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NOTE

*GSK v. Teva: The End of Generic
Skinny Labels?*

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INTRODUCTION

Generic drugs (“generics”) are medications created to work the same and provide the same benefit as a brand-name drug.¹ Generics often offer cheaper alternatives to the corresponding brand-name drugs because generics are unpatented, and generic developers do not need to repeat the clinical trials required of brand-name drugs to demonstrate safety and effectiveness before introducing generics to market.² Generic developers skip the expensive clinical trial phase by instead showing that the generic functions and has the same efficacy as the brand-name product.³ By providing cheaper, but equally effective alternatives to brand-name drugs, generics lower the cost of medications and make them accessible to a greater proportion of the general consumer population.⁴ According to the Association for Accessible Medicines, generics saved the U.S. healthcare system approximately \$2.2 trillion from 2009 to 2019.⁵ Rates of cost-related prescription medication underuse are highest among African Americans and Latinos,⁶ so generics also have great potential to increase equitable access to medicine by decreasing the cost barrier.⁷

To facilitate the development and availability of these cost-saving generics in the marketplace without discouraging pharmaceutical innovation by brand-name drug companies, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the

¹ *Generic Drugs: Questions & Answers*, U.S. FOOD & DRUG ADMIN. (Mar. 16, 2021), <https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers#q1> [<https://perma.cc/GE82-PWBT>].

² *Id.*

³ *The Generic Drug Approval Process*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/news-events-human-drugs/generic-drug-approval-process> (last updated Mar. 17, 2022) [<https://perma.cc/9A5C-4RHG>].

⁴ Joseph W. Arico, Andrea L.C. Reid & Carl A. Morales, *Skinny Labels and the Line Between Mere Information and Inducement to Infringe in ANDA Litigation*, BLOOMBERG L., (May 7, 2018, 7:33 AM), https://www.bloomberglaw.com/bloomberglawnews/health-law-and-business/X5K528QG000000?bna_news_filter=health-law-and-business#jcite [<https://perma.cc/J73Z-SV3G>].

⁵ ASS'N FOR ACCESSIBLE MEDS., 2020 GENERIC DRUG & BIOSIMILARS ACCESS & SAVINGS IN THE U.S. REPORT 4 (2020), <https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf> [<https://perma.cc/ANQ4-UZW2>].

⁶ Walid F. Gellad, Jennifer S. Haas & Dana Gelb Safran, *Race/Ethnicity and Nonadherence to Prescription Medications Among Seniors: Results of a National Study*, 22 J. GEN. INTERNAL MED. 1572, 1574 (2007).

⁷ See Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 859 (2016).

“Hatch-Waxman Amendments”).⁸ The Hatch-Waxman Amendments seek to remove barriers to generic drug market entry while still respecting the patent rights of brand-name drug developers.⁹ To that end, the statutory scheme implemented by the Hatch-Waxman Amendments contains a mechanism by which generic developers can omit, or “carve out” patent-protected uses for the drug from the generic’s label, resulting in a “skinny label.”¹⁰ Skinny labels thus allow generic developers to sell generics for unpatented uses, avoiding infringement of a brand company’s method-of-use patents that protect novel, useful, and non-obvious ways to use a drug.¹¹

However, the legal viability of skinny labeling has come into question with the Federal Circuit’s decision in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.* (“*GSK v. Teva*”).¹² In July 2014, GSK sued Teva in the District Court of Delaware for patent infringement, alleging induced infringement of GSK’s patent for use of its beta-blocker drug, Coreg, to treat congestive heart failure (“CHF”).¹³ Teva’s generic version, carvedilol, had a skinny label that carved out the generic’s use for treating CHF. GSK argued, with support from expert testimony and Teva’s marketing materials, that the skinny label still induced infringement in prescribing physicians.¹⁴ GSK argued that Teva’s skinny label contained an unpatented indication for Left Ventricular Dysfunction following a Myocardial Infarction (“Post-MI LVD”), which would encourage infringement of GSK’s patented CHF indication because physicians would recognize that a large subset of Post-MI LVD patients would also be classified as having CHF.¹⁵

GSK also pointed to Teva’s marketing materials, which described its generic carvedilol as “bioequivalent” to Coreg, arguing that this comparison would lead physicians to believe carvedilol could be prescribed interchangeably with Coreg for all indications.¹⁶ A jury agreed with GSK and awarded it \$235 million in damages, but the

⁸ D. Christopher Ohly & Sailesh K. Patel, *The Hatch-Waxman Act: Prescriptions for Innovative and Inexpensive Medicines*, 19 U. BALT. INTELL. PROP. L.J. 107, 111 (2011).

⁹ Sara W. Koblitiz, *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, FOOD & DRUG L. INST., https://www.fdli.org/2021/06/glaxosmithkline-llc-v-teva-pharmaceuticals-usa-inc/#_ftnref3 (last visited Aug. 18, 2021) [<https://perma.cc/2AAV-9XFX>].

¹⁰ *Id.*

¹¹ *See id.*

¹² 7 F.4th 1320 (Fed. Cir. 2021).

¹³ *Id.* at 1325.

¹⁴ *See id.* at 1327-30.

¹⁵ *See id.* at 1328.

¹⁶ *See GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347, 1354 (Fed. Cir. 2020).

district court granted Teva's motion for judgment as a matter of law and overturned the jury verdict.¹⁷ The court stated that no reasonable jury could have found that GSK had proven that Teva's marketing materials and skinny label had actually *caused* physicians to infringe.¹⁸ Upon appeal by GSK, the U.S. Court of Appeals for the Federal Circuit issued a controversial 2-1 decision in October 2020 reinstating the jury verdict for GSK.¹⁹ On August 5, 2021, after rehearing arguments and receiving several amicus curiae briefs, the court reaffirmed its decision that Teva was liable for induced infringement of GSK's patent on a method-of-use for Coreg, despite Teva's skinny label carving out the patented use.²⁰ Read broadly, the Federal Circuit's language implies that generic skinny labels that fully carve out infringing uses can still be susceptible to induced infringement liability based on external circumstantial evidence.²¹ This reading threatens the viability of generics, both in development and in the marketplace, and could revert years of progress towards increasing equitable access to medically necessary drugs.²² Courts therefore must carefully consider how they will interpret the Federal Circuit's ruling bearing in mind its potentially far-reaching effects on the pharmaceutical industry.

This Note proceeds in three parts. Part I provides an overview of U.S. Food and Drug Administration's ("FDA") pathway for generic drugs to enter the market and explores the legal background on issues of pharmaceutical patents and generic drug development.²³ Part II asserts that the court's holding in *GSK v. Teva* contradicts congressional intent in enacting the Hatch-Waxman Amendments and will make it difficult for generic developers to make informed decisions when marketing generics.²⁴ Finally, Part III argues that courts should hold the specific intent element for inducing infringement to a higher threshold of finding that the evidence encourages, recommends, or promotes infringing use by requiring evidence of actual causation.²⁵

¹⁷ *GlaxoSmithKline*, 7 F.4th at 1348 (Prost, C.J., dissenting).

¹⁸ *See id.* at 1325.

¹⁹ *GlaxoSmithKline*, 976 F.3d at 1357; *GSK v. Teva: Federal Circuit Opinion After Rehearing Confirms Induced Infringement Liability Despite Skinny Label*, COOLEY (Aug. 17, 2021), <https://www.cooley.com/news/insight/2021/2021-08-17-gsk-v-teva-federal-circuit-opinion-rehearing-induced-infringement-liability-skinny-label> [<https://perma.cc/G7XU-FMHN>].

²⁰ *See GlaxoSmithKline*, 7 F.4th at 1341-42.

²¹ Koblitz, *supra* note 9.

²² *See id.*

²³ *See infra* Part I.

²⁴ *See infra* Part II.

²⁵ *See infra* Part III.

I. BACKGROUND

Through the 1962 Kefauver-Harris Drug Amendments to the Federal Food, Drug, and Cosmetic Act, Congress established statutory authority for the FDA to review and approve all new drugs for safety and efficacy prior to introduction into interstate commerce.²⁶ Accordingly, the FDA requires drug developers to submit New Drug Applications (“NDAs”) that include, among other information, data from controlled human clinical trials that establish the proposed drug is safe and effective for its intended use.²⁷ The FDA also requires NDA holders to submit a list of patents for the drug, including patents for the active ingredient, formulation, and method-of-use or indications.²⁸ FDA will then compile this information in its publicly available list of Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”).²⁹ When the original patent protection for the brand drug for any and all uses (“composition-of-matter protection”) has expired, brand companies will often retain or continue to file new method-of-use patents for specific uses of the drug.³⁰

Until Congress enacted the 1984 Hatch-Waxman Amendments, the clinical trials requirement also applied to generic developers, making it cost-prohibitive for generics to obtain FDA approval.³¹ To address this situation, the Hatch-Waxman Amendments created an abbreviated pathway for generic developers to submit an Abbreviated New Drug Application (“ANDA”) showing that the generic is the same or bioequivalent to the brand-name drug without supplying independent clinical trials.³² ANDAs rely on the determined safety and effectiveness of the corresponding approved brand-name drug, also called the reference listed drug (“RLD”), for approval of a generic with the same active ingredient, route of administration, and concentration.³³ Once their ANDAs are approved, generics that meet necessary bioequivalence

²⁶ See 21 U.S.C. § 355 (2018); *Milestones in U.S. Food and Drug Law*, U.S. FOOD & DRUG ADMIN. (Jan. 31, 2018), <https://www.fda.gov/about-fda/fda-history/milestones-us-food-and-drug-law> [https://perma.cc/RC28-GXX4].

²⁷ Koblitz, *supra* note 9.

²⁸ See *id.*

²⁹ KEVIN T. RICHARDS, KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 10 (2020), <https://sgp.fas.org/crs/misc/R46221.pdf> [https://perma.cc/BRX7-H2TX].

³⁰ See Arico et al., *supra* note 4.

³¹ Koblitz, *supra* note 9.

³² *Generic Drugs: Questions & Answers*, *supra* note 1.

³³ Ohly & Patel, *supra* note 8, at 113; Koblitz, *supra* note 9.

standards for direct substitution to a RLD will receive an AB rating in the Orange Book.³⁴

Generally, the FDA requires that generic labels be exactly the same as those for the RLD.³⁵ However, ANDAs can instead choose to include a “section viii statement”, which informs the FDA that the ANDA holder is omitting or carving out an indication for the generic that is covered by the RLD’s method-of-use patent in the Orange Book without sacrificing safety and effectiveness.³⁶ The FDA often approves such carveouts because they allow immediate ANDA approval rather than tentative approval until all the RLD’s patents expire.³⁷ Correspondingly, the generic developer will carve out the patent-protected indication from the drug label to create a skinny label in order to avoid infringing the patent.³⁸

In practice, however, physicians still often prescribe skinny-labeled generics for patent-protected uses because generics are cheaper and equally effective as the brand-name drug.³⁹ Courts therefore recognize that while skinny labels do not directly infringe the brand-name drug’s method-of-use patent, they can induce infringement by prescribing physicians.⁴⁰ Pursuant to 35 U.S.C. Section 271(b), “[w]hoever actively induces infringement of a patent shall be liable as an infringer.”⁴¹ To recover for induced infringement of a pharmaceutical method-of-use patent, a plaintiff must prove, by a preponderance of evidence, that the defendant generic developer (1) knew of the asserted patent, and (2) had the specific intent to induce infringement in prescribing physicians.⁴² Mere knowledge or existence of direct infringement by prescribing physicians or users is not sufficient for induced

³⁴ The FDA assigns drugs that are therapeutically equivalent an “A” rating and those that have not been shown to be therapeutically equivalent a “B” rating. Each “A” and “B” rated generic is assigned a second letter reflecting the dosage, route of administration, and basis of the FDA’s therapeutic equivalence determination. Generics that have the same active ingredient, dosage form, and route of administration will generally receive an AB rating once submitted data has demonstrated bioequivalence. Koblitz, *supra* note 9.

³⁵ Arico et al., *supra* note 4.

³⁶ *See id.*

³⁷ Koblitz, *supra* note 9.

³⁸ *See* Arico et al., *supra* note 4.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ 35 U.S.C. § 271(b) (2018).

⁴² *See* Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1364 (Fed. Cir. 2003) (citing Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 554 (Fed. Cir. 1990)).

infringement by the generic developer.⁴³ To satisfy the requisite specific intent element, the skinny label must “encourage, recommend, or promote infringement.”⁴⁴ A plaintiff-patentee can prove both specific intent and direct infringement through circumstantial rather than direct evidence.⁴⁵ Thus, circumstantial evidence that the generic label would inevitably lead some physicians to infringe would satisfy the specific intent element for induced infringement.⁴⁶

In *GSK v. Teva*, the jury was presented with evidence from Teva’s press releases and other marketing materials that referred to Teva’s generic as “indicated for treatment of heart failure and hypertension”⁴⁷ and an “AB-rated generic equivalent of GlaxoSmithKline’s Coreg tablets.”⁴⁸ GSK’s physician expert testified that those marketing materials would lead a prescribing physician to believe the generic and Coreg were completely interchangeable for all indications, despite Teva’s physician expert testifying the opposite.⁴⁹ The jury found Teva had induced infringement, but the district court granted Teva’s motion for judgment as a matter of law.⁵⁰ The district court reasoned that physicians’ infringements were caused by physician’s prior assumptions and other resources rather than by Teva’s marketing materials.⁵¹ However, the U.S. Court of Appeals for the Federal Circuit reversed the district court, reinstating the jury verdict for GSK.⁵² The Federal Circuit held that “when the provider of an identical product knows of and markets the same product for intended direct infringing activity, the criteria of induced infringement are met.”⁵³ The Federal Circuit interpreted Teva’s marketing materials and deferred to physicians’

⁴³ See *Takeda Pharms. USA, Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015).

⁴⁴ *Id.*

⁴⁵ *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347, 1352 (Fed. Cir. 2020) (citing *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 824 F.3d 1344, 1347 (Fed. Cir. 2016)).

⁴⁶ See *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1369 (Fed. Cir. 2017).

⁴⁷ *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1336 (Fed. Cir. 2021).

⁴⁸ *GlaxoSmithKline*, 976 F.3d at 1353.

⁴⁹ See *id.* at 1354.

⁵⁰ *Id.* at 1350-51.

⁵¹ *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582, 594 (D. Del. 2018) (citing physicians’ prior knowledge, American Heart Association and American College of Cardiology guidelines, and other research studies as possible sources of the infringing use).

⁵² *GlaxoSmithKline*, 976 F.3d at 1356.

⁵³ *Id.* at 1355.

reliance on those materials to find that a jury could reasonably conclude Teva was encouraging physicians to infringe.⁵⁴ Though the majority insisted its holding was limited to the unique facts of the case,⁵⁵ *GSK v. Teva* leaves open a crucial question: how far can materials outside of a fully carved-out skinny label and doctors' interpretations of those materials go to demonstrate induced infringement?

II. A FLAWED NEW STANDARD FOR SKINNY LABEL INDUCED INFRINGEMENT

The Federal Circuit's decision holds potentially dire consequences for all generics with carved-out skinny labels. Given the importance of generics in healthcare,⁵⁶ several factors weigh in favor of setting a higher standard for the specific intent element of induced infringement. First and foremost, the decision contradicts congressional intent by threatening to upset the long-established balance between patent rights and access to drugs that Congress created through the Hatch-Waxman Amendments.⁵⁷ Second, the Majority's holding introduces ambiguity in the legal viability of skinny label carveouts, making it difficult for generic manufacturers to make informed marketing decisions.⁵⁸ Finally, policy considerations support rebalancing patent rights and generics' public health benefits in favor of the latter.⁵⁹

A. Congressional Intent

Congress enacted the Hatch-Waxman Amendments with two seemingly opposed policy goals in mind: facilitating access to affordable medicine by removing barriers to generics' entry into the market and continuing to reward pharmaceutical innovation through patent rights.⁶⁰ To maintain that balance, Congress specifically included section viii statements in the Hatch-Waxman Amendments. Through section viii statements, generic developers could carve out patent-

⁵⁴ See *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1336 (Fed. Cir. 2021).

⁵⁵ See *id.* at 1335 (“Thus, Teva’s AB rated representations *under these limited circumstances* . . . are further affirmative evidence supporting the jury’s inducement finding.” (emphasis added)).

⁵⁶ See 2020 GENERIC DRUG & BIOSIMILARS ACCESS & SAVINGS IN THE U.S. REPORT, *supra* note 5, at 4.

⁵⁷ See *infra* Part II.A.

⁵⁸ See *infra* Part II.B.

⁵⁹ See *infra* Part II.C.

⁶⁰ *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003).

protected uses for the generic drug from its label, creating a skinny label with only non-patented uses.⁶¹ Congress intended for this new pathway to allow generics to enter the market more quickly, because even after a brand company's composition-of-matter patent had expired, its method-of-use patents still proved to be significant obstacles in developing and marketing a generic without infringing.⁶²

Indeed, the Supreme Court in a later case recognized that "Congress understood a single drug may have multiple methods of use, only one or some of which a patent covers" and that the Hatch-Waxman Amendments "[contemplate] that one patented use will not foreclose marketing a generic drug for other unpatented ones."⁶³ Where previously generic manufacturers were stuck waiting for all of the brand company's patents to expire before beginning development of generic versions, skinny labeling and the section viii statement mechanism now allow generics to enter the market quickly after the brand company's composition-of-matter patent has expired.⁶⁴ As a result, cheaper medication is available to the public sooner with no infringement of any remaining method-of-use patents held by the RLD developer.⁶⁵ However, the Federal Circuit's recent ruling threatens the careful balance Congress struck.⁶⁶

In *GSK v. Teva*, Teva acted as Congress intended.⁶⁷ Teva waited until GSK's composition-of-matter patent on Coreg had expired, and filed a section viii statement that carved out GSK's patented method-of-use for treating CHF.⁶⁸ In its marketing materials, Teva noted carvedilol's AB-rated therapeutic equivalence to Coreg, as the FDA had assigned, but did not expressly mention any infringing uses for the drug.⁶⁹ In all this, Teva manifested an intent to *avoid* inducing infringement of GSK's patent.⁷⁰ Yet, the Federal Circuit seemingly deferred to GSK's expert testimony, which asserted that reasonable physicians would interpret Teva's marketing materials noting equivalence with Coreg as

⁶¹ See 21 U.S.C. § 355(j)(2)(A)(viii) (2018); Koblitz, *supra* note 9.

⁶² See Arico et al., *supra* note 4.

⁶³ *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 401 (2012).

⁶⁴ See Arico et al., *supra* note 4.

⁶⁵ *Id.*

⁶⁶ See *Caraco Pharm. Lab'ys*, 566 U.S. at 401 (endorsing the balance struck by Congress).

⁶⁷ *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347, 1358 (Fed. Cir. 2020) (Prost, C.J., dissenting).

⁶⁸ *Id.*

⁶⁹ *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1354 (Fed. Cir. 2021) (Prost, C.J., dissenting).

⁷⁰ *Id.* at 1342.

encouraging use of carvedilol for any indication for which Coreg had been approved.⁷¹ This included prescriptions for the patented use of treating CHF, due to a close connection between patients with Post-MI LVD and CHF.⁷²

Courts have previously allowed findings of active steps to encourage infringement when a company advertises an infringing use,⁷³ but the Federal Circuit has also clarified that such instructions must evince an active intent to encourage infringement.⁷⁴ Simply describing the infringing use is not sufficient.⁷⁵ Consequently, the Federal Circuit's precedent seems to have created an implicit causation prong within the specific intent element for induced infringement.⁷⁶ In *GSK v. Teva*, however, the Federal Circuit blurs the rule for the specific intent element and effectively erases the causation prong by allowing a prescribing physician's own interpretation of marketing materials and prior medical knowledge to cause marketing materials outside of a drug's label to constitute evidence of induced infringement.⁷⁷

In passing the Hatch-Waxman Amendments, Congress foresaw exactly the issue in the present case and created pathways for generic developers to avoid this kind of infringement.⁷⁸ In an amicus curiae brief for *GSK v. Teva*, former Congressman Henry Waxman, a co-sponsor of the Hatch-Waxman Amendments, maintained that the exact situation in the case at hand was considered by Congress members

⁷¹ See *id.* at 1330 (“The combination of Teva’s partial label, Dr. McCullough’s element-by-element testimony that the partial label explicitly instructs administering carvedilol for the claimed use of decreasing mortality caused by CHF, and Dr. Zusman’s admission that the Post-MI LVD indication falls within the definition of congestive heart failure is substantial evidence that supports the jury’s finding.”).

⁷² See *id.* at 1340.

⁷³ See, e.g., *Fromberg, Inc. v. Thornhill*, 315 F.2d 407, 412 (5th Cir. 1963) (finding induced infringement through demonstrations by sales staff of infringing uses); *Sims v. Mack Trucks, Inc.*, 459 F. Supp. 1198, 1215 (E.D. Pa. 1978) (finding inducement where infringing use was depicted by defendant’s promotional film and brochures).

⁷⁴ *Takeda Pharms. USA, Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015).

⁷⁵ *Id.*

⁷⁶ See *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582, 591 (“Without proof of causation, which is an essential element of GSK’s action, a finding of inducement cannot stand.”); see also *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347, 1358 (Fed. Cir. 2020) (Prost, C.J., dissenting) (“Thus, to prove induced infringement, GSK had to show that Teva *actually caused* doctors to directly infringe the ‘000 patent. It failed to do so.” (emphasis added)).

⁷⁷ See *GlaxoSmithKline*, 7 F.4th at 1357-59.

⁷⁸ See Brief for Former Congressman Henry A. Waxman as Amicus Curiae Supporting Petitioners at 4-5, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021) (Nos. 18-1976, 18-2023).

drafting the Amendments.⁷⁹ Congress understood that, even if a drug was approved for only limited uses, physicians would inevitably still prescribe the drug for other, possibly infringing uses.⁸⁰ Moreover, two years prior to the passage of the Hatch-Waxman Amendments, the FDA clarified, “[o]nce a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling.”⁸¹

The Federal Circuit itself recognized this congressional intent in the Amendments in an earlier case, stating that the Hatch-Waxman Amendments were “designed to enable the sale of [generics] for non-patented uses even though this would result in some off-label infringing uses.”⁸² Congress ultimately intended the Hatch-Waxman Amendments to support the generic pharmaceutical industry against the blockading force of patents by brand-name drug companies, in spite of potentially infringing use by physicians.⁸³ Thus, the implicit causation prong in the specific intent element for induced infringement serves to enforce congressional intent by insulating generics from infringement liability caused by physicians rather than the generic developer itself.⁸⁴

To allow liability for induced infringement in spite of Teva’s compliance with Congress’s express regulations would erode the effectiveness of the Hatch-Waxman Amendments and directly go against congressional intent in enacting the Amendments.⁸⁵ The Federal Circuit’s holding unravels Congress’s legislative plan to help usher generics to market, and thus misinterprets the ultimate purpose of the Hatch-Waxman Amendments.⁸⁶ By inadvertently encouraging other brand-name drug companies to wield a similar induced infringement

⁷⁹ *Id.*

⁸⁰ *Id.* at 5-6.

⁸¹ *Use of Approved Drugs for Unlabeled Indications*, 12 FDA DRUG BULL. 1, 4-5 (1982) (emphasis added).

⁸² *Takeda Pharms. USA, Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2017).

⁸³ See Brief for Former Congressman Henry A. Waxman as Amicus Curiae Supporting Petitioners at 11, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021) (Nos. 18-1976, 18-2023).

⁸⁴ See *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1357-58 (Fed. Cir. 2021) (Prost, C.J., dissenting).

⁸⁵ Matthew Lane, *Federal Circuit Should Restore Generics ‘Skinny Label’ Process*, BLOOMBERG L. (Jan. 12, 2021, 1:01 AM), <https://news.bloomberglaw.com/pharma-and-life-sciences/federal-circuit-should-restore-generics-skinny-label-process> [<https://perma.cc/2TFV-XCAL>].

⁸⁶ *Cf. King v. Burwell*, 576 U.S. 473, 498 (2015) (“[I]n every case [courts] must respect the role of the Legislature, and take care not to undo what it has done. A fair reading of legislation demands a fair understanding of the legislative plan.”).

theory to bar generics from market, the holding tips the balance again in favor of brand-name companies' monopolistic patenting practices that stifle necessary generic competition.⁸⁷ Brand companies use patenting practices such as "evergreening", in which companies seek to prolong effective periods of patent protection by obtaining multiple patents that cover different aspects of a drug,⁸⁸ to maintain high prices of drugs and deter generic competition.⁸⁹ Strikingly, a study by the Initiative for Medicines, Access, and Knowledge ("I-MAK") found that each of the twelve best selling drugs had an average of 125 patent applications filed, with seventy-one granted per drug.⁹⁰ The result of the *GSK v. Teva* decision is that, even after a brand company's composition-of-matter patent on the RLD has expired, its method-of-use patents can now effectively block generics competitors from being marketed.⁹¹

The Majority denied it was going against congressional intent, expressly stating in the opinion that the holding was narrow and specific to the facts of the case.⁹² They asserted that the fact-specific combination of Teva's marketing material expressing the therapeutic equivalence with Coreg combined with the connection between the patented CHF and Post-MI LVD indications led to a finding of induced infringement.⁹³ Though its reasoning seems to distinguish the case based on Teva's specific marketing materials rather than modify the law of induced infringement, the Federal Circuit's holding ignores the more far-reaching effect of the precedent it sets.⁹⁴ Its analysis seems to allow courts to make greater inferences based on circumstantial evidence to satisfy the specific intent element of induced infringement, regardless of a proper skinny label that fully carves out the patented use.⁹⁵ Without clearer guidance on what kind of marketing material could induce infringement, any generic that advertises therapeutic equivalence with

⁸⁷ Lane, *supra* note 85.

⁸⁸ KEVIN T. RICHARDS, KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 16 (2020), <https://sgp.fas.org/crs/misc/R46221.pdf> [<https://perma.cc/BRX7-H2TX>].

⁸⁹ Lane, *supra* note 85.

⁹⁰ I-MAK, OVERPATENTED, OVERPRICED: HOW EXCESSIVE PHARMACEUTICAL PATENTING IS EXTENDING MONOPOLIES AND DRIVING UP DRUG PRICES 6 (2018), <http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf> [<https://perma.cc/Q8HD-Y5MX>].

⁹¹ Lane, *supra* note 85.

⁹² *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1326 (Fed. Cir. 2021).

⁹³ *Id.*

⁹⁴ See Koblitz, *supra* note 9.

⁹⁵ See *id.*

the branded drug may be exposed to liability.⁹⁶ Given that therapeutic equivalence at lower cost is the main selling point of generics, this increased liability would have a wide chilling effect on marketing and use of generics.⁹⁷

Generic developers can no longer rely solely on a properly carved-out skinny label and compliance with the regulatory pathway that Congress set out in the Hatch-Waxman Amendments to avoid infringement.⁹⁸ In effect, the Federal Circuit's holding tips the balance Congress established back in favor of brand companies who wield blocking method-of-use patents.⁹⁹ Greater leeway in allowing inferences from circumstantial evidence to support a finding of induced infringement would greatly weaken skinny label and section viii statement viability.¹⁰⁰ The increased legal exposure for generic developers would lead to fewer generics on the market, exactly the opposite of congressional intent in enacting the Hatch-Waxman Amendments.¹⁰¹

B. Informing Marketing Decisions

A broad reading of the *GSK v. Teva* holding will also make it difficult for generic developers to make informed decisions in marketing generics.¹⁰² *Teva* met statutory and regulatory requirements for carving out a non-patented use for its generic, but was still found to have induced infringement in prescribing physicians.¹⁰³ Neither *Teva's* skinny label nor its marketing directly referenced *GSK's* patent-protected indication, the latter merely noting the generic's therapeutic equivalence with *Coreg*.¹⁰⁴ The court instead combined three distinct facts: physicians' interpretations of *Teva's* marketing materials, their assumptions about the complete interchangeability of generic carvedilol and *Coreg* for treatment of heart failure, and the known connection between Post-MI LVD and CHF.¹⁰⁵ Critically, the Majority found the court below had erred by deciding as a matter of law the question of

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ Lane, *supra* note 85.

⁹⁹ *See id.*

¹⁰⁰ *See* Koblitz, *supra* note 9.

¹⁰¹ *Id.*

¹⁰² *See id.*

¹⁰³ *Id.*

¹⁰⁴ *See* GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 976 F.3d 1347,1354 (Fed. Cir. 2020).

¹⁰⁵ *See* GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320, 1330 (Fed. Cir. 2021).

whether a Post-MI LVD indication would instruct physicians to prescribe carvedilol for the patented CHF indication.¹⁰⁶ The Majority opinion instead deferred to the jury's fact-finding on that issue and verdict of substantial evidence that Teva had encouraged, recommended, or promoted infringing use based primarily on expert testimony.¹⁰⁷ The Circuit's ruling thus opens up the possibility for infringement liability not on the actual content of a skinny label or generic manufacturer's affirmative intent, but on physicians' subjective interpretations of those materials.¹⁰⁸

Moreover, the decision blurs the previously established boundary between intentionally encouraging, recommending, or promoting an infringing use and merely describing that use.¹⁰⁹ The Federal Circuit has upheld a finding of induced infringement in a case involving a skinny label only once before, and that case had a crucial, distinguishing fact: the generic manufacturer *knew* about the infringement.¹¹⁰ In Teva's case, GSK presented meager evidence that Teva intended or even knew that their skinny label and marketing materials would cause physicians to engage in infringing use.¹¹¹ Even assuming the Post-MI LVD and CHF indications are so interrelated that encouraging the former can induce infringement of the latter, GSK's own expert testified that Teva's skinny label only "mentioned" Post-MI LVD.¹¹² At best, a reasonable jury could have found the skinny label *described* an infringing use.¹¹³ Describing does not rise to the level of encouraging, recommending, or promoting infringing use.¹¹⁴

As such, the blurred lines for induced infringement and resulting increased potential for legal exposure will make it difficult for generic

¹⁰⁶ See *id.* at 1330-31.

¹⁰⁷ See *id.*

¹⁰⁸ See *GSK v. Teva: Federal Circuit Opinion After Rehearing Confirms Induced Infringement Liability Despite Skinny Label*, *supra* note 19 ("Brands can build a circumstantial case to demonstrate inducement by pointing to how doctors may interpret the label as encouragement, and by relying on evidence beyond the label . . .").

¹⁰⁹ See *Takeda Pharms. USA, Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015).

¹¹⁰ See *Grunenthal GMBH v. Alkem Lab's Ltd.*, 919 F.3d 1333, 1340 (Fed. Cir. 2019) ("[*AstraZeneca*] held that specific intent could be inferred because the defendant proceeded with a plan to distribute the generic drug knowing that its label posed infringement problems."); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060-61 (Fed. Cir. 2010).

¹¹¹ *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1350-51 (Fed. Cir. 2021) (Prost, C.J., dissenting).

¹¹² *Id.* at 1351.

¹¹³ *Id.*

¹¹⁴ See *Takeda Pharms. USA, Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d at 631.

companies to use a skinny label to introduce their generics to market.¹¹⁵ In a 2021 study, researchers found that, from 2015 to 2019, 43% of generics had skinny labels with 38% of those skinny labels carving out method-of-use patents.¹¹⁶ The Federal Circuit's ruling will embolden other brand companies, wielding new theories of induced infringement based on *GSK v. Teva*, to bring suit against generic manufacturers.¹¹⁷ In fact, one such lawsuit for induced infringement by a generic manufacturer was decided less than a year after the Federal Circuit's decision in its August rehearing.¹¹⁸ In this more hostile environment, generic developers who abide by federal regulations and properly use skinny labels will nevertheless be hesitant to introduce their generics to market for fear that one of their communications to physicians will end up becoming evidence of induced infringement.¹¹⁹

GSK may argue that the Federal Circuit's fact-specific analysis does not affect the viability of skinny labels or the law of induced infringement, but instead draws their boundaries.¹²⁰ It would maintain that the holding merely clarifies the type of circumstantial evidence that could successfully substantiate an induced infringement claim, even given a fully carved-out skinny label.¹²¹ In this case, the holding was based on Teva's marketing materials and testimony from physicians who knew of and relied on such communications.¹²² However, the Majority's language and analysis leads to a different result. It implies that simply referencing a generic's AB-rated therapeutic equivalence in marketing materials, which the FDA itself assigned, could be enough to induce infringement in prescribing physicians.¹²³ It also gives brand companies the benefit of physicians' prior assumptions and knowledge

¹¹⁵ Lane, *supra* note 85.

¹¹⁶ Bryan S. Walsh, Ameet Sarpatwari, Benjamin N. Rome & Aaron S. Kesselheim, *Frequency of First Generic Drug Approvals with "Skinny Labels" in the United States*, 181 JAMA INTERNAL MED. 995, 995 (2021).

¹¹⁷ Brief for Former Congressman Henry A. Waxman as Amicus Curiae Supporting Petitioners at 10, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021) (Nos. 18-1976, 18-2023).

¹¹⁸ See *Amarin Pharma v. Hikma Pharms. United States*, 578 F. Supp. 3d 642, 645 (D. Del. 2022) (explicitly applying the induced infringement analysis from *GSK v. Teva* to attempt to combine a generic developer's skinny label and public statements).

¹¹⁹ Lane, *supra* note 85.

¹²⁰ See Koblitz, *supra* note 9.

¹²¹ See *id.*

¹²² See *GSK v. Teva: Federal Circuit Opinion After Rehearing Confirms Induced Infringement Liability Despite Skinny Label*, *supra* note 19.

¹²³ Koblitz, *supra* note 9.

about the brand drug when building their case.¹²⁴ As Chief Judge Prost rightly pointed out in her dissent, GSK's own expert physician admitted he had not read Teva's skinny label before prescribing carvedilol.¹²⁵ The testifying physician also revealed that "he was informed by prescribing guidelines established by the American Heart Association and the American College of Cardiology, medical research studying carvedilol, and even GSK's own Coreg label and the promotional materials advertising it."¹²⁶

The Majority's reliance on physician testimony and attenuated evidence linking Teva's materials with physicians' infringing use, in spite of ample evidence pointing otherwise, makes it difficult for generic manufacturers hoping to bring their drugs to market to make informed decisions.¹²⁷ The Circuit's purportedly fact-specific holding significantly hinders generic manufacturers by leaving them without proper guidance from the court on what kind of statements in marketing materials would induce infringement in prescribing physicians.¹²⁸

C. *Balancing Balancing Interests*

Lastly, policy considerations in balancing interests between patent rights and public health support the need for a stricter standard for induced infringement in cases involving a skinny label. The Majority's ruling in *GSK v. Teva* shifts the careful balance between countervailing interests set by the Hatch-Waxman Amendments to the detriment of public health.¹²⁹ A higher threshold for induced infringement would maintain the positive, incentivizing effects of patent rights in new drugs while also continuing to accelerate the introduction of cheaper generics.¹³⁰

Intellectual property rights in pharmaceuticals are typically justified as necessary to allow brand-name drug developers to recoup their substantial investments in research, development, and regulatory

¹²⁴ See *GSK v. Teva: Federal Circuit Opinion After Rehearing Confirms Induced Infringement Liability Despite Skinny Label*, *supra* note 19.

¹²⁵ *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347, 1358 (Fed. Cir. 2020) (Prost, C.J., dissenting).

¹²⁶ *Id.* at 1364.

¹²⁷ See *GSK v. Teva: Federal Circuit Opinion After Rehearing Confirms Induced Infringement Liability Despite Skinny Label*, *supra* note 19.

¹²⁸ See *id.*

¹²⁹ Koblitz, *supra* note 9.

¹³⁰ See *id.*

approval.¹³¹ Developing a new drug and getting it to market costs an average of \$1.4 billion.¹³² In the same vein, one of the major rationales in granting patent rights to pharmaceutical companies for various aspects of a new drug (method-of-use patents) is that such rights incentivize the companies to continue to innovate.¹³³ However, to ensure this right is not used in an overly monopolistic manner to exclude competitors in the market, patent rights expire after a defined time period, typically twenty years from the date the patent application was filed.¹³⁴ Additionally, new drugs receive the benefit of both patent rights and periods of exclusivity, during which the brand drug is fully protected from generic competition by the FDA.¹³⁵ Specifically, NDAs containing full clinical trials become eligible for five or three-year periods of exclusivity during which the FDA cannot receive or approve respective ANDAs for generic versions.¹³⁶

While patent and exclusivity rights certainly allow drug companies to recoup costs and incentivize them to continue to innovate,¹³⁷ they must be carefully balanced against the countervailing public health interest in generics. Generics offer an important opportunity to lower the cost of and provide more equitable access to healthcare.¹³⁸ In 2019, generics comprised 90% of prescriptions filled in the United States, saving consumers \$313 billion, including \$96.1 billion in Medicare savings and \$48.5 billion in Medicaid savings.¹³⁹ They also increase access to prescription drugs for populations that have historically underused drugs due to the prohibitive cost of brand drugs.¹⁴⁰ In a 2004 study of

¹³¹ KEVIN T. RICHARDS, KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 1 (2020), <https://sgp.fas.org/crs/misc/R46221.pdf> [<https://perma.cc/BRX7-H2TX>].

¹³² Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 31 (2016).

¹³³ RICHARDS ET AL., CONG. RSCH. SERV., R46221, at 1.

¹³⁴ 35 U.S.C. § 154(a)(2) (2018).

¹³⁵ *Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD & DRUG ADMIN. (Feb. 5, 2020), <https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#howlongexclusivity> [<https://perma.cc/UBA9-MALE>].

¹³⁶ Koblitz, *supra* note 9; see *Frequently Asked Questions on Patents and Exclusivity*, *supra* note 135.

¹³⁷ RICHARDS ET AL., CONG. RSCH. SERV., R46221, at 1.

¹³⁸ Koblitz, *supra* note 9.

¹³⁹ ASS'N FOR ACCESSIBLE MEDS., SECURING OUR ACCESS & SAVINGS: 2020 GENERIC DRUG & BIOSIMILARS ACCESS & SAVINGS IN THE U.S. REPORT 16, 20 (2020), <https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf> [<https://perma.cc/4PU3-BNHC>].

¹⁴⁰ See Gellad et al., *supra* note 6, at 1576.

chronically-ill adults in the United States, 18% reported cost-related medication underuse in the previous year.¹⁴¹ Given the importance of medication adherence for patients, especially those with chronic illnesses, generics could be a crucial intervention for reducing community-level morbidity.¹⁴² Thus, there is a significant public health interest in promoting the flow of generics into the marketplace.

With such significant interests on opposing sides, courts must consider the balance Congress established when they interpret the Hatch-Waxman Amendments and resulting regulatory scheme. The ANDA pathway and skinny labeling practice created by the Hatch-Waxman amendments establishes a necessary compromise between continuing to incentivize pharmaceutical innovation and increasing access to generics.¹⁴³ The five-year exclusivity period provides a limited time during which a brand company can maintain high drug costs, and thus profits, because it holds what is effectively a temporary monopoly over the drug.¹⁴⁴ This limited period gives brand companies the opportunity to recoup costs, therefore incentivizing continued innovation.¹⁴⁵ After the exclusivity period expires, generic developers are able to bring their generics to market, but still only for uses that are not still covered by method-of-use patents.¹⁴⁶ While method-of-use patents can be helpful to patients because they allow doctors to treat a new disease with an already approved drug with known safety profile,¹⁴⁷ respect for these patents should not come at the expense of availability of more cost-effective generic versions. To do so would be effectively denying access to prescription medication to a major proportion of the United States patient population.¹⁴⁸ By increasing the threshold standard for finding induced infringement, courts can return to the

¹⁴¹ John D. Piette, Michele Heisler & Todd H. Wagner, *Cost-Related Medication Underuse Among Chronically Ill Adults: The Treatments People Forgo, How Often, and Who Is at Risk*, 94 AM. J. PUB. HEALTH 1782, 1784 (2004).

¹⁴² See *id.* at 1786.

¹⁴³ See Brief for Former Congressman Henry A. Waxman as Amicus Curiae Supporting Petitioners at 2, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021) (Nos. 18-1976, 18-2023).

¹⁴⁴ See KEVIN T. RICHARDS, KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 7 (2020), <https://sgp.fas.org/crs/misc/R46221.pdf> [<https://perma.cc/BRX7-H2TX>].

¹⁴⁵ See Richard G. Frank & Paul B. Ginsburg, *Pharmaceutical Industry Profits and Research and Development*, HEALTHAFFAIRS (Nov. 13, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20171113.880918/full/> [<https://perma.cc/6GZF-JQGV>].

¹⁴⁶ Koblitz, *supra* note 9.

¹⁴⁷ Lane, *supra* note 85.

¹⁴⁸ See SECURING OUR ACCESS & SAVINGS: 2020 GENERIC DRUG & BIOSIMILARS ACCESS & SAVINGS IN THE U.S. REPORT, *supra* note 139, at 16.

delicate balance Congress intended in the Hatch-Waxman Amendments.

III. RESHARPENING THE STANDARD FOR SKINNY LABEL INDUCED INFRINGEMENT

Given the foregoing issues with the Federal Circuit's decision in *GSK v. Teva*,¹⁴⁹ courts must determine how to navigate skinny label induced infringement cases in light of the new precedent. One way to interpret the decision would be to read it as the Majority expressly stated: a narrow application of the law of induced infringement specific to the facts of the case.¹⁵⁰ However, such a reading fails to adequately address the widespread policy implications of such a decision on generics in the marketplace and thus on public health.¹⁵¹ These implications require a more far-reaching solution.

Courts could instead reintroduce a causation prong into the specific intent element for indirect infringement, including skinny label induced infringement. Patent infringement is itself a tort,¹⁵² and tort principles dictate that liability should only attach to one who is the legal, or proximate cause of the injury.¹⁵³ In tort law, the proximate causation requirement serves a crucial role in limiting a defendant's liability to only those cases in which the defendant's action or inaction is closely connected to the plaintiff's injury.¹⁵⁴ If courts did not limit liability in this way, defendants would have to avoid many activities that could unforeseeably lead to a plaintiff's injury due to factors outside of the defendants' control.¹⁵⁵ This excessive liability would have a chilling

¹⁴⁹ See *supra* Part II.

¹⁵⁰ See, e.g., *Lundbeck v. Lupin Limited*, No. 18-88-LPS, 2021 WL 4944963, slip op. at *106 (D. Del. Sept. 30, 2021) (finding for plaintiffs and distinguishing *GSK v. Teva* because plaintiffs only pointed to defendants' skinny labels, not external circumstantial evidence).

¹⁵¹ See *supra* Part II.

¹⁵² E.g., *Wordtech Sys., Inc. v. Integrated Networks Sols., Inc.*, 609 F.3d 1308, 1313 (Fed. Cir. 2010); see *Carbice Corp. of Am. v. Am. Pats. Dev. Corp.*, 283 U.S. 27, 33 (1931) ("Infringement, whether direct or contributory, is essentially a tort, and implies invasion of some right of the patentee.").

¹⁵³ RESTATEMENT (SECOND) OF TORTS § 9 cmt. a (AM. L. INST. 1965) ("To become liable to another under the principles of the law of Torts, an actor's conduct must not only be tortious in character but it must also be a legal cause of the invasion of another's interest.").

¹⁵⁴ See Mark F. Grady, *Proximate Cause Decoded*, 50 UCLA L. REV. 293, 294 (2002).

¹⁵⁵ See *id.*

effect on many activities, including those that are particularly valuable to society.¹⁵⁶

The same principles underlying the proximate causation requirement could be applied to skinny label induced infringement. For induced infringement, the specific intent element contains the relevant tort (encouraging, recommending, or promoting infringing use),¹⁵⁷ where the corresponding injury is infringing use by prescribing physicians.¹⁵⁸ The addition of a proximate causation requirement to the specific intent element would adequately limit generic manufacturers' legal exposure and thus avoid chilling the generics industry as a whole.¹⁵⁹ However, this causation requirement should also avoid absolutely insulating generics from induced infringement liability. To effect Congress's intent to balance promotion of generics with incentives for innovation through patent rights, the test courts should use for proximate causation should not go so far as to completely preclude the induced infringement cause of action altogether.

For these reasons, courts should apply the substantial factor test for proximate causation in induced infringement. As its name implies, the substantial factor test asks whether the defendant's conduct was a substantial factor in bringing about the plaintiff's injury compared to the effect of other factors.¹⁶⁰ It considers, among other elements, the number of other factors that contributed to the injury, the extent of the effect which those factors had in producing the injury, and the chain of events from the defendant's conduct to the injury.¹⁶¹ In doing so, the test distinguishes among a myriad of factors that potentially led to the plaintiff's injury to determine if the defendant was a major force in producing the injury, and thus should be held liable for it.¹⁶² This aspect of the test is crucial because, as *GSK v. Teva* has demonstrated, induced infringement cases often involve consideration of circumstantial evidence outside of the skinny label itself to prove that the label induced infringement.¹⁶³

¹⁵⁶ See *id.*

¹⁵⁷ See RESTATEMENT (SECOND) OF TORTS § 876 cmt. d (AM. L. INST. 1965) (noting that “[i]f the encouragement or assistance is a substantial factor in causing the resulting tort, the one giving it is himself a tortfeasor”).

¹⁵⁸ *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1357 (Fed. Cir. 2021) (Prost, C.J., dissenting).

¹⁵⁹ See Lane, *supra* note 85.

¹⁶⁰ RESTATEMENT (SECOND) OF TORTS § 876 (AM. L. INST. 1965).

¹⁶¹ *Id.* § 433.

¹⁶² See Grady, *supra* note 154, at 294.

¹⁶³ See, e.g., *Eli Lilly & Co. v. Teva Parenteral Meds. Inc.*, 845 F.3d 1357, 1369 (Fed. Cir. 2017).

Application of the substantial factor test in induced infringement cases would still allow brand companies to bring a case against a generic manufacturer based on circumstantial evidence, but would give courts and juries greater guidance on how far they can go to infer specific intent from that evidence.¹⁶⁴ The circumstantial evidence would need to prove that the generic manufacturer was a substantial factor in causing the infringing use, not just a factor.¹⁶⁵ The test would also place a greater burden on plaintiff brand companies to prove beyond mere speculation that the actions of the generic manufacturer itself, rather than forces outside of its control, led to infringing use by physicians.¹⁶⁶ As such, this solution squarely addresses the issue in *GSK v. Teva*. The substantial factor test would reduce the Federal Circuit's over-reliance on the assumptions of prescribing physicians. Instead, it would place more emphasis on the contents of the skinny label and the generic company's conduct. Consequently, the addition of a substantial factor test in the specific intent element would push the law of induced infringement back in line with congressional intent in enacting the Hatch-Waxman Amendments and provide necessary guidance for generic companies in the marketplace.

CONCLUSION

The cost of healthcare in the U.S. has grown exponentially over the past years,¹⁶⁷ so the need for more affordable drugs is more immediate than ever. In 2019, prescription drug spending increased 5.7% to \$369.7 billion, up from the 3.8% growth in 2018.¹⁶⁸ The increasingly high cost of prescription drugs raises particular concern for those who cannot afford medically necessary medication due to prohibitively high costs.¹⁶⁹ On the other hand, promoting generics should not come at the cost of incentivizing innovation in the pharmaceutical industry. The

¹⁶⁴ See RESTATEMENT (SECOND) OF TORTS § 433 cmt. A (AM. L. INST. 1965) (stating that the substantial factor test is important in presenting the appropriate question of causation to the jury and in informing judges when framing jury instructions).

¹⁶⁵ See *id.*

¹⁶⁶ See *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347, 1358 (Fed. Cir. 2020) (Prost, C.J., dissenting) (arguing that physicians' assumptions about the interchangeability of generics for the brand drug, external educational materials, and the fact that GSK's expert had not even read Teva's skinny label support that the Majority's opinion was based on mere speculation rather than analysis of the evidence).

¹⁶⁷ See NATIONAL HEALTH EXPENDITURES 2020 HIGHLIGHTS, at 1 (2020), <https://www.cms.gov/files/document/highlights.pdf> [<https://perma.cc/2KGW-S269>].

¹⁶⁸ *Id.*

¹⁶⁹ Kesselheim et al., *supra* note 7, at 864.

Federal Circuit's holding in *GSK v. Teva* threatens to destroy the balance between these countervailing interests by exposing generics companies to more liability than Congress intended.¹⁷⁰ In the absence of congressional intervention, the solution now is to limit this increased liability without dampening the incentives to innovate that patent rights offer. Introducing proximate causation with the substantial factor test as a required element for induced infringement properly balances these competing interests and continues to address the public health need for more generics in the marketplace.

¹⁷⁰ Lane, *supra* note 85.