Insurance Coverage and Induced Infringement: A Threat to Hatch-Waxman's Skinny Labeling Pathway?

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In the fall of 2020, Amarin Corporation—a brand-name drug company—brought an unprecedented claim in federal court. Instead of just suing a generic manufacturer for inducing infringement of its method patent, as is typical in litigation over skinny label generic drugs, Amarin also added a health insurance company as a defendant. In its complaint, Amarin alleged that Health Net induced infringement under 35 U.S.C. § 271(b) of the Patent Act by charging a lower co-pay for the generic, skinny label version of its brand-name drug. Industry commentators agreed that a finding of liability for Health Net would be a blow to the generic industry, as the precedent would dissuade insurers from covering skinny label generics in the future. Amarin's case withstood a motion to dismiss before the parties settled.

Using Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA Inc. *as a jumping off point, this Comment is the first piece of legal scholarship to examine whether, and under what circumstances, health insurers can induce infringement of a method patent by providing preferential coverage of a skinny label generic when it is distributed for a patented drug indication. An evaluation of this question requires examining the standard of causation in induced infringement cases, a subject that has received startlingly little judicial or scholarly inquiry. This Comment argues that the Delaware district court's decision in* Amarin *was based on an improper theory of causation that assumed insurance companies have a duty to prevent infringement. It then establishes that the proper counterfactual baseline for evaluating inducement claims against insurers reveals that insurance companies are rarely the but-for cause of infringement in the skinny label context. In proposing an application of the loss of chance doctrine to determine liability in future cases, this Comment also identifies and addresses a key legal error from the majority opinion in* GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*: a misapplication of causation principles in damages calculations for induced infringement. Ultimately, the Comment demonstrates that adopting a loss of chance theory of the injury in future cases would force courts to conduct often-ignored causation analysis and ensure that a finding of inducement corresponds with a proportionate damages award.*

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INTRODUCTION

Patent law seeks to balance a core tension: the need to incentivize innovation without disproportionately harming competition and open markets. Patents and other government-conferred exclusivity rights are thought to be particularly essential for encouraging pharmaceutical innovation because of the high-cost, high-risk, and time-consuming process of researching and commercializing new treatments for diseases.[1] Pharmaceutical development takes an average of twelve to sixteen years from start to the Food and Drug Administration's (FDA) approval and often carries a price tag of more than $1 billion per drug.[2] Moreover, upward of 90% of drugs fail at some point along the way, often

[1] *See* Rachel E. Sachs, *The Uneasy Case for Patent Law*, 117 MICH. L. REV. 499, 503 (2018); Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590, 593 (2018) (noting that "[a]lthough patent protection is a critical component of the incentive structure society provides for pharmaceutical development, . . . [t]he federal government offers more than 10 other forms of exclusivity that can be used to keep competitors at bay.").

[2] *See* Sachs, *supra* note 1, at 506.

due to safety and efficacy issues.[3] In comparison, imitating a preexisting drug in the form of a generic may require a mere $2 million and take less than two years.[4] As Professor Robin Feldman described it, "[t]he prospect that a second-comer could simply copy the drug after all that effort would deter even the heartiest of souls, and thus the intellectual property system provides the opportunity to secure a return."[5]

Commentators agree that without the promise of patent protection—which confers the right to exclude others from making, using, or selling a patented invention for a period of twenty years[6]—there simply would not be sufficient incentives for brand-name companies to innovate.[7] Society would then miss out on groundbreaking medical treatments that emerge from the drug development process.

However, the social benefit of incentivizing pharmaceutical innovation through limited monopoly rights also comes with a significant cost: many patients are unable to afford necessary medications. This inability to afford medication reduces the public's adherence to medical care regimens, which in turn results in worse health outcomes.[8] The inaccessibility of prescription drugs has long been a particularly acute problem in the United States.[9] In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act[10] (commonly referred to as Hatch-Waxman) in an attempt to strike "a balance between [these] two competing policy interests," which the Federal Circuit described as "(1) inducing pioneering research and development of new drugs and

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3 *See* Garrett T. Potter, *Beefing Up Skinny Labels: Induced Infringement as a Question of Law*, 97 NOTRE DAME L. REV. 1707, 1712–13 (2022).

4 *See* Sachs, *supra* note 1, at 506.

5 *See* Feldman, *supra* note 1, at 593.

6 *See* 35 U.S.C. § 271 (conferring the rights to exclude); 35 U.S.C. § 154(a)(2) (specifying a term of twenty years).

7 *See* Sachs, *supra* note 1, at 507–08.

8 *See* Bryan Walsh, *Skinny Labeling: A Pathway for Timely Generic Drug Competition*, COMMONWEALTH FUND (Oct. 19, 2021), https://perma.cc/3M3L-EMNW.

9 The United States spends far more on prescription drugs per capita than do most other countries. For example, U.S. residents pay between three and five times as much for brand-name prescriptions as Mexicans, Chileans, and the Swiss. *See* Katharina Buchholz, *U.S. Drug Prices Sky-High in International Comparison*, FORBES (July 22, 2022), https://perma.cc/4U25-AP96.

10 Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

(2) enabling competitors to bring low-cost, generic copies of those drugs to market."[11]

Hatch-Waxman successfully facilitated the takeoff of the generic drug industry in the United States. Prior to its passage, a mere 35% of top-selling drugs faced generic competition after patent expiration, whereas today, almost all do.[12] Generic drug use has also climbed steadily due to a combination of state policies and financial incentives that ensures that pharmacists dispense generic equivalents whenever available.[13] Generics now account for 90% of prescriptions filled.[14] But although brand-name drugs represent only the remaining 10%, they account for 82% of total spending on prescription drugs[15]—a jarring statistic that illustrates the extent of the pricing crisis for prescription drugs.

Because generic market entry consistently reduces prices—and brand-name companies want to keep prices high to maximize profits—brand-name companies have every incentive to extend their monopoly rights for as long as possible.[16] A typical method of "artificially extending the protection cliff" involves taking out additional patents (on top of the original patent on the drug itself) on a drug's formulation, dosing regimen, or form of administration.[17] These "follow-on" patents often represent only slight modifications to existing drugs and in turn tend to confer little therapeutic advantage to patients.[18] Critics allege that Hatch-Waxman and the patent regime are ill equipped to combat this practice of "patent evergreening," which has become increasingly prevalent over the past two decades.[19]

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

12 WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RSCH. SERV., R41114, THE HATCH-WAXMAN ACT: A QUARTER CENTURY LATER 5 (2012) (finding that generic competition reached almost 100% in the mid-2000s and has remained at nearly 100% since).

13 *See* Yan Song & Douglas Barthold, *The Effects of State-Level Pharmacist Regulations on Generic Substitution of Prescription Drugs*, 27 HEALTH ECON. 1717, 1728 (2018).

14 *See* ASS'N FOR ACCESSIBLE MEDS., THE U.S. GENERIC & BIOSIMILAR MEDICINES SAVINGS REPORT 6 (2021).

15 *See id.*; *see also* Feldman, *supra* note 1, at 594 ("It is no exaggeration to say that drug prices have skyrocketed. The cost of prescription medication is growing faster than any other form of health care spending, including hospitalization or nursing home care.").

16 IMS INST. FOR HEALTHCARE INFORMATICS, PRICE DECLINES AFTER BRANDED MEDICINES LOSE EXCLUSIVITY IN THE U.S. 3 (2016) (finding that on average oral generics cost 66% less than the brand-name equivalent twelve months after entry, 74% less after two years, and more than 80% less after five years).

17 *See* Feldman, *supra* note 1, at 590.

18 Uri Y. Hacohen, *Evergreening at Risk*, 33 HARV. J.L. & TECH. 479, 485 (2020).

19 *See* Feldman, *supra* note 1, at 617 ("The patent system is not functioning as a time-limited opportunity to garner a return, followed by open competition. Rather, companies throughout the industry seek and obtain repeated extensions of their competition-free

Hatch-Waxman did, however, create an important pathway for manufacturers to bring generic versions of drugs to market exclusively for uses (or "indications") that are no longer under patent protection, thus preventing companies from evergreening by repeatedly patenting new methods of use.[20] A method-of-use patent covers the use of a drug to treat a specific medical condition or patient population for which it was FDA-approved.[21] Under Hatch-Waxman's so-called "skinny labeling pathway," a generic company can receive FDA approval to market a drug for indications that are not patented, even if the brand-name company still has active patents on other indications.[22] For example, a brand-name company might originally take out a patent covering the use of its drug to treat asthma. Later, if it discovers that the drug is also effective at reducing blood pressure, the company might patent the use of the drug for treating high blood pressure. After the first patent on the asthma indication has expired, a generic competitor could receive FDA approval to market the drug with a "skinny label" that includes only the asthma indication. In contrast, the brand-name drug's label would include both the asthma indication and still-patented blood pressure indication.[23] Data indicates that skinny labeling represents a critical means of reducing prescription drug prices and getting generics to market.[24] Today, almost half of all generic medicines first launch with a skinny label.[25]

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zones."); *see also* Robin Feldman, *Understanding 'Evergreening': Making Minor Modifications of Existing Medications to Extend Protections*, 41 HEALTH AFFS. 801, 802 (2022) ("Thus, trends highlighted in these studies suggest that the government is granting more exclusivity for less innovation.").

20 *See* 21 U.S.C. § 355(j)(2)(A)(viii).

21 *See* Jonathan A. Bell, *Generic Drugs and the Future of "Skinny Labels"*, 35 HARV. J.L. & TECH. 659, 665 (2022).

22 *See id.* at 665–66; *see also* Potter, *supra* note 3, at 1708 ("[D]rug manufacturers can introduce a generic version of a pioneer drug to the market so long as any patented methods of use or treatment are 'carved out' of the drug label, making it a so-called 'skinny label.'").

23 A generic manufacturer can also bring a skinny label to market for an indication that the brand-name company has never patented, but that is a less common scenario than a method-of-use patent's expiring.

24 *See* 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, 996 (2021).

25 *See* Petition for Cert. at 3, Teva Pharms. USA v. GlaxoSmithKline LLC, 7 F.4th 1320 (Fed. Cir. 2021) (Nos. 2018-1976 and 2018-2023) [hereinafter GSK Cert. Pet.] ("Generic versions of no-longer-patented drugs with patented uses launch with a skinny label *almost half the time*, saving patients and the federal government billions." (emphasis in original)).

Litigation involving skinny labels typically proceeds under a theory of induced infringement, whereby a brand-name company sues a generic company for aiding and abetting infringement of its method-of-use patent.[26] To prove inducement, a brand-name company must show that the generic company intentionally caused another actor to directly infringe.[27] The direct infringer is typically a doctor who has prescribed the generic medication for the patented use. Suing a generic competitor for inducement rather than the direct infringer allows the brand-name company to "avoid the ill-advised strategy of suing one's customer base (here either physicians or patients) for the infringing activity."[28]

This usual strategy of suing only generic competitors in skinny label litigation changed recently when a brand-name company took on a market intermediary for the first time.[29] In the fall of 2020, Amarin Corporation (a brand-name pharmaceutical company) sued Hikma (a generic pharmaceutical manufacturer) for inducing infringement of Vascepa (Amarin's heart disease medication).[30] At first, the case appeared typical. Then, Amarin made an unprecedented move: it added Health Net, a health insurance company, as a defendant. Amarin claimed that Health Net induced infringement by charging a lower co-pay for the generic as opposed to brand-name Vascepa.[31] Industry experts immediately agreed that finding Health Net liable would cause insurers to stop covering skinny label generics, as the novel legal theory would expose insurance companies to massive damages awards.[32]

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[26] *See, e.g.*, AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1057–62 (Fed. Cir. 2010); Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp., 785 F.3d 625, 630–35 (Fed. Cir. 2015); Sanofi v. Watson Lab'ys Inc., 875 F.3d 636, 643–46 (Fed. Cir. 2017).

[27] *See* DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1305 (Fed. Cir. 2006) (quoting Warner–Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1364 (Fed. Cir. 2003)).

[28] *See* Bell, *supra* note 21, at 671.

[29] Prior to 2022, no litigation had been brought against other participants in the supply chain, such as pharmacists, physicians, health insurers, or pharmacy benefit managers. *See* Bryan S. Walsh, Aaron S. Kesselheim, Ameet Sarpatwari & Benjamin N. Rome, *Indication-Specific Generic Uptake of Imatinib Demonstrates the Impact of Skinny Labeling*, 40 J. CLINICAL ONCOLOGY 1102, 1106 (2022).

[30] *See* Amarin Pharma, Inc. v. Hikma Pharms. USA Inc., 578 F. Supp. 3d 642, 643 (D. Del. 2022).

[31] *See id.* at 648.

[32] *See, e.g.*, Sara W. Koblitz, *Is the Skinny Label Back from the Dead?*, FDA L. BLOG (Jan. 12, 2022), https://perma.cc/A8F9-2EB5 ("That insurers may have some liability for induced infringement merely by listing a skinny-labeled generic on a formulary could dissuade health insurers from covering skinny-labeled generics."); Robert Freedman, *Novel Issues Arise with Dismissal of Drugmaker, but Not Insurer, from Infringement Case*, LEGALDIVE (June 24, 2022), https://perma.cc/A2J3-73AX.

In a short but decisive opinion, Judge Richard Andrews of the District of Delaware—a highly important court in pharmaceutical patent law[33]—found Amarin's novel theory plausible and allowed the case to move past a motion to dismiss. The parties in *Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA Inc.*[34] settled in January 2022 after almost a year of discovery.[35] Thus, the only judicial opinion on the books on this issue accepts an argument that would expose insurers everywhere to liability for covering skinny labels.

Using *Amarin* as a test case, this Comment is the first piece of scholarship to investigate whether health insurers can induce infringement of a method patent by providing preferential coverage of a skinny label generic when it is disbursed for a patented drug indication.[36] An evaluation of this question requires examining the standard of causation in induced infringement cases, a subject that has received startlingly little judicial or scholarly inquiry.

This Comment makes two novel contributions. First, it demonstrates that, in the recent skinny label case *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*,[37] the Federal Circuit improperly upheld a damages award that did not reflect the lost profits *caused by* the defendant's inducement, setting a dangerous precedent for future inducement cases.[38] Although *GlaxoSmithKline* was a highly controversial opinion that received considerable attention, commentators have not examined the way that the court erred in its evaluation of causation for the purposes of calculating damages. Second, this Comment argues that the causation analysis adopted in the *Amarin* decision was contrary to Federal Circuit precedent and proposes a

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33 *See* Shawn P. Miller, *Venue One Year After* TC Heartland*: An Early Empirical Assessment of the Major Changes in Patent Filing*, 52 AKRON L. REV. 763, 803–04 (2019).

34 578 F. Supp. 3d 642 (D. Del. 2022).

35 *See* Christopher Yasiejko, *Amarin, Centene Unit Settle Patent Suit Over Vascepa Heart Drug*, BLOOMBERG L. (Jan. 3, 2023), https://perma.cc/K285-3JTT.

36 Until *Amarin*, insurance companies were considered off the table as potential targets for skinny label litigation. *See* Erika Lietzan, *Paper Promises for Drug Innovation*, 26 GEO. MASON L. REV. 168, 207 (2018) ("Payers are not appealing defendants for an innovator; they are the company's customers."). Thus, the theory has only ever been mentioned in passing in the footnotes of law review articles. *See e.g.*, *id.* at 194 n.123.

37 7 F.4th 1320 (Fed. Cir. 2021), *cert. denied*, 2023 WL 3440748 (U.S. May 15, 2023).

38 *See* Amicus Curiae Brief of Apotex Inc. at 8, GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320 (Fed. Cir. 2021) (No. 1:14-cv-878) ("*GSK II* [the precedential Federal Circuit opinion] has provided brands with a blueprint for securing crippling damages awards against generics who carve out patented methods to avoid Hatch-Waxman litigation.").

proper framework for courts to evaluate causation in cases involving insurers. The correct causation analysis reveals that most insurance companies likely induce a small fraction of the overall infringement that occurs under their insurance plans. Taking this conclusion in light of the damages and causation errors in *GlaxoSmithKline*, this Comment posits that there is a significant risk that brand-name pharmaceutical companies will be grossly overcompensated in infringement cases by insurers, who induce only a very small portion of the infringing acts. This conclusion is essentially an application of the incorrect precedent from *GlaxoSmithKline* to the results of a proper causation analysis.

To solve the problem, this Comment proposes an application of the "loss of chance" doctrine from tort law. A loss of chance framework would ensure that a court's finding of inducement corresponds with a damages award that is proportionate to the harm caused by the defendant's inducing acts. Moreover, the loss of chance approach forces courts to consider causation in inducement cases—a key prong of analysis that has been repeatedly ignored, and is thus inconsistently applied, to the detriment of defendants like those in *GlaxoSmithKline*. Finally, loss of chance fulfills the policy aims of Hatch-Waxman.

Part I provides background on skinny labeling, describes induced infringement, and analyzes the *GlaxoSmithKline* case. Part II discusses the generic substitution landscape, analyzes the *Amarin* opinion, and proposes a causation framework for evaluating inducement claims against insurers. Part III advocates for the loss of chance approach to liability. It begins with background on loss of chance, then details how loss of chance would apply to insurers and generic manufactures, and finally provides a brief overview of policy justifications.

I. SKINNY LABELS AND INDUCED INFRINGEMENT

The *GlaxoSmithKline* case represents the first time that a brand-name company successfully sued a generic manufacturer for a skinny label that was already on the market (or "postlaunch"). Before *GlaxoSmithKline*, skinny label cases always involved a brand-name company seeking an injunction barring a generic drug launch based on the argument that the generic's skinny label was improperly carved out and would induce infringement.[39] Thus, the courts had never before considered actual rather than

[39] *See, e.g.*, AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1045–46 (Fed. Cir. 2010).

hypothetical causation or a damages award as opposed to an injunction.[40] Because future cases involving insurance companies will be postlaunch cases like *GlaxoSmithKline*, they will also involve damages awards. Accordingly, courts are likely to replicate the error introduced in *GlaxoSmithKline* in cases involving insurers. This Part analyzes the *GlaxoSmithKline* decision and illuminates the damages error to provide necessary background for the implications of the district court's decision in *Amarin*. Ultimately, the nature of the damages error portends particularly punishing results for insurers, who this Comment argues are responsible—like generic companies—for inducing a relatively small fraction of the overall infringement.

Part I.A begins by situating the skinny labeling pathway within an explanation of Hatch-Waxman's central mechanism for accelerating generic drug approval. Part I.B then describes the successful elements of an induced infringement claim to provide background for understanding the classic skinny label suit. Part I.C focuses on the *GlaxoSmithKline* decision. It begins by outlining key precedent that has emerged from past skinny label litigation. It then describes the unprecedented nature of *GlaxoSmithKline* and details the case's complex litigation history and the controversy surrounding the decision. Finally, this Part makes the novel claim that the Federal Circuit erred in upholding the jury's damages award. It concludes by evaluating the implications of this faulty precedent for future postlaunch skinny label cases—like those involving insurers.

A. Hatch-Waxman and the Skinny Labeling Pathway

One of the main contributions of Hatch-Waxman was the establishment of the Abbreviated New Drug Application (ANDA)—a process by which manufacturers can seek market approval from the FDA for generic equivalents of a brand-name drug. Prior to Hatch-Waxman, generic companies had to conduct their own clinical trials to determine safety and efficacy and "could not begin this extremely lengthy and expensive testing process until *after* the relevant drug patent had expired."[41] The ANDA changed these requirements by allowing generic companies to use the

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[40] *See* GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 313 F. Supp. 3d 582, 596–97 n.14 (D. Del. 2018).

[41] Thomas Chen, Comment, *Authorized Generics: A Prescription for Hatch-Waxman Reform*, 93 VA. L. REV. 459, 463 (2007) (emphasis in original).

safety and efficacy data developed by brand-name manufacturers during the approval process.[42] Generic companies must now only establish that their drug is a "bioequivalent" to the brand-name drug.[43] Hatch-Waxman also "insulates ANDA-related clinical research from patent infringement liability," enabling generic manufacturers to conduct bioequivalence testing while the drug patent is active.[44] Thus, ANDAs accelerate the generic drug's approval process with the FDA and ensure that generics can enter the market as soon as the patent on the reference product expires.[45]

Normally, a company filing an ANDA must certify to the FDA that the patents on the reference brand-name drug do not exist, have expired, will expire, or are invalid in order to receive approval.[46] These certifications are called Paragraph I, II, II, and IV certifications. Filing an ANDA under Paragraph IV is often referred to as an "artificial act of patent infringement."[47] A Paragraph IV applicant must, under Hatch-Waxman, provide notice to the patent owner and New Drug Application (NDA) holder, which then has forty-five days to initiate patent infringement litigation.[48] Litigation over the validity of the patent then proceeds in federal court. If the patent is deemed invalid, the generic company will bring its drug to market and enjoy a 180-day marketing exclusivity period.[49]

However, under Hatch-Waxman, a company can also seek ANDA approval for a brand-name drug with a current

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42 *See* Bell, *supra* note 21, at 663–64.

43 *Id.* at 663. Bioequivalence means that the drug has the same active ingredient and pharmacokinetics as the brand-name drug. *See* Chen, *supra* note 41, at 463. The active ingredient refers to the chemical compound that produces a drug's therapeutic effect. *See id.* at 463 n.18. Pharmacokinetics describes the mechanisms by which the body absorbs, distributes, metabolizes, and excretes the drug. *See* Sophie C. Turfus, Rupika Delgoda, David Picking & Bill J. Gurley, *Pharmacokinetics*, *in* PHARMACOGNOSY: FUNDAMENTALS, APPLICATIONS AND STRATEGIES 495, 495 (Simone Badal & Rupika Delgoda eds., 2017).

44 Chen, *supra* note 41, at 464.

45 *See* Bell, *supra* note 21, at 663. The statute also provides brand-name companies with the opportunity to seek "patent term restoration," or extension of the patent term beyond the twenty-year statutory limit, to offset time lost during drug development and government approval. Chen, *supra* note 41, at 464. For example, a drug that was patented fifteen years prior to receiving approval from the FDA can get its patent term extended by five years and enter the market with ten years of patent protection left rather than five. In this way, the statute enables the timely entry of generic drugs but strengthens incentives for pharmaceutical innovation. *See id.*

46 *See* Bell, *supra* note 21, at 664 (discussing 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV), the section of Hatch-Waxman that outlines these requirements).

47 *See id.*

48 *See* Chen, *supra* note 41, at 465.

49 *See* 21 U.S.C. § 355(j)(5)(B)(iv).

method-of-use patent through a section viii[50] "carveout" statement. Section viii allows a manufacturer to assert that it will "market the drug for one or more methods of use *not* covered by the brand's patents," i.e., that it plans to go to market with a skinny label.[51] The section viii statement is referred to as a carveout because the generic manufacturer still uses the brand-name manufacturer's FDA-approved label as a basis in its ANDA but then carves out the patented indications.[52] The resulting generic label is the skinny label. A skinny label must be identical to a branded label but exclude mention of indications that remain patented.[53] Proposing and receiving approval for a skinny label is a complicated process, as

> [t]he FDA will approve an ANDA with a section viii statement only if (1) there is no overlap between the proposed label submitted by the ANDA applicant and the use described in the [patent], and (2) removing the information pertaining to the patented method of use from the label does not render the drug less safe or effective.[54]

However, going to market with a skinny label carries the significant upside of avoiding the risks and expenses associated with Paragraph IV litigation. Ultimately, the skinny labeling pathway serves the crucial function of allowing generic manufacturers to bring drugs to market that would otherwise remain at monopoly prices for years to come. By ensuring that brand-name companies cannot extend their monopoly rights over a drug by repeatedly patenting new uses, section viii furthers the balancing act contemplated by the Hatch-Waxman regime.

B. Elements of an Induced Infringement Claim

As soon as the FDA approves a generic company's proposed skinny label, the battle over patent infringement begins. There

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50 The section viii carveout refers to 21 U.S.C. § 355(j)(2)(A)(viii).

51 Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 406 (2012) (emphasis added).

52 *See id.* at 406.

53 *See* Bell, *supra* note 21, at 666.

54 *See* 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), https://perma.cc/QAM2-ZGV5 (first citing 21 C.F.R. § 314.127(a)(7); and then citing Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,682 (June 18, 2003)).

are two main types of patent infringement: direct infringement and indirect infringement. Direct infringement occurs when an entity that is not the patent holder makes, uses, offers to sell, sells, or imports any patented invention.[55] There is strict liability for direct infringement, meaning that liability is imposed regardless of the infringer's intent or knowledge.[56] In contrast, a third party may find itself liable for indirect infringement only if it intentionally causes another party to infringe.[57] The doctrine of indirect infringement arose out of the common law of torts, which has "long punished not only tortfeasors but also those who aid and abet the commission of a tort."[58] Generally speaking, indirect infringement liability serves the purpose of "giv[ing] patent owners effective protection in circumstances in which the actual infringer either is not the truly responsible party or is impractical to sue."[59]

The Patent Act,[60] the federal law that governs all patents in the United States, proscribes two kinds of indirect infringement: contributory infringement and induced infringement.[61] Although contributory infringement is not the focus of this Comment, it "generally covers situations where one party provides another with a part or component which when combined with other components infringes on an apparatus claim."[62] Induced infringement—the legal issue at stake in skinny label litigation—is codified at 35 U.S.C. § 271(b), which establishes that "[w]hoever actively induces infringement of a patent shall be liable as an infringer."[63] Inducement covers acts that "direct, facilitate, or abet infringement."[64]

To successfully bring a claim of induced infringement, the Federal Circuit requires a plaintiff to show that (1) direct infringement occurred;[65] (2) the defendant's actions "led" the direct

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55 *See* 35 U.S.C. § 271(a).

56 W. Keith Robinson, *Only a Pawn in the Game: Rethinking Induced Patent Infringement*, 32 SANTA CLARA HIGH TECH. L.J. 1, 19 (2015).

57 *See* Mark A. Lemley, *Inducing Patent Infringement*, 39 U.C. DAVIS L. REV. 225, 227 (2005).

58 *Id.*

59 *Id.* at 228.

60 35 U.S.C. § 271.

61 The Patent Act created the U.S. Patent and Trademark Office and governs all U.S. patents, from drugs to technology to utilities. In contrast, Hatch-Waxman is specific to pharmaceuticals and was passed in the form of amendments to both federal patent law and food and drug law.

62 Robinson, *supra* note 56, at 4.

63 35 U.S.C. § 271(b).

64 *See* Lemley, *supra* note 57, at 227.

65 *See Sanofi*, 875 F.3d. at 643.

infringer to infringe;[66] and (3) the defendant possessed "specific intent" to cause the direct infringement and "knew or should have known his actions would induce actual infringements."[67] The evaluation of each prong is a question of fact determined by a jury, and circumstantial evidence suffices to prove both the intent and causation elements.[68] To date, the majority of scholarship on induced infringement has focused on the level of intent and knowledge required and how it can be demonstrated[69]—topics that the Supreme Court has also visited multiple times over the past two decades.[70]

Under the intent prong of analysis, the Federal Circuit has established that "inducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities."[71] Thus, to demonstrate specific intent, a plaintiff must show evidence that the inducer took "active steps . . . to encourage . . . infringement, such as advertising an infringing use or instructing how to engage in an infringing use."[72] As the Supreme Court commented in *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*,[73] a trademark case in which the Court considered precedent from patent law, "[t]he classic instance of inducement is by advertisement or solicitation that broadcasts a message designed to stimulate others to commit violations."[74] However, actions ranging from assistance to encouragement to suggestion have all formed the basis of successful inducement claims.[75] On top of taking active steps, the inducer must also be aware of the patent in question

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66 *See* Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1274 (Fed. Cir. 2004).

67 *See* DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1304–06 (Fed. Cir. 2006).

68 *See GlaxoSmithKline*, 7 F.4th at 1326–27; Sanofi v. Watson Lab'ys Inc., 875 F.3d 636, 644 (Fed. Cir. 2017).

69 *See, e.g.*, Robinson, *supra* note 56; Lemley, *supra* note 57; Timothy R. Holbrook, *The Intent Element of Induced Infringement*, 22 SANTA CLARA COMPUT. & HIGH TECH L.J. 399 (2006); Gregory Bischoping, *The Analytical Framework for the Specific Intent to Induce Infringement in Hatch-Waxman Disputes*, 47 AIPLA Q.J. 99 (2019).

70 *See, e.g.*, Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 936–37 (2005); Glob.-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 766 (2011); Commil USA, LLC v. Cisco Sys., Inc., 575 U.S. 632, 642 (2015).

71 *See DSU*, 471 F.3d at 1306.

72 *Grokster*, 545 U.S. at 936 (quoting Oak Indus., Inc. v. Zenith Elecs. Corp., 697 F. Supp. 988, 992 (N.D. Ill. 1988) (quotation marks omitted).

73 545 U.S. 913 (2005).

74 *Id.* at 937.

75 *See* Robinson, *supra* note 56, at 48.

and understand that the induced actions "constitute patent infringement" to meet the high mens rea requirement for intent.[76]

Although the plaintiff must show a causal connection between the inducing acts and the direct infringement per the causation prong, induced infringement cases rarely involve robust causation analysis.[77] This may be because there is often no evidence that can be used to prove the direct infringement that occurs in a "classic" inducement case other than the information provided to consumers (the direct infringers) in the offending advertisement or user manual. For example, in *Anthrocare Corp. v. Smith & Nephew Inc.*,[78] the Federal Circuit found Smith & Nephew liable for induced infringement because it provided sales literature that instructed doctors to perform the steps of Anthrocare's method patent during electrosurgery, but using Smith & Nephew's electrosurgical probes.[79] Thus, establishing that the defendant took "active steps" with the requisite intent and that direct infringement occurred was the beginning and end of the analysis because the causal mechanism was clear. In *Golden Blount, Inc. v. Robert H. Peterson Co.*[80]—where causation evidence included an instruction sheet that came packaged with the products—the court similarly noted that "nothing in the record suggests that either [the defendant] or any end-user ignored the instructions," making the finding of causation straightforward.[81]

The most explicit causation analysis in induced infringement cases typically relates to damages calculations. The Patent Act provides that a "court shall award the [plaintiff] damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer."[82] Courts recognize two kinds of compensatory damages for both direct and indirect infringement: lost profits and "the reasonable royalty [the patentee] would have received through arms-length bargaining."[83] A plaintiff can receive both kinds of damages. The lost-profits approach is less common "because it essentially

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76 *Commil*, 575 U.S. at 639 (quoting *Glob.-Tech Appliances*, 563 U.S. at 766).

77 *See* Mark Bartholomew & Patrick F. McArdle, *Causing Infringement*, 64 VAND. L. REV. 675, 705 (2011) ("[J]udges give causation relatively little attention in deciding [induced infringement] cases.").

78 406 F.3d 1365 (Fed. Cir. 2005).

79 *Id.* at 1377.

80 438 F.3d 1354 (Fed. Cir. 2006).

81 *See id.* at 1363.

82 35 U.S.C. § 284.

83 *See* Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1324 (Fed. Cir. 2009).

requires the plaintiff to be a commercially active entity and presents some difficulties of proof, though it typically results in a higher recovery than the reasonable-royalty measure."[84] Because lost profits are the focus of this Comment's analysis of *GlaxoSmithKline* and will be at issue in future litigation involving insurance companies, the rest of this Section focuses on lost-profit damages.

Typically, lost-profit damages correspond to lost sales—in other words, the sales that the patent owner would have made in the absence of infringement. In order to prove lost profits, the Federal Circuit requires the patentee to establish "(1) the extent of demand for the patented product, (2) the absence of noninfringing substitutes for that product, (3) the patentee's ability to meet the additional demand by expanding manufacturing capacity, and (4) the extent of profits the patentee would have made."[85] In order to establish the value of the damages, the patent holder must show "'causation in fact,' establishing that 'but for' the infringement, he would have made additional profits."[86] The but-for causation standard was clearly articulated in *Grain Processing Corp. v. American Maize-Products Co.*,[87] which also held that the amount of lost profits demanded cannot be based on speculation. The court held that the number has to reflect "sound economic proof of the nature of the market and likely outcomes with infringement factored out of the economic picture."[88] Thus, the but-for world cannot take infringing alternatives into account, meaning that lost-profits analysis must be based on a world in which infringement of the asserted patent does not exist, not one in which other infringing products would have accounted for the lost sales.[89] As Section C.3 demonstrates, the *GlaxoSmithKline* court erred in applying the but-for requirement from *Grain Processing* to a case of *indirect* infringement where the defendant was not a but-for cause of all of the infringement.

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84 *See* Dmitry Karshtedt, *Damages for Indirect Patent Infringement*, 91 WASH. U. L. REV. 911, 932 (2014) (citations omitted).

85 *See* Mark A. Lemley, *Distinguishing Lost Profits from Reasonable Royalties*, 51 WM. & MARY L. REV. 655, 657 (2009). The standard is often referred to as the "*Panduit* test" as it was developed from the Sixth Circuit case *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978).

86 Grain Processing Corp. v. Am. Maize-Prods. Co., 185 F.3d 1341, 1349 (Fed. Cir. 1999).

87 185 F.3d 1341 (Fed. Cir. 1999).

88 *Id.* at 1350.

89 *See GlaxoSmithKline*, 7 F.4th at 1341.

C. Background on Skinny Label Induced Infringement Suits

Before examining the *GlaxoSmithKline* decision, this Section describes what a skinny label suit typically looks like and details Federal Circuit precedent from past cases. Because generics rapidly take over the market and drive down prices, litigation over skinny labels is common and can be make-or-break for brand-name companies seeking to maintain their monopoly.[90] Yet brand-name companies have not, until the *Amarin* case, actually targeted the mechanism propelling skinny labels to market dominance: substitution at the pharmacy counter (discussed *infra* Part II.A). Instead, millions of dollars in legal fees have exchanged hands based on the theory that improperly carved-out labels, sometimes accompanied by marketing materials or press releases, will induce doctors to prescribe skinny label generics for infringing uses.[91]

A typical induced infringement claim involves a brand-name company suing a generic company before it launches a skinny label generic under the theory that the generic company's proposed ANDA drug label is improperly carved out (i.e., that it contains information that teaches or instructs doctors on an infringing use of the drug). Drug labels are presented as "a critical piece of evidence in proving active inducement"[92] because they contain information for prescribing physicians, such as a description of the drug, its indications, warnings, clinical safety information, dosage, and administration instructions.[93] Thus, the brand company will typically argue that in a hypothetical, postlaunch world, the skinny label will induce doctors to infringe.[94]

The Federal Circuit has developed a specific standard for extrapolating intent to induce from a drug label: "The label must encourage, recommend, or promote infringement."[95] Despite this seemingly high bar, plaintiffs have successfully established inducement by arguing that information in the "[i]ndications and [u]sage," "[d]osage and [a]dministration," and "[c]linical [s]tudies" sections of proposed skinny labels would cause doctors to infringe.[96]

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90 *See* Potter, *supra* note 3, at 1715–16.

91 *See, e.g.*, *AstraZeneca*, 633 F.3d 1042, 1047–48; Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp., 785 F.3d 625, 628 (Fed. Cir. 2015); *Sanofi*, 875 F.3d. at 639.

92 Arico et al., *supra* note 54.

93 *See* Bell, *supra* note 21, at 665.

94 *See, e.g.*, *AstraZeneca*, 633 F.3d at 1057–62.

95 *Takeda Pharms.*, 785 F.3d at 631.

96 *See, e.g.*, *GlaxoSmithKline*, 7 F.4th at 1337; *AstraZeneca*, 633 F.3d at 1059–60; *Sanofi*, 875 F.3d at 644–45.

In reality, doctors know that generics are therapeutically equivalent to brand-name drugs and will often prescribe a generic without reading its label.[97] Moreover, as Part II.A describes, pharmacists indiscriminately substitute skinny label generics for their brand-name equivalent at the pharmacy counter—ensuring widespread infringement.[98] Thus, brand-name companies pursue the label-inducement theory because it allows them to get injunctions that delay or prevent the generic drugs from entering the market, not because doctors reading skinny labels actually account for much of the infringement that would occur if the drugs launched. Suing a generic competitor prelaunch is simply the only way to maintain market share that the brand-name company is certain to lose out on (regardless of what information the skinny label includes) postlaunch.

D. The *GlaxoSmithKline* Decision

This Section first provides the classic account of the *GlaxoSmithKline* decision, focusing particularly on the majority and dissent's disagreement about causation. It then expands upon that standard account, demonstrating that the Federal Circuit contradicted its own precedent and fundamental principles of tort law in upholding the jury's damages verdict. Because this precedent applies directly to cases involving insurers, this Section concludes by foreshadowing the impact that the damages error could have on insurance companies facing inducement suits. Ultimately, any analysis pertaining to the question of whether and under what circumstances insurers induce infringement must take the ramifications of the *GlaxoSmithKline* damages error into account, as future cases involving insurers are likely to snowball the error. Furthermore, the risk of massive *GlaxoSmithKline*-esque damages awards is likely to deter insurers from covering skinny label generics,[99] which would in turn spell trouble for the generic industry and the Hatch-Waxman scheme.

The controversial *GlaxoSmithKline* case marked the first time that a generic company was found liable for inducing infringement in the postlaunch context. Thus, it was the first time

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97 *See, e.g.*, *GlaxoSmithKline*, 7 F.4th at 1342 (Prost, C.J., dissenting) ("[E]very expert cardiologist at trial said he *didn't even read* the label to make prescribing decisions." (emphasis in original)).

98 *See* Walsh et al., *supra* note 29, at 1104–05.

99 *See, e.g.*, Koblitz, *supra* note 32.

that the Federal Circuit considered actual, rather than hypothetical, causation.[100] The dearth of causation and lost-profit analysis in prior inducement cases outside of the skinny label context likely laid the groundwork for this decision, which runs counter to basic tenets of causation and damages measurement. However, because *GlaxoSmithKline* generated so much controversy for its novel skinny label infringement theory, the causation-based damages error has not been the subject of subsequent analysis.

The litigation proceeded as follows: GlaxoSmithKline, a major brand-name pharmaceutical company, sued the generic company Teva Pharmaceuticals for infringement of patents related to GlaxoSmithKline's drug Coreg, which treats congestive heart failure.[101] Coreg is approved for three indications: congestive heart failure (CHF), left ventricular dysfunction (LVD) following a heart attack in clinically stable patients, and high blood pressure.[102] Long before the suit, Teva had received section viii approval to market generic Coreg (carvedilol) with a skinny label that carved out the entire CHF indication—the only indication that remained patented.[103] GlaxoSmithKline sued, arguing that the LVD indication on the generic label contained information that encouraged infringement of the patented CHF indication because a physician would know that some LVD patients would also have CHF.[104] GlaxoSmithKline also argued that Teva's press release and marketing materials identifying carvedilol as a generic equivalent to Coreg induced infringement, because a physician would know that Coreg can be used to treat both LVD and CHF.[105] GlaxoSmithKline's argument was unprecedented, as it asserted that even if a generic had carved out all the language that had been identified by the brand-name company as covering patented uses, the generic could still be sued for inducing infringement based on information required in the LVD section of the label.

In an "unusual set of proceedings," the case began with a jury trial and ultimately generated two separate panel opinions from the Federal Circuit, a petition for rehearing en banc that inspired three different dissents, and a denied petition for certiorari to the

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[100] *See GlaxoSmithKline*, 313 F. Supp. 3d at 596–97 n.14 (distinguishing *GlaxoSmithKline* from prelaunch cases).

[101] *See GlaxoSmithKline*, 7 F.4th at 1323.

[102] *See id.*

[103] *See id.* at 1324.

[104] *See id.* at 1327, 1336–37.

[105] *See id.* at 1335–36.

Supreme Court.[106] The jury found that Teva's label and press releases induced doctors to prescribe Teva's carvedilol for GlaxoSmithKline's patented indication and awarded $234.1 million in lost profits and $1.4 million in reasonable royalty damages to GlaxoSmithKline.[107] The district court then overturned the jury's verdict on causation grounds, holding that "substantial evidence does not support a finding by a reasonable factfinder that even at least one doctor was induced to prescribe generic carvedilol to be used in an infringing manner due to Teva's actions, as opposed to the various other factors supported in the record."[108] The "other factors" identified at trial included proof that doctors prescribed carvedilol based on the American Heart Association and American College of Cardiology guidelines, medical textbooks and treatises, GlaxoSmithKline's marketing, and their own knowledge and experience.[109] Even GlaxoSmithKline's own expert admitted that he did not read Teva's generic label prior to writing prescriptions for carvedilol.[110]

The Federal Circuit reversed the district court's decision in a sharply divided opinion that led to significant backlash, including from Congressman Henry Waxman himself, fifty-seven law professors, and the generic drug industry, all of whom asserted that the decision opened generic companies up to liability even when they had correctly followed the section viii pathway.[111] The court then granted a petition for rehearing and issued a new decision that upheld its own prior decision over a blistering dissent, generating further backlash.[112] Many commentators argued that Teva had correctly followed the skinny labeling pathway and thus that the finding of inducement destabilized the precedent that a properly carved-out skinny label is a safe harbor from inducement liability.[113] In its petition for certiorari, Teva accordingly asked

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[106] *See GlaxoSmithKline*, 7 F.4th 1320 (Fed. Cir. 2021), *cert. denied*, 2023 WL 3440748 (U.S. May 15, 2023).

[107] *See GlaxoSmithKline*, 7 F.4th at 1348.

[108] *GlaxoSmithKline*, 313 F. Supp. 3d at 596 (emphasis omitted).

[109] *See GlaxoSmithKline*, 7 F.4th at 1339.

[110] *See id.* at 1357 (Prost, C.J., dissenting).

[111] *See* Perry Cooper, *Teva Racks Up Outside Support for Redo of Skinny Label Ruling*, BLOOMBERG L. (Dec. 31, 2020), https://perma.cc/43DR-E57Y; Amy L. Baker, William Tolin Gay & Tawana B. Johnson, *The Wide-Ranging Effects of the Federal Circuit's Assault on Skinny Labels*, NAT'L L. REV. (Dec. 4, 2020), https://perma.cc/2X8Y-8FZC.

[112] *See* Potter, *supra* note 3, at 1710–12 (discussing the backlash).

[113] *See* Ian Lopez, *Teva Gets Generic Drugmakers' Backing in Bid to Redo Label Case*, BLOOMBERG L. (Dec. 9, 2021), https://perma.cc/JHF5-XXU3 (describing the criticism and anticipated implications of the majority opinion).

whether a generic that has carved out "all of the language that the brand manufacturer has identified as covering its patented uses" can still be "held liable on a theory that its label still intentionally encourages infringement of those carved-out uses."[114]

The majority's holding is best explained by its general reticence to allow the district court to overturn a jury verdict, an action that appellate courts view as system-destabilizing. Emphasizing that "a district court should grant JMOL [judgement as a matter of law] 'sparingly' and 'only if, viewing the evidence in the light most favorable to the nonmovant[,] . . . there is insufficient evidence from which a jury reasonably could find liability,'"[115] the Federal Circuit concluded that the district court reweighed the evidence when it should not have.[116] The majority repeatedly emphasized that "we must uphold the jury's verdict . . . so long as substantial evidence supports it," and focused on surveying feasible interpretations of the evidence provided at trial.[117]

In an impassioned dissent, then–Chief Judge Prost outlined how the majority "defie[d] basic tort law by eviscerating the causation prong of inducement."[118] She explained that GlaxoSmithKline's theory required the jury to find that doctors

> read [the label] to make prescribing decisions (even though all three testifying expert cardiologists said they didn't); infer those doctors pieced together the portions of the label to uncover a description of the infringing use (maybe); infer those doctors interpreted that description as an encouragement (no evidence); and then infer those doctors relied on that description to make their prescribing decisions.[119]

A reasonable jury simply could not have concluded that GlaxoSmithKline induced doctors in this way, Chief Judge Prost contended, particularly given the numerous other explanations that better account for prescribing practices.[120] She went on to note that the theory supporting causation for the press release was equally implausible and unsupported.[121] By accepting these—

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114 *See* GSK Cert. Pet., *supra* note 25, at i.

115 *GlaxoSmithKline*, 7 F.4th at 1326 (quoting Marra v. Phila. Hous. Auth., 497 F.3d 286, 300 (3d Cir. 2007)).

116 *Id.* at 1331.

117 *Id.* at 1328.

118 *Id.* at 1343 (Prost, C.J., dissenting).

119 *See id.* at 1359.

120 *See GlaxoSmithKline*, 7 F.4th at 1359.

121 *See id.* at 1354.

highly attenuated at best, nonexistent at worst—chains of causation, the Federal Circuit destabilized the essential doctrinal requirement that there be a finding of but-for causation *independent* from a finding of intentional encouragement to induce, Chief Judge Prost emphasized.[122]

While the Federal Circuit's decision to uphold the jury's finding of inducement strains credulity on causation grounds, its acceptance of the damages verdict is even more incomprehensible: it flatly contradicts its own precedent and fundamental principles of tort law. The *GlaxoSmithKline* majority conducted only a cursory evaluation of the eye-popping $234 million damages sum awarded for lost profits by the jury.[123] The court reiterated the requirement from *Grain Processing* that "the patent owner must show 'causation in fact,' establishing that 'but for' the infringement, he would have made additional profits."[124] However, it did not distinguish induced infringement from direct infringement when evaluating the lost-profits estimate. The court approvingly noted that "[GlaxoSmithKline]'s expert's analysis accounted for Teva's sales for the infringing use."[125] However, it failed to note that the expert analysis should have accounted for the sales for the infringing use that a jury could reasonably conclude were induced rather than *all* the infringing sales. The court then focused on dismissing one of the arguments Teva had made at trial: that the presence of many alternative generics on the market meant that, even without the presence of Teva's product, GlaxoSmithKline would not have made any additional sales.[126] The majority held that generics that would have been used in an infringing manner constitute "infringing alternatives" under *Grain Processing*,[127] and so could not be factored into a but-for analysis.[128]

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[122] *See id.* at 1359 ("[T]he majority's opinion suggests that there is no independent causation element for inducement; intentional encouragement might always suffice to infer causation too. Add that to the majority's weakening of intentional encouragement . . . and finding inducement becomes possible based largely on speculation.").

[123] It is worth noting that Teva's revenues from selling carvedilol were only $74 million, as generics sell products for much less money than brand-name companies. GlaxoSmithKline LLC v. Teva Pharms. USA, LLC, 976 F.3d 1347, 1363 n.3 (Fed. Cir. 2020) (Prost, C.J., dissenting), *vacated*, *GlaxoSmithKline*, 7 F.4th at 1326. It had made no profits from carvedilol even prior to the decision.

[124] *GlaxoSmithKline*, 7 F.4th at 1340 (quoting *Grain Processing*, 185 F.3d at 1349).

[125] *Id.* at 1341.

[126] *Id.*

[127] *See Grain Processing*, 185 F.3d at 1351.

[128] *See GlaxoSmithKline*, 7 F.4th at 1341.

This approach reveals a misplaced focus on but-for infringement rather than but-for *induced* infringement.

The court failed to address Teva's argument that because GlaxoSmithKline failed to even take a stab at quantifying the amount of lost profits *caused by* Teva's inducement—the injury in question—the damages award could not stand.[129] Indeed, GlaxoSmithKline based its damages demand (and the jury in turn based its calculation) on the assumption that 100% of the infringing sales were induced by Teva[130] even though "evidence from both sides showed that doctors relied primarily on medical guidelines, experience, education, and journals when making their prescribing decisions."[131]

It is a central principle of tort law that compensatory damages "are intended to redress the concrete loss that the plaintiff has suffered by reason of the defendant's wrongful conduct."[132] As the Federal Circuit has confirmed, patent cases are no different because, "[i]n patent cases, as in other commercial torts, damages are measured by inquiring: had the tortfeasor not committed the wrong, what would have been the financial position of the person wronged?"[133] In this instance, the "wrong" in question was *induced* infringement, not direct infringement. Thus, the damages needed to correspond not to all the infringement that occurred, but rather only to the infringement that Teva had induced with its label and press release.

The jury instructions confirm the logic that damages should correspond to induced infringement, not all infringement. The jury was told that GlaxoSmithKline "is not entitled to lost profits based on any infringement of the [method] patent that was not caused by Teva's inducement."[134] The instructions also reflect the requirement from *Grain Processing* that lost-profit damages cannot be based on speculation; instead, the plaintiff must provide

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[129] *See* Transcript of Jury Trial – Volume G at 1915, GlaxoSmithKline LLC et al. v. Teva Pharms. USA Inc. (Fed. Cir. 2021) (No. 1:14-cv-878) (Defendant Teva Pharms.' Closing Statement and Plaintiff's Rebuttal).

[130] *See* Transcript of Jury Trial – Volume C at 833, 835–36, GlaxoSmithKline LLC v. Teva Pharms. USA Inc. (Fed. Cir. 2021) (No. 1:14-cv-878) [hereinafter Jury Trial Transcript, Vol. C].

[131] *See GlaxoSmithKline*, 7 F.4th at 1352 (Prost, C.J., dissenting).

[132] Cooper Indus., Inc. v. Leatherman Tool Grp., Inc., 532 U.S. 424, 432 (2001).

[133] Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1579 (Fed. Cir. 1992).

[134] *See* Transcript of Jury Trial – Volume G at 1824, GlaxoSmithKline LLC et al. v. Teva Pharms. USA Inc. (Fed. Cir. 2021) (No. 1:14-cv-878) (Final Jury Instructions) [hereinafter Final Jury Instructions].

the jury with "sound economic proof" of lost profits.[135] Accordingly, the instructions stipulated that GlaxoSmithKline "has the burden of proving the amount of any direct infringement that was caused by Teva's inducement with reasonable certainty."[136] Yet instead of attempting to quantify the induced infringement—as was its burden—GlaxoSmithKline based its estimate on the premise that 100% of the infringing sales were induced.[137] Thus, the majority, in laboring to uphold the jury's verdict that Teva's label and press release caused "even at least one" incidence of infringement, upheld a damages calculation premised on the assumption that Teva had caused *all* the many million incidences of infringement.[138]

Judicial precedent clearly demands that even if the majority had upheld the verdict of induced infringement, it should have remanded the case for a proper damages calculation based on the infringement that was induced. The court has a responsibility to remand damages awards that are "clearly not supported by the evidence, or based only on speculation or guesswork."[139] Because GlaxoSmithKline did not even attempt to quantify the infringement that was induced, its estimate was "not supported by evidence" and was "based only on speculation."

The court's failure to require but-for causation for damages (or failure to appreciate that the jury's damages did not reflect but-for causation) reflects a larger misapplication of causation principles in the court's handling of damages for indirect infringement. Because these cases typically involve royalties and not lost profits, the only scholarship on the matter relates to determining royalties.[140] However, Professor Dmitry Karshtedt identified the overarching problem in an article on reasonable royalty liability: "the principle of formally imputing the wrongdoings of primary tortfeasors to the indirect infringer has confounded the courts' management of patent damages."[141] Although "the nature of the inducing acts and the manner in which they cause infringement to occur should inform how we think of damages for inducement

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135 *Grain Processing*, 185 F.3d at 1350.

136 *See* Final Jury Instructions, *supra* note 134, at 1824.

137 *See* Jury Trial Transcript, Vol. C, *supra* note 130, at 836–37.

138 *GlaxoSmithKline*, 313 F. Supp. 3d at 591.

139 *Lucent Techs.*, 580 F.3d at 1310 (quoting State Contracting & Eng'g Corp. v. Condotte Am., Inc., 346 F.3d 1057, 1072 (Fed. Cir. 2003)).

140 *See generally* Karshtedt, *supra* note 84.

141 *See id.* at 920.

of infringement,"[142] the Federal Circuit has applied directly conflicting approaches, Karshtedt found.[143] Ultimately, the Federal Circuit's lack of attention to causation in inducement cases has resulted in confused legal standards at the damages-calculation stage.

Set against the backdrop of an already undertheorized legal doctrine, the *GlaxoSmithKline* decision provides precedent for litigants to demand damages awards that encompass all infringement after a finding of inducement in postlaunch skinny label litigation. Indeed, generic companies have accepted that future postlaunch copycat litigation—which encompasses litigation targeting insurers—will result in similarly massive lost-profit awards.[144] Many industry commentators have identified the potential chilling effect of this precedent.[145] However, what commentators have importantly failed to point out is that this precedent is legally unsound. If courts apply the law correctly, these unfounded damages awards can be avoided entirely.

II. GENERIC SUBSTITUTION AND *AMARIN*

This Part analyzes the *Amarin* case to explore the central question of if—and when—health insurance plans induce infringement by covering generic drugs with skinny labels. Part II.A provides background about the process and drivers of generic substitution at the pharmacy level. It establishes that FDA therapeutic equivalence ratings, state substitution laws, and profit incentives for pharmacists combine to ensure that most brand-name drugs are substituted for generics at the pharmacy counter irrespective of whether a patient has health insurance or what kind of insurance they have. Such substitution accounts for most of the infringement that ultimately occurs. This serves as essential background for Part II.B, which explores the facts of the *Amarin* case. Part II.C.1 evaluates Amarin's argument that Health Net's insurance plan induced infringement by incentivizing pharmacists to substitute its brand-name drug for a generic equivalent. Part II.C.2 concludes that the district court erred in its causation analysis by adopting an improper but-for counterfactual.

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142 *Id.* at 928–29.

143 *See id.* at 951–54.

144 *See, e.g.*, Amicus Curiae Brief of Apotex Inc. at 8, GlaxoSmithKline LLC v. Teva Pharms. USA, Inc. (Fed. Cir. 2021) (No 1:14-cv-878).

145 *See, e.g.*, Potter, *supra* note 3, at 1734 (discussing the industry reaction and anticipated chilling effect).

Part II.C.3 proposes that courts should instead evaluate causation by considering whether, but for the insurance coverage, there would be less substitution and resultant infringement. This causation analysis suggests that mandatory substitution plans (like Health Net's) likely induce a small amount of the infringement that occurs under these companies' plans (with the majority occurring regardless of whether a patient has insurance). Part II.C.4 concludes by considering the ramifications of *GlaxoSmithKline* for insurance suits, as the case sets a dangerous precedent for situations where the inducer induces a small fraction of the overall infringement but will be held responsible for complete lost-profit damages.

A. The Generic Substitution Landscape

In the 1970s, states began to adopt laws mandating or encouraging the substitution of cheaper generic equivalents for the brand-name drugs that physicians prescribed.[146] States passed these laws against the backdrop of rising prescription drug prices to reduce state healthcare spending budgets and increase accessibility for consumers.[147] To assist states in determining which drugs were substitutable, the FDA began publishing a list of all prescription drugs it approved along with determinations of therapeutic equivalency, denoting therapeutic equivalence with an "AB" rating.[148] The publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (more commonly known as the Orange Book and now on its forty-second edition), instructs that "products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product can be expected to have the same clinical effect and safety profile as the prescribed product."[149]

In its more than forty years of publishing the Orange Book, "[the] FDA has never taken the position that the two [drugs] must be labeled for the same uses to be deemed therapeutically equivalent"[150] because therapeutic equivalency is based on "tangible product features and bioavailability in the body, not the scope of

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146 Lietzan, *supra* note 36, at 186.

147 Henry G. Grabowski & John M. Vernon, *Substitution Laws and Innovation in the Pharmaceutical Industry*, 43 L. & CONTEMP. PROBS. 43, 49 (1979).

148 Lietzan, *supra* note 36, at 186–87.

149 U.S. DEP'T OF HEALTH & HUM. SERVS., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, at viii (42d ed. 2022).

150 Lietzan, *supra* note 36, at 188.

regulatory approval."[151] Thus, skinny labels always receive an AB rating, the letter grade that signifies that these drugs are therapeutically equivalent, just like other generics. Because an AB rating from the FDA tends to trigger substitution at the pharmacy counter under state pharmacy laws,[152] and pharmacists have strong economic incentives to substitute generics, the average rate of generic substitution hovers above 90%.[153]

There are two kinds of state laws that regulate pharmacist substitution. One governs whether it is mandatory or permitted for a pharmacist to substitute an AB-rated generic. The other regulates whether a pharmacist can presume a patient's consent or if they have to explicitly ask for consent prior to substitution.[154] States "can choose any combination of the two policy tools."[155] For example, Florida's laws are explicit and mandatory, meaning that a pharmacist must substitute a generic but must ask for consent before doing so.[156] Alabama's laws are presumed and permissive, meaning that a pharmacist can exercise discretion about whether to substitute a generic but can assume that the patient consents to them doing so.[157]

Tellingly, there is not a statistically significant difference in substitution rates between states with mandatory versus permissive substitution laws.[158] This is because "gross profit dollars [for pharmacies] are approximately 50% higher for generic drugs than for brand-name drugs."[159] Pharmacists tend to dispense generic drugs over brand-name drugs "whenever possible"[160] due to the profit incentives, and thus, the mandatory or permissive regulations have little to no impact.[161]

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151 *Id.* at 187.

152 *Id.* at 188.

153 *See* Jodi B. Segal, Oluwadamilola Onasanya, Matthew Daubresse, Chia-Ying Lee, Mischka Moechtar, Xia Pu, Sarah K. Dutcher & Robert J. Romanelli, *Determinants of Generic Drug Substitution in the United States*, 54 THERAPEUTIC INNOVATION & REG. SCI. 151, 154 (2020).

154 Yan Song & Douglas Barthold, *The Effects of State-Level Pharmacist Regulations on Generic Substitution of Prescription Drugs*, 27 HEALTH ECON. 1717, 1719 (2018).

155 *Id.* at 1718.

156 *Id.* at 1719.

157 *Id.*

158 *Id.* at 1728.

159 Song & Barthold, *supra* note 154, at 1728.

160 *Id.* at 1733.

161 *Id.* at 1728.

In contrast, there is a statistically significant difference in substitution rates between states with explicit as opposed to presumed consent laws because patients in states that require explicit consent have the opportunity to refuse substitution and choose a brand-name drug.[162] The rate of generic substitution typically decreases when patients are given greater agency because many consumers mistakenly interpret the lower cost of generics as a mark of inferiority, remaining loyal to brand-name drugs with which they are familiar.[163] One study found that explicit consent laws increase the probability of consumers receiving a brand-name drug by 3% overall and 15% if the consumer has previous experience using the branded drug.[164] The 15% difference indicates that brand-name loyalty plays a non-negligible role in patients' decision-making. If a consumer who has previously taken a brand-name drug walks into a pharmacy in a state with a permissive consent law, they are 15% more likely to refuse substitution than the average consumer, even though the generic is the cheaper option and medically indistinguishable from the brand drug. Another study found that laws requiring patient consent prior to generic substitution resulted in 25% lower rates of generic substitution.[165]

Insurance companies also design health plans to increase generic usage, although they do not always succeed unless they mandate substitution themselves.[166] Insurers list generic and brand-name prescriptions that they provide reimbursement for (or "cover") in a table called a formulary.[167] Drugs are organized into different "tiers" within the formulary that correspond to varying co-pays (how much the insurance company will charge the

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[162] *Id.*

[163] *See* Kendra R. Manigault, Gabriela A. Marcheva & Samuel K. Peasah, *Insights into Effective Generic Substitution*, 41 GENERIC DRUG REV. 29, 30 (2016).

[164] Song & Barthold, *supra* note 154, at 1730, 1728.

[165] William H. Shrank, Niteesh K. Choudhry, Jessica Agnew-Blais, Alex D. Federman, Joshua N. Liberman, Jun Liu, Aaron S. Kesselheim, M. Alan Brookhart & Michael A. Fischer, *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 HEALTH AFF. 1383, 1388 (2010).

[166] *See* Jennifer N. Howard, Ilene Harris, Gavriella Frank, Zippora Kiptanui, Jingjing Qian & Richard Hansen, *Influencers of Generic Drug Utilization: A Systematic Review*, 14 RSCH. IN SOC. & ADMIN. PHARM. 619, 622 (2018); David A. Mott & Richard R. Cline, *Exploring Generic Drug Use Behavior: The Role of Prescribers and Pharmacists in the Opportunity for Generic Drug Use and Generic Substitution*, 40 MED. CARE 662, 670–71 (2002) (finding that the rate of substitution is approximately the same with no statistical difference for uninsured people and those with private third-party health plans, but significantly higher for those with Medicaid, which has mandatory substitution).

[167] *See, e.g.*, *List of Drugs (Formulary)*, HEALTHNET (2023), https://perma.cc/L634-DSYW.

consumer for the drug). Tier-one drugs include generics that have the lowest co-pay and are referred to as "preferred"; tier-two drugs cost more than tier-one drugs and usually include nonpreferred generics and some brand-name medications; tier-three drugs include preferred brands with no generic counterpart and nonpreferred brands that have a generic equivalent listed in tier one.[168] Many insurance plans now mandate the substitution of AB-rated generics and refuse to reimburse a tier-two or tier-three brand-name drug if a tier-one generic is available.[169] Studies suggest that this changes the behavior of customers who would otherwise opt for a brand-name drug over a generic drug if the plan covered both.[170] For example, if a plan reimburses a patient for both a generic and a brand-name drug but charges different co-pays for each, a patient might ask the pharmacist not to substitute a generic and opt to pay a $50 co-pay over a $10 co-pay. If a plan mandates generic substitution and thus does not reimburse a patient for a brand-name drug, the options would then become a $10 co-pay versus the difference in cost between the generic and brand-name drug plus the co-pay for the brand-name drug (which could be in the hundreds of dollars), and consumers will usually not refuse generic substitution.

In this way, the "presence of insurance (which lowers the patient's share of the price) promotes the choice of a more expensive treatment" when a traditional commercial formulary is used, but not when mandatory substitution is required and the consumer has to internalize the out-of-pocket cost of the brand-name drug.[171] One study that investigated the relationship between insurance type and generic-substitution rate found similar substitution rates for private third-party and uninsured patients (about 81–82%) and a higher rate for Medicaid patients (94%).[172] The 12% difference between the private third-party plan (no mandatory substitution) and the Medicaid plan (mandatory substitution) demonstrates that health plans with mandatory substitution policies increase the rate of generic substitution. Another more recent study confirmed that one year after generic entry, the substitution rate for the leukemia drug imatinib was 81% for

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168 Ana G. Ivey, *A Guide to Medication Formularies*, GOODRX HEALTH (Nov. 22, 2022), https://www.goodrx.com/insurance/health-insurance/medication-formulary.

169 *Just the Facts: Prescription Drug Utilization Management*, AM. CANCER SOC'Y (Feb. 25, 2014), https://perma.cc/YPE7-GYMB.

170 *See* Song & Barthold, *supra* note 154, at 1728; Mott & Cline, *supra* note 166, at 663.

171 Mott & Cline, *supra* note 166, at 663.

172 *Id.* at 671.

commercially insured patients and 91% for Medicare Advantage patients.[173] This again suggests that Medicare plans—which mandate generic substitution—result in marginally higher substitution rates.

Because the major factors that ensure generic substitution—the AB rating, state pharmacy law, and economic incentives for pharmacists—apply indiscriminately to all generics, skinny label drugs are substituted at the same rate as any other generic, even for the uses still under patent.[174] For example, just one year after skinny label imatinib became available, more than 88% of patients with gastrointestinal stromal tumors received a generic version, even though gastrointestinal stromal tumors were excluded from the generic's approved indications because it was separately patented.[175] Thus, method-of-use patents are rendered more or less useless once a skinny label generic enters the market. As Professor Erika Lietzan described, "[t]he law intends drug companies to have exclusive sales for the new uses they develop. But partial labeling to respect protected uses is functionally irrelevant when FDA deems a generic drug AB-rated to the innovator's drug."[176] Some industry players have accordingly called the FDA's therapeutic equivalency system a "government-run program that essentially institutionalizes patent infringement"[177] and have strongly criticized it as "flatly contrary to the intent of federal law."[178]

Although these critiques certainly appear meritorious when evaluated in a vacuum or from a purely textualist perspective, they fail to account for the larger landscape of widespread evergreening by brand-name pharmaceutical companies. As Part III.D describes, skinny labeling serves as one of the few "effective counter-strateg[ies] to brand-name manufacturers' efforts to prolong their revenues" by collecting follow-on patents claiming drug features that were already under protection.[179] Thus, even though the AB rating system results in infringement, the skinny labeling pathway helps "achieve[ ] the intended policy goal of ensuring that secondary patents d[o] not extend the brand-name

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[173] *See* Walsh et al., *supra* note 29, at 1104.

[174] *See* Lietzan, *supra* note 36, at 191.

[175] *See* Walsh et al., *supra* note 29, at 1104.

[176] Lietzan, *supra* note 36, at 191.

[177] Terry G. Mahn, *Skinny Labeling and the Inducement of Patent Infringement*, Nov/Dec 2010 UPDATE: FOOD & DRUG L. INST. 39, 42.

[178] *See* Lietzan, *supra* note 36, at 196.

[179] *See* Walsh, *supra* note 29, at 1104.

drug's monopoly and delay patient access to less expensive generics"[180] whereas other evergreening strategies are not as easy to counter.[181]

B. The *Amarin* Decision

In one of the first skinny label cases following *GlaxoSmithKline,* Amarin brought two claims in the District of Delaware. The first directly copied GlaxoSmithKline's argument: Amarin sued the generic manufacturer Hikma Pharmaceuticals for inducing infringement of its blockbuster drug, Vascepa, through Hikma's skinny label and press releases.[182] Vascepa is FDA-approved for the treatment of severe hypertriglyceridemia (SH) and cardiovascular risk reduction (CV). Hikma received FDA approval to enter the market and sell a generic version (icosapent ethyl caps) for the SH indication under the section viii carveout regime, because Amarin has an active patent for CV but not SH. The court found that "Amarin's complaint [ ] failed to plead inducement based on Hikma's label or public statements" and thus granted Hikma's motion to dismiss.[183] The second claim, which the court allowed to proceed, represents the novel legal issue that is the subject of this Comment's discussion.

Amarin added Health Net, an insurance company, as a defendant. Amarin argued that Health Net's placement of the skinny label generic in its first formulary tier and Vascepa in the third tier induced infringement by encouraging pharmacists to substitute, and thus patients to use, the generic drug as opposed to Vascepa for the CV indication.[184] Prior to the launch of the generic skinny label, Health Net covered Vascepa as a tier-three brand-name drug. Health Net added Hikma's generic equivalent to its formulary as a preferred tier-one generic when it became available, as is common practice among all insurance companies. Amarin's central argument was that the placement of Hikma's generic on a lower tier directed the substitution and use of "Hikma's generic version of V[ascepa] for any indication it may be

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180 *See id.*

181 *See* Feldman, *supra* note 1, at 639.

182 *See Amarin*, 578 F. Supp. 3d at 645–46. Amarin's claim against Hikma is currently on appeal to the Federal Circuit. Oral argument occurred in February of 2022.

183 *Id.* at 648.

184 *Id.*

prescribed for," including the patented indication.[185] Amarin posited that Health Net had induced infringement by "provid[ing] economic incentives to the pharmacists to dispense and patients to use the generic to infringe Amarin's patents,"[186] which resulted in "many prescriptions for the CV indication [being] switched to Hikma's generic product, as Health Net knows and intends."[187]

This central argument about Health Net's formulary is applicable to almost every health insurer in the United States. As discussed in the previous Section, insurance companies do not treat skinny label generics differently than other AB-rated generics, and co-pays are always lower for generics because they reflect the discrepancy between generic and brand-name prices.

The second part of Amarin's claim against Health Net involved Health Net's "prior authorization" (PA) process. Before the release of the generic icosapent ethyl, Health Net refused to pay for off-label prescriptions of Vascepa, authorizing Vascepa prescriptions only for patients diagnosed with the SH or CV indication. This kind of PA requirement is increasingly common.[188] To ensure that a prescription is granted for an approved indication, payers mandate that medical providers submit a form documenting the patient's diagnosis (e.g., the SH or CV indication) and confirming that they meet the PA criteria. Only then will the insurance company authorize payment for the prescription.[189]

When Health Net added the icosapent ethyl caps to its formulary, it maintained the PA requirement on certain health plans. Instead of creating different forms for the generic and the brand-name Vascepa, it used one form, which asked prescribers to report whether the patient had either been diagnosed with the CV or SH indication.[190] Thus, the form showed that Health Net

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185 Complaint at 37, Amarin Pharma, Inc. v. Hikma Pharms. USA Inc., No. 20-1630 (D. Del. Aug. 3, 2021).

186 Plaintiffs' Response in Opposition to Defendant Health Net, LLC's Motion to Dismiss at 10, Amarin Pharma, Inc. v. Hikma Pharms. USA Inc., No. 20-1630, (D. Del. Aug. 3, 2021).

187 *Id.* at 8.

188 Joanne Finnegan, *More Medical Services Now Require Prior Authorizations, According to Physicians*, FIERCE HEALTHCARE (Jan 28, 2020), https://perma.cc/ZD5Y-JDQD.

189 Gerardo Sison, *What You Need to Know About Prior Authorization*, SINGLECARE (Mar. 29, 2022), https://perma.cc/PHX2-3YP6.

190 Amarin Pharma, Inc. v. Hikma Pharms. USA Inc., 2021 WL 3396199, at *4 (D. Del. Aug. 3, 2021), *report and recommendation adopted in part and rejected in part*, 578 F. Supp. 3d 642 (D. Del. 2022) ("To obtain prior authorization from the plan, the patient's medical provider must submit documentation demonstrating that the prescription is being given for either the SH or the CV indication.").

was aware of what indication the drug was prescribed for and covered the skinny label generic regardless of whether it was prescribed for the patented indication.[191]

The court found that Amarin had plausibly pleaded induced infringement (i.e., that Health Net intentionally committed affirmative acts that caused pharmacists to substitute and patients to infringe). Specifically, it held that adding generic icosapent ethyl to its formularies could be an affirmative act because of "the incentives the formulary puts in place"[192]: "Health Net's placement of generic icosapent ethyl on a preferred tier encourages the substitution of the generic for the branded drug, including for the patented indication."[193] It also found that the PA form "supports an inference of specific intent because it lists the patented indication on the generic icosapent ethyl capsules form."[194]

C. Did Health Net Induce Infringement?

This Section examines whether Health Net induced infringement. It first sets aside the prior authorization form as a nondispositive element of Amarin's claims. It then demonstrates that the district court's causation analysis—which would have held Health Net responsible for all the substitution and subsequent infringement under its health plan—ran counter to Federal Circuit precedent. Then, this Section proposes a proper counterfactual for evaluating but-for causation in induced infringement cases involving health insurers. The results of an application of this accurate causation framework suggest that mandatory-substitution health plans, like Health Net's, induce a small fraction of the overall substitution that occurs. Although these insurance companies should in turn only be responsible for a small damages sum, the erroneous precedent from *GlaxoSmithKline* may indicate otherwise.

1. The prior authorization form is not dispositive.

Prior to discussing whether Health Net's tiered formulary induced infringement—and thus whether *Amarin* is generalizable

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[191] *See id.* at *8 ("Plaintiffs allege that Health Net knows when a particular beneficiary is using Hikma's product for the CV use because Health Net's prior authorization process requires the beneficiary's provider to submit documentation supporting the use for which it has been prescribed.").

[192] *Amarin*, 578 F. Supp. 3d at 649.

[193] *Id.* at 648.

[194] *Id.*

to the health insurance industry at large—it is necessary to establish that the PA form, which sets Health Net apart from the average insurer, is not a dispositive element of the claim. Insurance companies typically do not know why a certain drug is prescribed; medical diagnoses are confidential information that are kept private unless requested for prior authorization purposes. Therefore, in most instances, an insurer with a tiered formulary can predict that it will pay for infringing uses a certain percentage of the time but will not know exactly which prescriptions are infringing. In contrast, the PA form demonstrates that Health Net knew exactly when it was paying for infringing uses of icosapent ethyl.

Critically, this kind of specific knowledge is not necessary for establishing induced infringement. Most induced infringement claims are based on a theory of class-wide inducement that does not require the inducer to know every time the direct infringement happens. For example, generic companies do not need to know every time doctors infringe to be found guilty of inducement; they must simply intend for a skinny label or piece of marketing material to cause direct infringement.[195] Therefore, the PA form essentially demonstrates a level of specific knowledge that Health Net is not required to possess—inducers do not need to *know* when an advertisement or instruction manual induces direct infringement. They just need to take specific steps—i.e., producing the instruction manual or, potentially, a drug formulary—that causes direct infringement. Thus, unless the PA form itself induced infringement, it does little for Amarin's case. It does not matter that HealthNet is able to track which prescriptions led to infringement; it matters whether they induced that infringement by taking specific actions.

And there is no indication that the PA form itself induced infringement. The form cannot be likened to a label, advertisement, or instruction manual because a doctor does not interact with the form until after they have diagnosed a patient with either the SH or CV indication and written the prescription for the generic or

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[195] *See GlaxoSmithKline*, 7 F.4th at 1340 ("[W]e have affirmed induced infringement verdicts based on circumstantial evidence of inducement (e.g., advertisements, user manuals) directed to a class of direct infringers (e.g., customers, end users) without requiring hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material." (quoting Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 843 F.3d 1315, 1335 (Fed. Cir. 2016))).

brand-name Vascepa. Even though the form "describe[d] the infringing mode,"[196] it did not recommend, encourage, or instruct physicians (unlike a drug label), but rather gathered information about a diagnosis and prescribing choice that a physician already made. And it didn't induce pharmacists to infringe; pharmacists do not fill out or interact with the content of PA forms.

We can therefore conclude that the PA form demonstrates knowledge but does not improve Amarin's main argument, which was based on the incentives that the formulary puts in place and is thus generalizable industry-wide.

2. The district court's causation analysis is incorrect.

To establish inducement, Amarin was required to show that Health Net's tiered formulary caused pharmacists to substitute Vascepa prescriptions (for the patented CV indication) with icosapent ethyl. Amarin framed its argument in terms of Health Net's decision to cover the generic, arguing that but for Health Net listing icosapent ethyl as a tier-one generic, pharmacists would not have substituted it for Vascepa.[197] The district court implicitly adopted the counterfactual baseline of Health Net not "add[ing] generic icosapent ethyl capsules to its formularies," although like the reasoning in many inducement opinions, the court's analysis focused almost exclusively on intent and knowledge rather than causation.[198]

Amarin's causation argument has intuitive appeal. If Health Net had only covered Vascepa, its formulary would have skewed the pricing difference between the generic and brand-name drugs such that Vascepa (priced at a $50 co-pay)[199] would be cheaper than generic icosapent ethyl ($85 for over-the-counter generic).[200] This pricing difference would in turn have stopped pharmacists from following state substitution laws, which condition substitution on the generic drug being cheaper for the customer than the brand-name drug. For example, Florida law stipulates that "[a] pharmacist who receives a prescription for a brand-name drug

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196 *See* Toshiba Corp. v. Imation Corp., 681 F.3d 1358, 1365 (Fed. Cir. 2012).

197 *See Amarin*, 578 F. Supp. 3d at 648–49.

198 *See id.* at 648.

199 *See* HEALTH NET, SUMMARY OF BENEFITS AND COVERAGE 2 (2022).

200 The but-for formulary would have listed Vascepa as a tier-three drug with a corresponding co-pay of $50. *See id.* It would not have covered generic icosapent ethyl, meaning for somebody with Health Net insurance, the generic would cost the out-of-pocket price of about $85. *See Icosapent Ethyl*, GOODRX (2023), https://www.goodrx.com/icosapent-ethyl.

shall, unless requested otherwise by the purchaser, substitute a *less expensive*, generically equivalent drug product."[201] Thus, even in a state that requires mandatory substitution, a pharmacist cannot substitute an $85 generic for a $50 brand-name drug, because the generic is not "less expensive" for the patient. In this way, Amarin's but-for formulary ties the pharmacists' hands by introducing a novel situation where the brand is cheaper for the customer than the generic.

Under the district court's approach to causation, any insurance company that covers generic drugs at lower co-pays (the common practice of all insurance companies) is liable for all the substitution and subsequent infringement that occurs under its plan. As discussed *supra* Part II.A, substitution accounts for the vast majority of infringement. Thus, if courts accept this theory—as the district court's opinion suggests they are willing to do—insurance companies could face hundreds of millions of dollars in damages for covering generic drugs with skinny labels.

However, there is strong reason to doubt that Amarin is entitled to its counterfactual, as it imposes a duty on Health Net to prevent something that would happen in the absence of any health insurance coverage at all: generic substitution. The Federal Circuit has repeatedly held that 35 U.S.C. § 271(b) does not require third parties to take action to *prevent* infringement. For example, in *Tegal Corp. v. Tokyo Electron Co.*[202] the Federal Circuit rejected Tegal's theory "that by taking no action to prevent it, [Tokyo Electron]was guilty" of inducing infringement.[203] The court emphasized that "permitting [another] party to commit infringing acts"[204] or "failure to stop infringement," cannot form the basis of an induced infringement claim.[205] Similarly, in the skinny label case *Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceutical Corp.*,[206] the Federal Circuit held that "Takeda needs to show that Hikma took affirmative steps to induce, not affirmative steps to make sure others avoid infringement."[207] As the District of Delaware itself recently summarized,

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201 FLA. STAT. ANN. § 465.025(2) (emphasis added).
202 248 F.3d 1376 (Fed. Cir. 2001).
203 *Id.* at 1378.
204 *Id.*
205 *Id.* at 1379.
206 785 F.3d 625 (Fed. Cir. 2015).
207 *Id.* at 632 n.4.

"Section 271(b) does not require that Defendants actively protect Plaintiff's patents from third-party direct infringement."[208]

When this precedent is applied to Amarin's theory, it becomes clear that the counterfactual the court considered would require Health Net to "prevent" infringement that would have happened even in the absence of Health Net's policies. In the absence of insurance coverage, pharmacists are more likely than not to substitute generics for brand names, especially because uninsured patients face high over-the-counter prices. If a patient has insurance that covers both drugs (for example, at Health Net's tier-one co-pay of $5 and a tier-three co-pay of $50),[209] pharmacists are also more likely than not to substitute. The only situation in which substitution would not happen is when HealthNet actively prevents it by covering only the brand name, which is precisely what cannot be required under § 271(b). Yet this scenario is what Amarin proposed as the basis of its causation analysis.

3. The correct but-for counterfactual is a patient with no insurance coverage.

To establish whether the formulary causes substitution, a court should instead consider the counterfactual of what would happen if insurance was eliminated from the picture entirely. If a patient walked into the pharmacy and did not have a health plan that covered the generic *or* the brand name, would a pharmacist substitute the two drugs? As explained *supra* Part II.A, the answer is yes in the vast majority of situations. State law and profit incentives would continue to operate on pharmacists, who would also be motivated to help uninsured patients purchase the cheapest medication available. Thus, most pharmacists would substitute the generic regardless, meaning that an insurance plan is rarely a but-for cause of substitution.

Insurance plans that merely pass on the pricing difference between brand-name and generic drugs—i.e., formularies that charge $5 for the generic and $50 for the brand name but allow a patient to opt for the brand name—likely do not result in more infringement than would occur at the baseline no-insurance counterfactual. This is because these formularies do not skew the market

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[208] Takeda Pharms., U.S.A., Inc. v. W.-Ward Pharm. Corp, 2018 WL 6521922, at *5 (D. Del. Dec. 12, 2018).

[209] *See* Health Net, *supra* note 199, at 2.

further toward the generic; they replicate existing economic incentives created by the pricing differential between generic and brand-name drugs. In contrast, insurance plans that *mandate* the substitution of tier-one drugs for tier-three drugs increase the rate of substitution to nearly 100%. Thus, these plans further increase the rate of substitution by adding an additional incentive: on top of the pharmacists' own profit incentives and state laws, the insurance plan mandates substitution. For example, if 85% of pharmacists substitute generics when they encounter a patient without insurance, an insurance plan is likely responsible for the remaining 15% of infringement. Because Health Net requires mandatory substitution—it will only pay for brand name Vascepa after a lengthy prior authorization process—it is likely that Health Net's plan does induce a small amount of infringement on the margins. In order to determine how much, Amarin would compare data on the generic substitution rate of Vascepa under Health Net's plan with the substitution rate for uninsured patients (12.2% of the adult population for ages 19–64).[210]

Under this proposed causation analysis, the infringement an insurer induces is whatever infringement would not have occurred if a patient had no insurance whatsoever. Although Health Net is likely liable under both counterfactuals—assuming it meets the intent and knowledge requirements of § 271(b)—it is responsible for a much smaller fraction of the infringement that occurs under the no-insurance counterfactual as opposed to all the infringement under Amarin's counterfactual.

4. The damages problem: a return to *GlaxoSmithKline*.

The outcome of the no-insurance counterfactual is reminiscent of *GlaxoSmithKline* in that a jury *could* find inducement, but the inducement would account for a very small fraction of the overall infringement. Just like doctors are rarely induced by labels or press releases, pharmacists are rarely induced by insurance plans. Thus, the causation and damages errors in *GlaxoSmithKline* set a dangerous precedent for future induced infringement cases involving insurance companies. Under *GlaxoSmithKline*, once a litigant proves infringement by inducement, the inducer is liable for all the infringement that occurred. This results in grossly inflated

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210 *Uninsured Rates for the Nonelderly by Age*, KAISER FAM. FOUND., https://perma.cc/UJK9-84W6 (referring to 2021 data).

damages awards in the rare cases where the majority of infringement is not induced. *GlaxoSmithKline*'s critical problem with causation and damages will go unremedied, as the Supreme Court denied certiorari.[211] The possibility of being held responsible for all infringement occurring under their plan rather than a small fraction will in turn deter health insurers from covering skinny labels. This will effectively allow brand-name companies to evergreen with method-of-use patents, even though the skinny labeling pathway was intended to prevent such behavior.

Furthermore, the issue is not necessarily limited to the skinny label context. Now that pharmaceutical litigants have tested the theory of an insurance company's inducing infringement, medical device companies and others might do the same. It is imperative that the Federal Circuit adopt a uniform method for weighing causation and damages in cases involving insurers, as the chains of causation are complex and involve multiple actors. Continuing to give short shrift to causation and damages will further engrain the faulty *GlaxoSmithKline* approach.

III. APPLICATION OF THE LOSS OF CHANCE DOCTRINE AND POLICY CONSIDERATIONS

This Part proposes using the loss of chance doctrine to determine liability, as an application of loss of chance rather than the classic all-or-nothing principle of recovery forces courts to consider causation properly and ensures that a finding of inducement will correspond with a proportionate rather than absolute damages award. The loss of chance framework is also particularly responsive to induced infringement, as the injury in question (inducement influencing multiple actors and thereby increasing the overall rate of infringement) can be understood as probabilistic in nature.

A. Background on the Loss of Chance Doctrine

In tort law, the loss of chance doctrine allows a plaintiff to assert a claim against a defendant whose conduct "increase[d] the probability of the ultimate harm, even if the likelihood of incurring that injury was greater than fifty percent in the absence of

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[211] *See GlaxoSmithKline*, 7 F.4th 1320 (Fed. Cir. 2021), *cert. denied*, 2023 WL 3440748 (U.S. May 15, 2023).

the defendant's [actions]."[212] The modern theory rose to prominence in the 1980s—particularly in the context of medical malpractice cases—after the publication of an influential article by Professor Joseph King in 1981. King theorized that "the loss of a chance of achieving a favorable outcome or of avoiding an adverse consequence should be compensable and should be valued appropriately, rather than treated as an all-or-nothing proposition."[213] Today, more than half of the jurisdictions in the United States that have considered the loss of chance doctrine have embraced it in the medical malpractice context (a total of twenty-five states).[214]

King's canonical example is a patient with only a 30% chance of surviving cancer.[215] Under the traditional all-or-nothing rule of causation, a doctor that negligently fails to diagnose the patient and reduces their chance of survival from 30% to 5% cannot be held liable, because death was always the more likely result. Yet this outcome insufficiently deters doctors from negligent conduct in dealings with high-risk patients and fails to account for the fact that being deprived of a chance to live constitutes a material injury in and of itself. King argued that patients should be allowed to recover for the loss of a chance at survival, i.e., the value of the 25% chance. To find otherwise would "subvert[ ] the deterrence objectives of tort law by denying recovery for the effects of conduct that causes statistically demonstrable losses," he asserted.[216]

Early cases that employed a version of loss of chance characterized the theory as involving a relaxation of the burden of proof on causation rather than a reconceptualization of the injury itself. For example, in the seminal case *Herskovits v. Group Health Co-Op of Puget Sound*,[217] the Washington Supreme Court held that a reduction in the decedent's chance of survival from 39% to

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[212] Cahoon v. Cummings, 734 N.E.2d 535, 539 (Ind. 2000).

[213] Joseph H. King, Jr., *Causation, Valuation, and Chance in Personal Injury Torts Involving Preexisting Conditions and Future Consequences*, 90 YALE L.J. 1353, 1354 (1981).

[214] *See* Lauren Guest, David Schap & Thi Tran, *The "Loss of Chance" Rule as a Special Category of Damages in Medical Malpractice: A State-by-State Analysis*, 21 J. LEGAL ECON. 53, 59 (2015). In addition to the twenty-four states compiled in this study, the Oregon Supreme Court in 2017 accepted loss of chance in *Smith v. Providence Health & Servs.—Oregon*, 393 P.3d 1106, 1113 (Or. 2017), bringing the number up to twenty-five. In 2020, the Hawaii Supreme Court ruled that loss of chance is not a separate compensable injury, but a factfinder may consider a loss of chance theory in determining legal causation. *See* Est. of Frey v. Mastroianni, 463 P.3d 1197, 1208–12 (Haw. 2020).

[215] *See* King, *supra* note 213, at 1363–64.

[216] *See id.* at 1377.

[217] 664 P.2d 474 (Wash. 1983).

25% was "sufficient evidence of causation" to allow the jury to consider whether the physician's failure to timely diagnose the illness caused the decedent's death.[218] "To decide otherwise would be a blanket release from liability for doctors and hospitals any time there was less than a 50 percent chance of survival, regardless of how flagrant the negligence," the court stated.[219]

But today, King's original conceptualization of loss of chance as a theory of the *injury* "is favored by commentators and the majority of courts in [ ] jurisdictions that have approved of the loss-of-chance doctrine."[220] As the Indiana Supreme Court summarized, "loss of chance is better understood as a description of the injury than as either a term for a separate cause of action or a surrogate for the causation element of a negligence claim."[221] Treating the tortious deprivation of a chance to live as the injury itself resolves the criticism that the doctrine "upends the long-standing preponderance of the evidence standard" and "alters the burden of proof in favor of the plaintiff" because the plaintiff must still establish causation by preponderance of the evidence.[222] To prove loss of chance, a plaintiff must still establish by a preponderance of the evidence that a physician's negligence was the but-for cause of a reduction in the likelihood of *survival* (as opposed to the traditional claim requiring the plaintiff to prove the physician caused the death).[223]

Damages are typically calculated using the proportional damages approach originally advanced by King. To calculate proportional damages, a jury values the full wrongful-death damages (say $1 million) and multiplies that figure by the percentage that the patient's chances of survival were reduced.[224] For example, if medical negligence reduced the chance of survival from 40% to 10%, the jury would multiply $1 million by 30% for a damages award of $300,000. Courts have commented that loss of chance is

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[218] *See id.* at 476–77.

[219] *Id.* at 477.

[220] *Smith*, 393 P.3d at 1113.

[221] Alexander v. Scheid, 726 N.E.2d 272, 279 (Ind. 2000).

[222] *See* Matsuyama v. Birnbaum, 890 N.E.2d 819, 831 (Mass. 2008), *abrogated by* Doull v. Foster, 163 N.E.3d 976, 984 n.9 (Mass. 2021). The Massachusetts Supreme Court recently abrogated one aspect of the causation analysis in *Matsumaya*, but it did not overturn the loss of chance analysis. *Doull*, 163 N.E.3d at 984 n.9.

[223] *See Smith*, 393 P.3d at 1114.

[224] *See, e.g.*, *Matsuyama*, 890 N.E.2d at 839–40.

particularly appropriate in the medical malpractice context because "ample reliable scientific evidence about the statistical probability of various medical outcomes is available."[225]

The loss of chance doctrine has only been extended to a few contexts outside of medical malpractice—most notably to calculate damages in cases of employment discrimination. Judge Richard Posner, writing for the Seventh Circuit in 1996, observed that loss of chance "strikes us as peculiarly appropriate in employment cases involving competitive promotion," because the theory accounts for situations in which a plaintiff or class of plaintiffs was never more likely than not to get the job, but whose chances at getting the job were further reduced by discriminatory hiring practices.[226] In *Biondo v. City of Chicago*,[227] the court formally affirmed that the "loss of [ ] chance method is the best way to handle [the] probabilistic injuries" that arise in Title VII cases involving discriminatory promotion for the purposes of calculating compensatory damages.[228] Three years later, the court's framing of the doctrine affirmed that it is best conceptualized as a theory of the injury: "[loss of chance] appropriately quantifies each plaintiff['s] monetary loss when what they in fact lost was a chance to compete on fair footing, not the promotion itself."[229] Courts continue to use the *Biondo* loss of chance framework for "handl[ing] probabilistic injuries" in employment discrimination.[230]

B. Application to Insurance Plans

Loss of chance offers similar advantages in determining insurance company liability, as the doctrine accounts for the factors that make pharmacists more likely than not to substitute regardless of whether a patient has insurance coverage. Background conditions underlying substitution, like the AB rating of the drug, substitution mandated by state laws, and pharmacists' economic incentives, are analogous to a preexisting condition. They represent background risk to the plaintiff—in this case, rather than having a greater than 50% chance of a negative medical outcome,

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225 *See Smith*, 393 P.3d at 1115.

226 Doll v. Brown, 75 F.3d 1200, 1206 (7th Cir. 1996).

227 382 F.3d 680 (7th Cir. 2004).

228 *Id.* at 688 (quotation marks omitted).

229 *See* Alexander v. City of Milwaukee, 474 F.3d 437, 449 (7th Cir. 2007).

230 *See, e.g.*, Ernst v. City of Chicago, 2018 WL 6725866, at *16 (N.D. Ill. Dec. 21, 2018) (alteration in original) (quoting *Biondo*, 382 F.3d at 688).

the patent holder has a greater than 50% chance of infringement before the insurance company steps in at all, because pharmacists are always more likely than not to substitute. Liability should ensue only when the formulary increases the *rate* of substitution above the baseline no-insurance condition, just as a doctor should only be liable when they increase the likelihood of a negative medical outcome for a high-risk patient. This rate increase represents the total impact of the number of pharmacists substituting who would not otherwise substitute. In this way, loss of chance ensures that a court will premise its causation analysis on the correct counterfactual—uninsured versus the insurance plan in question—and find liability *only* for the *induced* infringement.

Under a loss of chance framework, a plaintiff would still have to show that direct infringement had occurred and that the payer possessed affirmative intent to induce infringement per 35 U.S.C. § 271(b). The causation analysis would simply shift from considering whether the formulary caused infringement to considering whether the formulary caused an increased *chance* of infringement. Thus, the factfinder would be tasked with determining whether the rate of infringement would have been lower in the absence of the formulary, and if so, by how much. If the answer to this question is yes, then the payer should be held liable for inducing infringement and damages would be calculated proportionately. Damages would correspond to causing the drug company's lost opportunity to sell its drug for the patented indication (the percentage increase in infringement attributable to the inducing actions).

An application of loss of chance is feasible, as specific data exists (and can be procured) on the rate of generic substitution under various insurance plans. Past studies have directly compared the rate of generic substitution between uninsured patients and those with different insurance types[231] or used regression analyses to track the relationship between substitution ratios and various other demographic factors, including insurance.[232] Ultimately, this is the same data that would be required for a proper

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[231] *See, e.g.*, Mott & Cline, *supra* note 166, at 671 (calculating the generic substitution rate for uninsured, Medicaid, third-party, and indemnity insurance types, and finding a 94% substitution rate among Medicaid patients and an 81% substitution rate among the uninsured).

[232] *See, e.g.*, Segal et al., *supra* note 153, at 153–54 (breaking down substitution rates for twenty-six drug classes, and using mixed-effects logistic regression to estimate the independent relationship between factors like pharmacy type, insurance type, and gender and substitution); Walsh et al., *supra* note 29, at 1103 (using logistic regression to track

damages calculation under the no-insurance counterfactual even if a court did not implement a loss of chance theory of the injury. Either way, the plaintiff must quantify with "reasonable certainty" the amount of infringement that the insurer *caused*.[233] A central advantage of loss of chance is that a jury could not find liability if a brand-name pharmaceutical company failed to demonstrate *induced* infringement (rather than infringement caused by other factors). Because circumstantial evidence is accepted for establishing inducement,[234] a study demonstrating the substitution rate under a mandatory substitution insurance plan compared to a study demonstrating the rate of substitution among uninsured patients would suffice, so long as strong testimony established that insurance accounted for the difference.

Insurer liability under loss of chance does not significantly threaten the skinny labeling pathway. First, it is unlikely that brand-name companies would think it worthwhile to sue insurers for inducement if they could only recoup 10–15% of the lost profits from the infringing sales. And even if they were to bring suit, the damages awards would not be sizable enough to deter insurers from covering skinny labels at all—which is the central risk that insurer liability under Amarin's theory poses to the skinny labeling pathway. Furthermore, insurers could protect themselves from liability by not imposing mandatory substitution for skinny label generics; this would reduce substitution rates and therefore limit the likelihood that brand-name companies could demonstrate induced infringement. Ultimately, loss of chance would likely force brand-name companies to directly target pharmacies, which are best positioned to limit substitution based on indication but have never been sued as they are the brand-name companies' customers.

C. Potential Application to Cases Like *GlaxoSmithKline*

If the court in *GlaxoSmithKline* had used the loss of chance doctrine to determine liability, it would have had to disaggregate the infringement Teva induced from the infringement caused by other factors in order to make a facial showing of inducement. The

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the use of generic versus brand-name imatinib, and adjusting for demographics, which includes insurance type).

[233] *See* Final Jury Instructions, *supra* note 134, at 1824.

[234] *See GlaxoSmithKline*, 7 F.4th at 1339.

plaintiffs could have accomplished this through a survey instrument that asked a nationally representative sample of doctors whether either Teva's label or press releases induced or would induce them to prescribe carvedilol (the generic) for the patented indication. Any finding of causation—i.e., causing a percentage lost chance opportunity to sell its drug for the patented indication attributable to Teva's actions—would have corresponded directly to inducement, not overall infringement. Upon determining liability, the court would have already engaged with the evidence that is required for correctly determining damages: the percentage of infringement attributable to Teva's inducing acts. Because "both sides' expert cardiologists said under oath and without contradiction that medical texts, education, and experience caused their prescribing decisions,"[235] it seems unlikely that a jury would have found that Teva's label and press releases caused a measurable increase in the rate of infringement. However, if the jury had made a finding of liability, the finding would have reflected the relatively small percentage of doctors that made prescribing decisions based on Teva's actions. The damages award would have, in turn, been next to nothing in lost profits rather than $234 million—as it should have been if the court had correctly applied *Grain Processing*.

Ultimately, the two approaches generate the same result in terms of liability and damages, which is exactly as intended because they are fundamentally asking the same question: How much infringement did the defendant cause that would not have occurred but for the defendant's actions? The loss of chance framework essentially forces courts that have inconsistently conducted causation analyses and improperly considered damages to consider these questions in a rigorous and uniform way that is consistent with the judicial precedent that governs the basic requirements for causation and lost-profit damages.[236]

D. Policy Considerations Further Justify the Loss of Chance Framework

If future courts accept Amarin's theory of induced infringement, some insurers will likely stop covering skinny label generics,

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[235] *Id.* at 1359 (Prost, C.J., dissenting).

[236] *See* Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1274 (Fed. Cir. 2004) ("To prevail under a theory of indirect infringement, [the plaintiff] must first prove that the defendants' actions led to direct infringement."); *Grain Processing*, 185 F.3d at 1349 ("To recover lost profits, the patent owner must show 'causation in fact.'").

thereby upending a carefully constructed set of incentives developed by state and federal law and driven by the market. Alternatively, even if courts conduct a proper causation analysis based on the no-insurance counterfactual, precedent from *GlaxoSmithKline* suggests that insurers may find themselves on the hook for grossly inflated damages awards. Either outcome would put the skinny labeling pathway at risk. In contrast, the loss of chance approach provides an avenue for reestablishing the balance envisioned by Hatch-Waxman—at least where skinny labels are concerned.

As described *supra* Part III.B, the potential damages awards for brand-name companies targeting insurers or generic manufacturers would rarely be worth the cost of litigation if courts applied a loss of chance framework. Thus, loss of chance would disincentivize litigation based on dubious theories of inducement that do not account for a significant portion of the infringement that actually occurs. In turn, generic manufacturers would not have to weigh the risks of major *GlaxoSmithKline*-like damages or insurers unwilling to cover their drugs when deciding whether to bring a skinny label generic to market. In the wake of *GlaxoSmithKline*, industry players were rightfully concerned that the case would "have a chilling effect on future generic carveouts and thus thwart cheaper copies until all of a brand's approved indications are off patent" because generic manufacturers simply would not want to face the possibility of such expensive liability.[237] Loss of chance eliminates this problem as applied to both insurers and generic manufacturers. In this way, the proposed framework furthers Congress's original intent that "one patented use [ ] not foreclose marketing a generic drug for other unpatented ones."[238]

Eliminating roadblocks that prevent generic manufacturers from pursuing the skinny labeling pathway in this way is now more important than ever. Experts view the skinny label as an essential (but woefully insufficient) counterweight to a patent regime that increasingly supports anticompetitive and predatory behavior on the part of brand-name companies.[239] In the groundbreaking study

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[237] Beth Snyder Bulik, *GSK, Teva On-Again, Off-Again Lawsuit Is Back On: Will "Skinny Labeling" Get a Reprieve?*, FIERCE PHARMA (Feb. 11, 2021) https://perma.cc/XUU4-GF6H.

[238] *See* Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 414–15 (2012).

[239] *See, e.g.*, Hacohen, *supra* note 18, at 510 (detailing one way that brand-name companies keep skinny label generics off the market); ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET

May Your Drug Prices Be Evergreen, Feldman analyzed all drugs on the market between 2005 and 2015, examining "every instance in which a company added a new patent."[240] The findings "show a startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals" as 78% of drugs associated with new patents were not new at all, but rather existing drugs.[241] The patents related to these drugs typically did not reflect meaningful medical progress, but rather were created to repeatedly "hold off the type of competitive entry that is fundamental to our innovative system."[242] The incidence of such evergreening "steadily increased" between 2005 and 2015.[243] AbbVie, the manufacturer of the blockbuster drug Humira, for example, built a wall of 165 patents and aggressively sued potential rivals, ultimately extending its exclusivity by over a decade to the detriment of patients and taxpayers.[244] The skinny labeling pathway is a critical bulwark against this kind of behavior. The loss of chance approach—as applied to both insurers and generic companies—ensures that generic manufactures will not stop bringing skinny labels to market out of fear that insurers might not cover their drugs or that they could get slammed with massive, disproportionate damages awards.

In the wake of *GlaxoSmithKline*, even President Joe Biden's administration weighed in to support skinny labels, commenting that "we are committed to taking steps as appropriate to ensure" that "the practice of carving out patent-protected indications for generic drugs" "remain[s] available."[245] Ultimately, the loss of chance approach will ensure that pharmaceutical companies cannot use the courts to prevent generic companies from following the skinny labeling pathway—an essential piece of the Hatch-Waxman compromise.

102–05 (2017) (describing a different tactic that brand-name companies use to block skinny labels).

240 Feldman, *supra* note 1, at 590.

241 *See id.* at 597.

242 *Id.* at 596.

243 *Id.* at 617.

244 *See* Rebecca Robins, *How a Drug Company Made $114 Billion by Gaming the U.S. Patent System*, N.Y. TIMES (Jan. 28, 2023), https://www.nytimes.com/2023/01/28/business/humira-abbvie-monopoly.html.

245 XAVIER BECERRA, U.S. DEP'T OF HEALTH & HUM. SERVS., COMPREHENSIVE PLAN FOR ADDRESSING HIGH DRUG PRICES 21 (2021).

CONCLUSION

The skinny labeling pathway is a critical element of the Hatch-Waxman regime, as it allows generic manufacturers to enter the market and drive down prescription drug prices as soon as the first method patent on a brand-name drug expires. In recent years, skinny labels have catalyzed dramatic price reductions for important blockbuster drugs, including imatinib (which treats leukemia) and apriprazole (which treats schizophrenia), allowing consumers to benefit from more affordable medication years before they otherwise would have.[246] Without the skinny labeling pathway, some may never have had access to such lifesaving medication. Yet future litigation based on Amarin's novel legal theory would dramatically alter insurance companies' assessment of the risk in covering skinny labels, which would disincentivize generic manufacturers from pursuing section viii approval.

This Comment concludes that the district court's *Amarin* decision was based on an improper theory of causation that assumed insurance companies have a duty to prevent infringement. It establishes that the proper counterfactual baseline for evaluating inducement claims against insurers—a world in which there is no insurance coverage—reveals that insurance companies are rarely the but-for cause of infringement in the skinny label context. In proposing an application of the loss of chance doctrine to determine liability in future cases, this Comment addresses a key legal error from the majority opinion in *GlaxoSmithKline*: a misapplication of causation principles in damages calculations for induced infringement. Adopting the loss of chance framework in future cases would force courts to conduct often-ignored causation analyses and ensure that findings of inducement correspond with proportionate damages awards. Loss of chance would also fulfill the policy aims of Hatch-Waxman, as loss of chance liability would disincentivize brand-name manufacturers from bringing suits against generics and insurers for massive damages awards that do not correspond to the infringement for which they are responsible.

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[246] *See* Walsh, *supra* note 8.