406 ("A section vii statement is typically used when the brand's patent on the drug compound has expired, and the brand holds patents on only some approved methods of using the drug.").

59. Djung, *supra* note 33, at 240.

60. *Caraco Pharm.*, 566 U.S. at 405 ("One type [of drug patent] protects the drug compound itself.").

61. *Id.* ("Another kind [of drug patent] . . . gives the brand manufacturer exclusive rights over a particular method of using the drug.").

62. Djung, *supra* note 33, at 240.

63. *Caraco Pharm.*, 566 U.S. at 406.

64. Djung, *supra* note 33, at 239.

65. *Caraco Pharm.*, 566 U.S. at 406; *see* 21 U.S.C. § 355(j)(2)(A)(viii).

paragraph IV certification,[66] a section viii statement is not an act of infringement, and therefore does not carry the same risk of infringement litigation.[67]

If pursuing a section viii statement, a generic manufacturer will "carve out" the patented uses from the brand-name label yielding a so-called "skinny label" for their new, generic drug.[68] Because it has been carved up, a skinny label should contain only non-infringing uses of the generic drug.[69] The FDA will only approve a section viii statement if there is no overlap between the label proposed by the ANDA applicant and the patented method of use, and removing the information about the patented method of use does not render the drug less safe or effective.[70] But the line between an infringing and non-infringing use is not always clear.[71] Because of this thin line between infringement and noninfringement in a skinny label, there is a rich history of patent infringement liability within the generic pharmaceutical industry.[72] This thin line, and disagreements about which side Teva's conduct falls on, is where the *GSK v. Teva* litigation begins.

III. SUMMARY OF CASE

GSK sells the drug carvedilol under the brand name COREG®.[73] Carvedilol is a beta-blocker approved by the FDA for the treatment of hypertension, left ventricular dysfunction following a myocardial infarction (the post-MI LVD indication), and congestive heart failure (CHF).[74] CHF is the indication at issue in this case.[75] When GSK began researching the potential of carvedilol in the treatment of CHF, many doctors and pharmaceutical companies expressed skepticism because beta-blockers were contraindicated for the treatment of CHF.[76] This is because beta-blockers tend to decrease the heart's capacity to pump

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66. *See* 21 U.S.C. § 355(j)(5)(B)(iv). The first ANDA applicant is given a 180-day exclusivity period during which final approval of other ANDAs with paragraph IV certifications will be blocked. *Id.* This does not apply to section viii statements. *Id.* In these 180 days, the first-to-file generic manufacturer will have a lucrative "virtual market monopoly for its formulation." Fei Mei Chan, *Generic-Drug Firms Compete for Profits*, FORBES (Dec. 12, 2001, 9:00 AM), http://www.forbes.com/2001/12/12/1212sf.html.

67. Djung, *supra* note 33, at 239.

68. *Id.*

69. *Id.* at 240. ("[A] generic company seeking a section viii statement proposes a label that is not identical and does not overlap with any of the [patented] uses.").

70. Bayer Schering Pharma AG v. Lupin, Ltd., 676 F.3d 1316, 1318 (Fed. Cir. 2012); *see also* 21 C.F.R. § 314.127(a)(7).

71. *See, e.g.*, *GlaxoSmithKline*, 7 F.4th at 1328 (presenting expert evidence that the post-MI LVD indication is "intertwined with heart failure" and thus satisfies the "decreasing mortality caused by congestive heart failure in a patient" claim limitation).

72. *See generally* DONALD S. CHISUM, 5 CHISUM ON PATENTS § 17.04(4)(f)(ii) (2023).

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

74. *Id.*

75. *See id.*

76. *Id.*

blood and slow the heart rate, a potentially dangerous combination for CHF patients.[77] Despite much skepticism, GSK's research was successful in reducing mortality rates and led to a new standard of care for heart failure patients.[78]

In 1985, the composition patent for carvedilol (the '067 Patent) was issued.[79] In 1998, the method-of-use patent (the '069 Patent) was issued.[80] The '069 Patent claimed the innovative method of administering the beta-blocker carvedilol in conjunction with one or more of an ACE inhibitor, diuretic, and digoxin to reduce mortality rates in CHF patients.[81]

In 2002, Teva filed an ANDA with the FDA for its generic carvedilol product covering all three approved uses: hypertension, the post-MI LVD indication, and CHF.[82] Teva's ANDA included a paragraph III certification, which asserted that Teva would not sell its generic product until the '067 composition patent expired in 2007.[83] Teva's ANDA also included a paragraph IV certification which asserted that the '069 method-of-use patent was invalid, unenforceable, or not infringed.[84] As required under the Hatch-Waxman Act,[85] Teva notified GSK of their paragraph IV certification, alleging that the claims of the '069 patent were anticipated or would have been obvious.[86] At this time, GSK did not pursue Teva for patent infringement.[87] Shortly thereafter, in 2004, Teva received tentative FDA approval for its generic carvedilol product "for treatment of heart failure and hypertension" to become effective upon expiration of the '067 patent in 2007.[88]

Meanwhile, GSK applied for the reissue[89] of the '069 method-of-use patent,[90] and on January 8, 2008, the Patent and Trademark Office granted Reissue Patent No. RE40,000 ('000 Patent).[91] The '000 Patent, asserted in this case, claims the innovative method of administering

77. *GlaxoSmithKline*, 7 F.4th at 1323.
78. *Id.*
79. *Id.*; U.S. Patent No. 4,503,067 (filed April 4, 1983) ('067 Patent).
80. *GlaxoSmithKline*, 7 F.4th at 1323; *see* U.S. Patent No. 5,760,069 (filed Jun. 7, 1995) ('069 Patent).
81. '069 Patent, col. 1, l. 59–67.
82. *GlaxoSmithKline*, 7 F.4th at 1323.
83. *Id.*; *see* 21 U.S.C. § 355(j)(2)(A)(vii)(III).
84. *GlaxoSmithKline*, 7 F.4th at 1323–24; *see* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).
85. *See* 21 U.S.C. § 355(b)(3)(C).
86. *GlaxoSmithKline*, 7 F.4th at 1324; 35 U.S.C. § 103 (describing when a patent will be found to be obvious and therefore invalid); *see* 35 U.S.C. § 102 (describing when a patent will be anticipated and therefore invalid).
87. *GlaxoSmithKline*, 7 F.4th at 1324.
88. *Id.*
89. Pursuant to 35 U.S.C. § 251.
90. *GlaxoSmithKline,* 7 F.4th at 1324.
91. *Id.*

carvedilol in conjunction with at least one other therapeutic agent for decreasing the mortality of CHF patients.[92]

In a section viii certification prior to the launch of its generic carvedilol in 2007, Teva certified to the FDA that it would exclude the CHF indication from its generic label.[93] The generic label would include only the FDA-approved indications that were not covered by the method-of-use patent: the post-MI LVD and hypertension indications.[94]

However, throughout the litigation and the resulting jury trial, GSK presented evidence that Teva did not remove CHF entirely from its carvedilol product offering.[95] For example, in 2004, upon receiving tentative FDA approval to launch their generic carvedilol tablets, Teva issued a press release touting the new generic as the "AB-rated generic equivalent of GlaxoSmithKline's COREG® Tablets" which was "indicated for treatment of heart failure and hypertension."[96] The Federal Circuit pointed to this 2004 press release along with other evidence of Teva's product catalogs, advertising activities, prescribing instructions, and testimony from experts and Teva's company witnesses as substantial evidence from which a jury could reasonably conclude Teva induced infringement.[97]

In 2011, Teva amended its generic label to include a chronic heart failure indication.[98] As it did for the pre-2011 partial label period,[99] the Federal Circuit noted substantial evidence, including press releases, marketing materials, and educational materials, from which a jury could reasonably conclude that Teva specifically intended to encourage prescribers to use the generic for an infringing use.[100] Because the court held that the jury's verdict was supported by substantial evidence, the Federal Circuit vacated the district court's grant of JMOL and reinstated the jury's $235 million damages award.[101]

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92. U.S. Patent No. RE40,000 E col. 1, l. 17–25 (filed Nov. 25, 2003) ('000 Patent).

93. *GlaxoSmithKline*, 7 F.4th at 1324.

94. *Id.*

95. *See id.*

96. *Id.* at 1335–36.

97. *Id.* at 1333, 1336.

98. *Id.* at 1325. After GSK de-listed the original method-of-use '069 Patent from the FDA Orange Book, the FDA requested that Teva submit labeling which included the CHF indication for its generic. The FDA also requested information concerning Teva's position on the '000 Patent. Teva amended its label to include CHF but did not make a certification as to the '000 Patent. *Id.* at 1324–25.

99. The district court instructed the jury to consider induced infringement liability for two distinct time periods: the "partial label" period and the "full label" period. The partial label period, during which the generic label contained only the non-infringing indications of post-MI LVD and hypertension, lasted from January 8, 2008, to April 30, 2011. The full label period, during which the generic label contained all three FDA-approved indications, including the CHF indication, lasted from May 1, 2011, to June 7, 2015. *Id.* at 1325.

100. *Id.* at 1339.

101. *Id.* at 1323, 1340–41. The Federal Circuit also addressed the district court's jury instructions for calculating damages on a cross-appeal from Teva. *Id.* at 1340–41. The appeal

IV. ANALYSIS

A. The Origins of Induced Infringement

To understand how the *GSK v. Teva* case could change the law of induced patent infringement, one must first understand the basics of direct and indirect patent infringement. An unauthorized party who makes, uses, offers for sale, or sells a patented product will be liable for patent infringement.[102] This cause of action is often referred to as *direct* infringement.[103] However, direct infringement is not a patent owner's only path for recourse if its patent has been infringed.[104] Under the modern patent statute, a patent owner may also bring a cause of action for induced or contributory infringement[105] predicated on an underlying instance of direct infringement.[106] Induced and contributory infringement are often referred to as *indirect* patent infringement.[107] Under 35 U.S.C. § 271(b), a patentee may hold liable anyone who "actively induces infringement" of their patent.[108] Developed out of the tort principle of aiding and abetting, indirect infringement is premised on the idea that one who assists in the commission of a tort is just as culpable as the primary tortfeasor.[109]

If a generic drug is used in the patented method, i.e., prescribed or taken to treat a condition covered by the method-of-use patent, a brand-name manufacturer may pursue a case of direct patent infringement.[110] However, it behooves a brand-name manufacturer to avoid the imprudent strategy of suing its customers (i.e., physicians or patients) for the infringement.[111] A brand-name manufacturer will instead pursue

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presented a question of whether the presence of alternative but *infringing* manufacturers in the carvedilol market should be accounted for when calculating GSK's lost profits damages. *GlaxoSmithKline*, 7 F.4th at 1341. The court held that only non-infringing alternatives were relevant to the calculation of damages, and therefore, the district court did not err in its instruction to the jury. *Id.* at 1341–42. Though essential to the impact of the Federal Circuit's decision, because this does not implicate the law of induced infringement liability, it is outside the scope of this article.

102. 35 U.S.C. § 271(a).

103. *See, e.g.*, Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 759 (2011) (noting that the defendant had directly infringed the plaintiff's patent in violation of 35 U.S.C. § 271(a)).

104. *See* 35 U.S.C. § 271 (b)–(c).

105. *Id.*

106. Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1272 (Fed. Cir. 2004) ("Indirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement . . . .").

107. *Id.*

108. 35 U.S.C. § 271(b).

109. S. Rep. No. 82-1979, 2394, 2402 (1952) [hereinafter *Senate Report*] ("[35 U.S.C. § 271(b)] recites in broad terms that one who aids and abets an infringement is likewise an infringer."); Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990) ("Such liability [for indirect infringement] was under a theory of joint tortfeasance, wherein one who intentionally caused, or aided and abetted, the commission of a tort by another was jointly and severally liable with the primary tortfeasor.").

110. *See* Bell, *supra* note 22, at 671.

111. *Id.*

the generics manufacturer under an induced infringement cause of action.[112] But this strategy will only succeed if the generic manufacturer "actively induces infringement" in some way,[113] for example, by distributing marketing materials that teach the infringing use.[114]

This idea that a patent owner may hold liable a defendant who, though not infringing themselves, encourages or assists others to infringe is not new.[115] Long before the indirect infringement provisions of our modern patent statute, courts recognized this source of liability.[116] Some of the earliest indirect infringement cases sustained liability for those who made or sold a component which was especially made to be used in a patented combination or process.[117] Courts extended this patent infringement liability to cases when the component was not specifically made for an infringing combination but was accompanied by the defendant's active inducement in the forms of, for example, instructions or advertising that demonstrated the defendant's intent for the component to be used in the patented method or combination.[118]

As the court developed this doctrine and Congress codified it into law,[119] the specific intent of the defendant has become central to the question of liability. A plaintiff is required to show that a defendant intended to induce actions knowing that such actions would be patent infringement.[120] In the case of generic drugs, a court will find a manufacturer who knowingly and intentionally induces physicians and patients to use their generic in an infringing way liable for patent infringement.

While direct evidence of intent to induce infringement would be sufficient, it is not necessary.[121] A court will allow circumstantial evidence of intent, or even evidence of willful blindness,[122] to satisfy the

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112. Bell, *supra* note 22, at 671.

113. 35 U.S.C. § 271(b).

114. Bell, *supra* note 22, at 671.

115. *See, e.g.*, Wallace v. Holmes, 29 F. Cas. 74, 80 (No. 17,100) (C.C.D. Conn. 1871) (holding a defendant liable for patent infringement for making and selling a component especially made for use in a patented combination).

116. *Id.*

117. *Id.*

118. *See, e.g.*, Holly v. Vergennes Mach. Co., 4 F. 74, 82 (C.C.D. Vt. 1880) (holding defendant liable for patent infringement for selling water pump, which did not infringe until used by customer in patented water system, because the defendant "participated and concurred" in the direct infringement by "furnishing the pumps for that purpose.").

119. *Senate Report*, *supra* note 109 (stating that one of the major changes of the 1952 Patent Act was "incorporating . . . the judicial doctrine of contributory infringement in § 271.").

120. Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 766 (2011).

121. *GlaxoSmithKline*, 7 F.4th at 1327; *see Global-Tech*, 563 U.S. at 759.

122. Under the doctrine of willful blindness, a defendant who subjectively believes that there is a high probability that a given fact exists and takes deliberate actions to avoid learning that fact may be found to be willfully blind of that fact. The Supreme Court has ruled that willful blindness may satisfy the knowledge requirement for indirect infringement. *Global-Tech*, 563 U.S. at 769–70.

intent requirement.[123] This circumstantial evidence may include the generic label, user manuals, advertising, etc.[124] Specifically, a generic label may be circumstantial evidence of intent to induce infringement if the label encourages, recommends, or promotes infringement.[125] Here, though lacking direct evidence of intent, the Federal Circuit ruled that substantial circumstantial evidence supported the jury's finding that Teva intended to induce direct infringement of GSK's patent.[126]

B. The Federal Circuit's Decision: It's in the Label

Because a jury may reasonably infer Teva's intent to induce infringement from circumstantial evidence, this case does not represent a significant change in induced infringement jurisprudence, and the Federal Circuit properly affirmed the jury verdict. The court opened its analysis by assuring the parties and concerned amici that the "careful balance" crafted within the induced infringement jurisprudence for skinny label generics has not been disturbed.[127] Rather, the court reaffirmed that the central question is intent.[128] A defendant will not be held liable for "merely marketing and selling under a 'skinny' label omitting all patented indications, or for merely noting (without mentioning any infringing uses) that FDA had rated a product as therapeutically equivalent to a brand-name drug."[129] However, a defendant, like Teva, could be held liable when they intentionally induce doctors and patients to use their generic drug in an infringing way.[130]

The court described in detail what evidence may support a reasonable juror's finding that Teva intentionally induced infringement, starting with the skinny label itself.[131] First, Dr. McCullough, GSK's cardiology expert, compared GSK's patent to Teva's skinny label.[132] Claim 1 of GSK's '000 Patent recites:

> 1. A method of decreasing mortality caused by congestive heart failure in a patient in need thereof which comprises administering a therapeutically acceptable amount of carvedilol in conjunction with one or more other therapeutic agents, said agents being

123. *GlaxoSmithKline*, 7 F.4th at 1327 (stating that circumstantial evidence may suffice to show intent); *see Global-Tech*, 563 U.S. at 766 (affirming the finding of requisite intent under the doctrine of willful blindness).

124. *GlaxoSmithKline*, 7 F.4th at 1340 (quoting Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 843 F.3d 1315, 1335 (Fed. Cir. 2016)).

125. Takeda Pharm. USA, Inc. v. West-Ward Pharm. Corp., 785 F.3d 625, 631 (Fed. Cir. 2015).

126. *GlaxoSmithKline,* 7 F.4th at 1340.

127. *Id.* at 1326.

128. *See id.*

129. *Id.*

130. *Id.*

131. *Id.* at 1328.

132. *Id.*

> selected from the group consisting of an angiotensin converting enzyme inhibitor (ACE), a diuretic, and 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.*[133]

Dr. McCullough compared this to the post-MI LVD indication on Teva's skinny label, which stated:

> 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 ≤ 40% (with or without symptomatic heart failure) (*see CLINICAL STUDIES [14.1]*).[134]

Dr. McCullough described how each element of claim 1 was present in Teva's label: decreasing mortality caused by CHF; administering a therapeutically acceptable amount; conjoining with an ACE inhibitor, diuretic, or digoxin; and administering daily maintenance dosages for over six months.[135]

Dr. McCullough noted that a patient who, as Teva's label describes, has a "left ventricular ejection fraction of less than or equal than 40% with symptomatic heart failure" would be diagnosed as having CHF as defined in this case.[136] The corresponding Dosages and Administration section of Teva's label instructed a user to administer "a therapeutically acceptable amount" and "daily maintenance dosages."[137] And as the post-MI LVD indication explicitly refers to, the Clinical Studies § 14.1 demonstrates patients taking carvedilol with ACE inhibitors and diuretics for longer than six months.[138]

Teva challenged this testimony, arguing that to find all limitations of the patent claim in their label required the "cobbling together of disparate portions of the partial label."[139] But, the court promptly rejected this position, noting that all claim limitations could be found in the Indication section; the Clinical Study section, which the Indication section explicitly refers to; and the Dosages and Administration section, which immediately follows the Indication section.[140] A jury could reasonably conclude these sections should be read together and, together, these sections instruct a user to practice the infringing method.[141]

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133. '000 Patent, claim 1 (alteration in original).
134. *GlaxoSmithKline*, 7 F.4th at 1328 (alteration in original).
135. *Id.* at 1328–29.
136. *Id.*
137. *Id.* at 1328.
138. *Id.* at 1328–29.
139. *Id.* at 1329 (cleaned up).
140. *Id.*
141. *GlaxoSmithKline*, 7 F.4th at 1334.

However, a reasonable juror need not infer inducement from Teva's label alone.[142] The court pointed to "extensive expert testimony along with Teva's marketing efforts, catalogs, press releases, and testimony from Teva's own witnesses, showing that Teva encouraged carvedilol sales for CHF" despite its removal of CHF from the generic skinny label.[143] For example, a 2004 Teva press release touts their generic carvedilol as the "AB-rated generic equivalent of GlaxoSmithKline's Coreg® Tablets" which are "indicated for *treatment of heart failure* and hypertension."[144] This extrinsic evidence alone may not support a finding of intent to induce infringement, however, the totality of Teva's labels, press releases, product catalogs, and marketing materials is substantial evidence to support the jury's finding of induced infringement.[145]

Similarly, the court found that a reasonable jury could infer from the totality of evidence that Teva's action caused doctors or patients to directly infringe GSK's patent.[146] To prove that a defendant induced infringement, a plaintiff must show that the defendant's actions actually caused the direct infringer to take actions that constitute infringement.[147] Like the intent prong of indirect infringement, circumstantial evidence of causation (e.g., marketing materials, user instructions) that is directed to a class of direct infringers (e.g., customers) may support a finding of inducement.[148] Accordingly, the court found the circumstantial evidence here (e.g., the label, press releases, marketing materials), which was directed to a class of direct infringers (doctors and patients), was sufficient to sustain the jury's finding that Teva caused doctors and patients to infringe.

The court recognized that it was constrained by the procedural posture of this appeal and the applicable standard of review: substantial evidence.[149] For Teva to prevail on its renewed motion for JMOL following a jury trial, it must show that the jury's findings are unsupported by substantial evidence.[150] This, the majority explained, is where the district court erred.[151] Intent and causation are questions of fact for the jury, not questions of law for the district court or the court of appeals to review de novo.[152] Though the record contained evidence to the contrary, the jury was entitled to weigh the evidence as it saw

142. *Id.* at 1335.
143. *Id.*
144. *Id.* at 1335–36 (alteration in original).
145. *See id.* at 1337–38.
146. *Id.* at 1340.
147. *Id.* at 1339.
148. *Id.* at 1340.
149. *Id.* at 1340, 1326.
150. *Id.* at 1326.
151. *Id.* at 1330.
152. *GlaxoSmithKline*, 7 F.4th at 1330.

fit.[153] Because the jury's findings aligned with the current law of induced infringement, the Federal Circuit overturned the district court's erroneous decision.[154]

C. The Not-So-New Law of Induced Infringement

GSK v. Teva is not the seismic shift that critics of the decision allege; in fact, it is the natural result of a gradual development of induced infringement jurisprudence and proper application of the current law. The Federal Circuit properly affirmed the finding of induced infringement because the jury reasonably inferred Teva's intent to infringe from the circumstantial evidence,[155] just as the Federal Circuit has affirmed liability before.[156] Examples of circumstantial evidence sufficient to support liability for induced infringement, like the evidence presented by GSK, can be seen even in early induced-infringement-by-skinny-label precedents.[157]

i. All Roads Lead to GSK v. Teva

In *AstraZeneca LP v. Apotex, Inc.* (2010), the Federal Circuit held that language from the defendant's generic label would "inevitably" lead consumers to infringe,[158] and this label, along with other circumstantial evidence, sufficiently demonstrated the defendant's intent to encourage, recommend, or promote infringement.[159] The plaintiff's patent covered a method of administering the brand-name drug once daily.[160] The defendant's generic label specifically omitted this once-daily instruction.[161] However, the defendant's label retained FDA-required language instructing patients to incrementally decrease the dosage to the lowest effective dose once they achieved the desired therapeutic

153. *Id.* at 1329.

154. *See id.* at 1341.

155. *See id.* at 1326.

156. *See*, *e.g.*, AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1060–61 (Fed. Cir. 2010) (holding that circumstantial evidence, including a skinny label, was sufficient to support a finding of specific intent).

157. The analysis in this article does not begin with the 2003 Federal Circuit ANDA-induced infringement cases *Warner-Lambert Co. v. Apotex Corp.,* 316 F.3d 1348 (Fed. Cir. 2003), and *Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322 (Fed. Cir. 2003), because the facts of said cases are notably different from *GSK v. Teva*. For example, in *Warner-Lambert*, the method-of-use patent covered a non-FDA approved indication and the defendant sought to market and sell their generic for only an FDA-approved indication. *Warner-Lambert*, 316 F.3d at 1362. However, in the 2003 cases, the Federal Circuit does state that intent to induce is required for liability and circumstantial evidence may suffice to prove requisite intent. *See id.* at 1363.

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

159. *Id.* at 1060–61.

160. *Id.* at 1046.

161. *Id.* at 1047.

effect.[162] Inevitably, many consumers would decrease their consumption to a lowest effective dose that was taken once daily, infringing the plaintiff's method-of-use patent.[163] Because the generic label language instructed consumers to take actions that the plaintiff knew to be infringing, there was sufficient evidence of intent to induce infringement.[164]

The Federal Circuit's decision in *AstraZeneca* faced many of the same criticisms as *GSK v. Teva*. For example, critics of both cases point to the defendants' FDA-compliance and allege that to find these defendants liable runs afoul of the Hatch-Waxman scheme.[165] But both technically FDA-compliant labels were clouded by evidence of intent to induce infringement. In both cases, the court points to circumstantial evidence, from the labels themselves to the defendant's business activities, to find inducement. In *AstraZeneca*, the defendant proceeded with sales distribution of the generic despite infringement problems.[166] The generic label in *AstraZeneca* itself was deemed circumstantial evidence of intent.[167] Here, in *GSK v. Teva*, there was similar evidence of inducement found in Teva's product catalogs, press releases, and generic labels.[168] The 2010 *AstraZeneca* decision did not lead to the demise of the pharmaceutical industry as many critics warned; rather, it prompted a line of inducement-by-skinny-label cases, which naturally led to *GSK v. Teva*.[169]

For example, in *Eli Lilly & Co. v. Teva* (2017), the Federal Circuit affirmed the district court's ruling that the defendant induced infringement because the defendant's label would "inevitably lead some physicians to infringe" and therefore established intent to induce.[170] The court distinguished its previous holding in *Takeda v. West-Ward* (2015) where "vague label language" that required a physician to look outside the label to receive the full instruction to infringe was insufficient to support a finding of inducement.[171] Like the *GSK v. Teva* court, the *Eli*

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162. *AstraZeneca*, 633 F.3d at 1047 (noting that the brand-name label instructed a patient that "[o]nce the desired clinical effect is achieved, consideration should be given to tapering to the lowest effective dose" and that "the proposed [generic] label retained the FDA-mandated downward-titration language.").

163. *Id*. at 1060.

164. *Id*. at 1061.

165. *GlaxoSmithKline*, 7 F.4th at 1342 (Prost, J., dissenting); Terry G. Mahn, *Skinny Labeling and the Inducement of Patent Infringement*, (November/December 2010), FISH & RICHARDSON, https://www.fr.com/files/uploads/attachments/Skinny_Labeling_Inducement_of_Patent_Infringement_Nov-Dec-2010.pdf.

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

167. *Id.* at 1060–61.

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

169. DONALD S. CHISUM, 5 CHISUM ON PATENTS § 17.04(4)(f)(ii)(C)(2023).

170. Eli Lilly & Co. v. Teva Parenteral Meds., Inc., 845 F.3d 1357, 1369 (Fed. Cir. 2017).

171. *Id.* at 1369; Takeda Pharm. USA, Inc. v. West-Ward Pharm. Corp., 785 F.3d 625, 634 (Fed. Cir. 2015).

Lilly court did not focus its analysis on the "prevalence of the induced activity," i.e., if all physicians would follow the instructions and infringe. Rather, the court focused its analysis on the clarity of the label's instructions.[172]

The Federal Circuit's induced infringement cases continued to permit an inference of intent to rest on label instructions. In *Sanofi v. Watson Laboratories* (2017), the court held that the label's "indications of use and the internally referred-to elaboration of those indications" were sufficient to infer specific intent to encourage infringement.[173] In *GSK v. Teva*, like in *Sanofi*, the indication section of the label refers the reader to a clinical studies section, and the combined instructions of these sections were found to induce infringement.[174] A label need not contain "explicit" instructions to practice the patented method to support an inference of intent to induce.[175]

Again, in *Vanda Pharmaceuticals v. West-Ward Pharmaceuticals* (2018), the Federal Circuit affirmed the district court's finding of induced infringement, reiterating that circumstantial evidence such as "advertising an infringing use or instructing how to engage in an infringing use" or even the "contents of the label itself" may support a finding of inducement.[176] The court in *Vanda*, citing *AstraZeneca,* also held that a plaintiff may satisfy its burden to prove predicate direct infringement by showing the defendant's label would inevitably lead users to infringe.[177] Contrary to the dissent by Judge Prost in *GSK v. Teva*,[178] the Federal Circuit's well-developed case law does not require a plaintiff to present direct evidence to prove either intent to induce or actual inducement.

However, in *Grunenthal GmbH v. Alken Laboratories* (2019) and *HZNP Medicines v. Actavis Laboratories* (2019), the Federal Circuit demonstrated the limits of circumstantial evidence and affirmed the district court's findings of no induced infringement.[179] In *Grunenthal*, the court contrasted the labels in *AstraZeneca* that "would inevitably lead some consumers to practice the claimed method" and held that Alkem's labels "do not implicitly or explicitly encourage or instruct users to take action that would inevitably lead" to direct infringement.[180] The court found that Alkem's label *could* result in some users practicing the

172. *Eli Lilly*, 845 F.3d at 1368–69.

173. Sanofi v. Watson Labs. Inc., 875 F.3d 636, 646 (Fed. Cir. 2017).

174. *Id.* at 645; *GlaxoSmithKline*, 7 F.4th at 1328–29.

175. *Sanofi*, 875 F.3d at 646.

176. Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd., 887 F.3d 1117, 1129 (Fed. Cir. 2018) (citing Takeda, 785 F.3d at 630–31).

177. *Id.* at 1130 (citing AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1057. (Fed. Cir. 2010)).

178. *See GlaxoSmithKline*, 7 F.4th at 1358 (Prost, J., dissenting) (noting that "the majority identifies no direct evidence of causation by Teva.").

179. Grunenthal GmbH v. Alkem Labs. Ltd., 919 F.3d 1333, 1340–41 (Fed. Cir. 2019); HZNP Meds. LLC v. Actavis Labs. UT, Inc., 940 F.3d 680, 702 (Fed. Cir. 2019).

180. *Grunenthal*, 919 F.3d at 1340.

infringing method but did not specifically encourage actions that would *inevitably* result in infringement.[181] Similarly, in *HZNP*, the court held that, while some end users may infringe HZNP's three-step method-of-use patent, Actavis's label only contained instructions[182] for step one and therefore could not demonstrate intent to induce all three steps.[183]

The majority in *GSK v. Teva* specifically distinguished *Grunenthal* and *HZNP* to support its finding of induced infringement.[184] Unlike in *Grunenthal*, where the label's instructions encouraged actions which did not necessarily result in infringement, Teva's label explicitly instructs actions which necessarily result in the user practicing the infringed method.[185] And unlike in *HZNP*, where the label instructed only one step of a three-step patented method, Teva's label contains instructions for each claimed step.[186] Despite the warnings from concerned amici,[187] the Federal Circuit's decision in *GSK v. Teva* is not an outlier, but rather is an application of well-established induced infringement precedents.

ii. Finding Induced Infringement in the Evidence

As can be seen from this line of induced infringement cases, a generic drug label—even standing alone—may constitute sufficient circumstantial evidence to support induced infringement.[188] A plaintiff, like GSK, need not always point to specific instances of direct infringement or show the prevalence thereof.[189] A defendant could even show that some users ignore the label's instructions, and the label may still support a finding of inducement because the relevant question is not one of frequency of direct infringement, but rather is one of intent to cause infringement.[190]

This idea—that a label alone is enough for inducement liability—scares amici.[191] Amici touted fears that, under the new *GSK v. Teva* precedent, a manufacturer could be held liable for marketing and selling a generic drug with a skinny label that omits all patented indications or merely mentioning that their generic is therapeutically equivalent to a

181. *Grunenthal*, 919 F.3d at 1339.

182. Actavis's label also contained an "if/then" warning which alluded to steps two and three of the patented method. The court found this warning to be insufficient to constitute *encouragement*, and therefore the warning did not change the court's finding of no induced infringement. *HZNP*, 940 F.3d at 702.

183. *HZNP*, 940 F.3d at 702.

184. *GlaxoSmithKline*, 7 F.4th at 1329–30.

185. *Id.*

186. *Id.* at 1330.

187. *See id.* at 1326.

188. *See, e.g.*, *Vanda*, 887 F.3d at 1129 (stating that "[t]he contents of the label itself may permit the inference of specific intent to encourage, recommend, or promote infringement.") (quoting Sanofi, 875 F.3d at 646).

189. *Id.* at 1129–30.

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

191. *GlaxoSmithKline*, 7 F.4th at 1326.

brand-name drug.[192] They fear that, with no other evidence of intent, or even evidence of actual infringement, a label can be read to induce infringing actions that may be the basis for a $235 million liability.[193] However, these fears are misplaced because Teva did not omit all patented indications or merely note that its generic is therapeutically equivalent to COREG®.[194]

The court discussed in detail the evidence that the jury could have relied on to find inducement.[195] The jury was entitled to find that Teva intended its Prescribing References, which encouraged infringement, to influence how doctors prescribed their generic.[196] The jury could have relied on marketing materials, including Teva's Spring 2008 and Spring 2009 Product Catalogs, which described their generic as equivalent to COREG®. The jury could have inferred that Teva intended doctors to prescribe their generic for the patented chronic heart failure indication from Teva's press releases in which they said their generic was "indicated for the treatment of heart failure."[197] This circumstantial evidence is also sufficient, the court held, to infer causation.[198] Because there is sufficient circumstantial evidence in the form of marketing materials, catalogs, press releases, and expert testimony, the court determined that it need not address if the label alone would support a finding of liability.[199]

Throughout its analysis, the court emphasized the applicable standard of review: substantial evidence.[200] The jury was entitled to weigh the circumstantial evidence as it saw fit.[201] While the record was not devoid of evidence to the contrary,[202] the court held that the jury had substantial evidence to support their finding of induced infringement.[203] Thus, the court vacated the district court's grant of JMOL and reinstated the jury's verdict.[204]

D. The Changing Business Risk Analysis

Despite *GSK v. Teva*'s de minimis change to the induced infringement jurisprudence, the Federal Circuit's decision is likely to impact the risk analysis for generics manufacturers. For starters, this

192. *GlaxoSmithKline*, 7 F.4th at 1326.
193. *See id.*
194. *Id.*
195. *Id.* at 1333–39.
196. *Id.* at 1335.
197. *Id.* at 1335–36.
198. *Id.* at 1340.
199. *Id.*
200. *See, e.g.*, *id.* at 1328.
201. *Id.* at 1340.
202. *Id.* at 1331.
203. *Id.* at 1340.
204. *Id.* The court also ruled on a question of damages not relevant to this article.

case is a harsh reminder of the scope of circumstantial evidence that can be used to infer intent.[205] Further, the sheer size of the jury award affirmed here compared to the sales by the defendant in the relevant time should give potential defendants pause.[206] This case is a reminder of the Federal Circuit's strict induced infringement jurisprudence and perhaps hostility towards the Hatch-Waxman scheme.[207]

First, a generics manufacturer should reconsider its labeling strategy. *GSK v. Teva* is a reminder that different sections of a label may, together, instruct an infringing use. Teva unsuccessfully argued that GSK was merely "cobbling together disparate portions" of its label to find instructions to infringe.[208] Nonetheless, the court found that the Indication, Clinical Study, and Dosage and Administration sections—read together—contained each claim limitation and supported the jury's finding that the label instructed the infringing use.[209]

Further, generics manufacturers should reevaluate their communications strategies for existing or prospective generics including advertising materials, website content, prescribing instructions, and press releases. The language used to describe a generic and its uses matters, especially in the case of potentially overlapping indications. For example, Teva's failure to "parse between congestive heart failure or post-MI LVD" plus direct reference to GSK's COREG® in their 2004 press release was sufficient for the jury to conclude that Teva's intent in issuing the press release was to encourage users to substitute Teva's tablets for GSK's Coreg® tablets to treat congestive heart failure.[210] Generics manufacturers should provide all business functions, including sales, marketing, and public relations, with a clear, permissible vocabulary with which they can describe their generic without implicating its brand-name counterpart.

GSK v. Teva also serves as a reminder that merely having an FDA-compliant skinny label will not automatically shield against liability. Information provided by the FDA to ANDA applicants is not meant to replace the applicant's review of the potentially relevant patents.[211] As discussed at trial and in oral argument before the Federal Circuit, the FDA has no expertise in patent law and no ability to determine patent rights.[212] Despite an approved ANDA, a plaintiff like GSK may still

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205. *See, e.g.*, *GlaxoSmithKline*, 7 F.4th at 1335 (pointing to a 2004 press release which pre-dated the launch of Teva's generic by three years).

206. *See* Lane, *supra* note 9.

207. *See, e.g.*, *GlaxoSmithKline*, 7 F.4th at 1353 (Prost, J., dissenting) (arguing that the majority's ruling exposes generic manufacturers to liability merely for describing their drugs as "generic equivalent[s]" contrary to congressional intent).

208. *Id.* at 1329.

209. *Id.*

210. *Id.* at 1336.

211. *Id.* at 1331–32.

212. *Id.*

present sufficient circumstantial evidence to sustain a finding of induced infringement.[213]

The urgency of business action is heightened by the sheer size of the damages assessed against Teva. Here, the Federal Circuit affirmed damages of $234,110,000 in lost profits plus $1,400,000 for a reasonable royalty payment.[214] This verdict is notably more than three times Teva's profits during the same time period.[215] Though the Federal Circuit described its decision as a "narrow, case-specific review,"[216] the damages award will play a significant role in the changing business risk analysis.

For example, the court's decision may increase the desirability of a paragraph IV certification over a section viii carve out. If a defendant is likely to find themselves in costly litigation over either their paragraph IV certification or their proposed skinny label, it may be wise to offensively seek to invalidate the underlying patent or obtain a declaratory judgment of noninfringement, rather than merely defend against what could be a sizable verdict.

Such a change in generics strategy should be made thoughtfully and deliberately. Here, Teva initially made a paragraph IV certification in its 2002 ANDA.[217] But just prior to launch in 2007, Teva certified to the FDA that it would launch as a section viii carve out.[218] Despite Teva's official pivot to launch its generic with a skinny label, its press releases and marketing materials retained references to its generic as a treatment for heart failure.[219] These references would later be used as evidence of intent to infringe.[220]

Most of all, generics manufacturers should proceed with caution. It is unclear just how far-reaching the Federal Circuit's decision will be. There is evidence that district courts are interpreting the decision case as another application of long-standing rules.[221] However, there is also evidence to the contrary; that courts are reading *GSK v. Teva* as an expansion of the induced infringement doctrine.[222] Whether the

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213. *GlaxoSmithKline*, 7 F.4th at 1324 (noting that Teva received tentative FDA-approval for its generic "for the treatment of heart failure and hypertension" to become effective when GSK's composition patent expired in 2007).

214. *Id.* at 1340–41.

215. *See* Lane, *supra* note 9.

216. *GlaxoSmithKline*, 7 F.4th at 1326.

217. *Id.* at 1324.

218. *Id.*

219. *Id.*

220. *Id.* at 1336.

221. *See* Novartis Pharms. Corp. v. Alkem Lab'ys Ltd. *(In re Entresto Sacubitril/Valsartan),* No. 20-2930-RGA, 2022 U.S. Dist. LEXIS 174611, at *15 (D. Del. Sept. 27, 2022) (treating *GSK v. Teva* as a "narrow, case-specific review").

222. *See* Salix Pharm., Ltd. v. Norwich Pharm., Inc., No. 20-430-RGA, 2022 U.S. Dist. LEXIS 142335, at *32–33 (D. Del. Aug. 10, 2022) (relying on *GSK v. Teva* to support the proposition that multiple sections of a generic label may, together, encourage infringing use, even if the indication

decision was a faithful application of precedent or an upheaval to the entire doctrine of induced infringement, the decision nonetheless gives generics manufacturers a compelling reason to reevaluate their generics strategies.

V. CONCLUSION

The Federal Circuit's decision to vacate the district court's grant of JMOL and reinstate the jury's $235 million verdict against Teva was met with mixed reactions. Critics tout the decision as a "direct contravention of the Hatch-Waxman Act."[223] Supporters praise the Federal Circuit for applying the correct legal standard.[224] Despite the fact that the Federal Circuit's decision does not represent a material shift in induced infringement jurisprudence, it nonetheless will have a significant impact on the generics market. This impact is only solidified by the Supreme Court's refusal to hear the case.[225] Love it or hate it, *GSK v. Teva* is the law of the land.

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section does not specifically direct the reader to look at those other sections); Amarin Pharma v. Hikma Pharm. United States, 578 F. Supp. 3d 642, 644 (D. Del. 2022) ("A generic manufacturer can be liable for inducing infringement of a patented method even when the generic has attempted to 'carve out' the patented indications.").

223. *GlaxoSmithKline*, 7 F.4th at 1326.

224. *See, e.g.*, Corrected Brief of *Amicus Curiae* Pharmaceutical Research and Manufacturers of America in Support of GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited at 5–8, GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 2018 U.S. Fed. Cir. BRIEFS LEXIS 2164 (2018) (No. 18-1976).

225. *See* Teva Pharms. USA, Inc. v. GlaxoSmithKline LLC, 143 S. Ct. 2483 (2023) (denying petition for writ of certiorari).