BEEFING UP SKINNY LABELS: INDUCED INFRINGEMENT AS A QUESTION OF LAW

*Garrett T. Potter**

INTRODUCTION

The cost of pharmaceuticals has a massive influence on the healthcare system. The global pharmaceutical industry had a revenue of $1.27 *trillion* in 2020, with revenue of sales in North America accounting for approximately half of that.[1] This colossal market is seen as a burden to many, and a majority of United States citizens shows unified support for decreasing the price of drugs.[2] Government officials from both Democratic and Republican parties have floated plans to decrease the cost of healthcare by incorporating more use of generic drugs which would serve as competition to brand drug manufacturers that otherwise retain a monopoly on the drug market.[3]

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* Candidate for J.D., Notre Dame Law School, 2023; Ph.D. in Chemistry, The University of Manchester, 2015; B.S. in Biochemistry/Chemistry, University of California San Diego, 2007. I would like to thank Professor Sean B. Seymore for his feedback throughout the many steps of drafting this Note, Professor Jay Tidmarsh for his counterarguments, and my colleagues on *Notre Dame Law Review* for their edits. I would like to especially thank my wife, Marjorie, for the mental breaks and moments of Fika, and for graciously putting up with me going back to school one more time. Enormous thanks to my family for all of their support. All errors are my own.

1 Matej Mikulic, *Global Pharmaceutical Industry—Statistics & Facts*, STATISTA (Sept. 10, 2021), https://www.statista.com/topics/1764/global-pharmaceutical-industry/ [https://perma.cc/T6QP-EGP5]. The generic drug industry itself is a behemoth in the global marketplace, with the market size estimated at $391 billion in 2020, and projected to rise to $575 billion by 2027. *Generic Drugs Market Size to Reach USD 574.63 Billion by 2027*, PRECEDENCE RSCH., https://www.precedenceresearch.com/generic-drugs-market [https://perma.cc/3WQH-WCHG]; *Global Generic Drugs Market Size, Share, Trends, Growth & COVID-19 Impact Analysis Report—Segmented by Type (Pure Generic Drugs, Branded Generic Drugs), Application (Central Nervous System (CNS), Cardiovascular, Dermatology, Oncology, Respiratory, Others), Region—Industry Report (2021 to 2026)*, MKT. DATA FORECAST (Apr. 2021), https://www.marketdataforecast.com/market-reports/global-generic-drugs-market [https://perma.cc/S5KG-KFFJ].

2 Elisabeth Rosenthal, *Public Opinion Is Unified on Lowering Drug Prices. Why Are Leaders Settling for Less?*, KHN (Nov. 18, 2021), https://khn.org/news/article/public-opinion-prescription-drug-prices-democratic-plan/ [https://perma.cc/2VZX-LX47].

3 *Fact Sheet: President Biden Calls on Congress to Lower Prescription Drug Prices*, WHITE HOUSE (Aug 12, 2021), https://www.whitehouse.gov/briefing-room/statements-

Brand manufacturers consistently seek to expand their patent coverage to maintain a monopoly on the market, often with patents covering particular excipient formulations, dosage regimes, administration forms, and methods of treatment.[4] Periodically, a brand manufacturer discovers a new method of treatment using a drug that has already been on the market and seeks patent coverage for that method of treatment.

One way that generic drug manufacturers are able to compete with brand manufacturers is through the use of "skinny labels." Under the Hatch-Waxman Act of 1984, drug 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."[5] This allows the generic manufacturer to produce the drug without directly or indirectly infringing the patented method of treatment. Such skinny labels remove an average of over three years' time from the brand drug manufacturer's monopoly, with high-revenue brand-name drugs being a key target.[6]

The pioneer drug manufacturers, in response, seek other means of enforcing control over their intellectual property. In 2000, SmithKline Beecham argued generic manufacturers should not be able to copy elements of its drug labels because it would be copyright

releases/2021/08/12/fact-sheet-president-biden-calls-on-congress-to-lower-prescription-drug-prices/ [https://perma.cc/WM3F-DM96] ("Alongside other steps, the federal government will be working with states and Tribes to import safe, lower-cost prescription drugs from Canada and accelerating the development and uptake of generic and biosimilar drugs that give patients the same exact clinical benefit but at a fraction of the price."); Natalie Grover, *Republicans Unveil a Drug Price Bill to Rival the Democrats—Promising Lower Prices and More Cures*, ENDPOINTS NEWS (Dec. 10, 2019), https://endpts.com/lower-prices-more-cures-republicans-pitch-a-utopian-drug-price-bill-to-rival-the-democrats/ [https://perma.cc/4VNA-5HGZ] ("Some of the proposals in HR19 also mirror policies advocated by bipartisan legislation currently under consideration in the Senate, including the CREATES act which is designed to ensure generic drugmakers can access branded drugs to develop copycats, and prohibits 'pay-for-delay' deals, where manufacturers of branded drugs maintain their monopolies by offering generic companies rewards for delaying the launch of knockoff products.").

4 Jan Berger, Jeffrey D. Dunn, Margaret M. Johnson, Kurt R. Karst & W. Chad Shear, *How Drug Life-Cycle Management Patent Strategies May Impact Formulary Management*, 22 AM. J. MANAGED CARE (SUPP.) S487, S487 (2016).

5 *See* Terry G. Mahn, *Generics Behaving Badly: Carve Outs, Off-Label Uses*, LAW360 (Mar. 24, 2009), https://www.law360.com/health/articles/93495/generics-behaving-badly-carve-outs-off-label-uses [https://perma.cc/NCM6-KJHA]. *See generally* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 21, 35, and 42 U.S.C.).

6 Bryan S. Walsh, Ameet Sarpatwari, Benjamin N. Rome & Aaron S. Kesselheim, *Frequency of First Generic Drug Approvals with "Skinny Labels" in the United States*, 181 JAMA INTERNAL MED. 995, 995–96 (2021).

infringement.[7] The Second Circuit held that the Hatch-Waxman Act trumps copyright law, and SmithKline Beecham's arguments fell flat.[8] Brand manufacturers have also entered "pay-for-delay" agreements in litigation settlements, essentially paying generic manufacturers to not compete—potential antitrust issues notwithstanding.[9] Pioneer drug manufacturers have also succeeded in arguing that generic manufacturers' labels contribute to indirect infringement of their patents, including induced infringement.[10]

Induced infringement "is often described as activity that 'aids and abets' infringement" of a patent.[11] It requires that the alleged inducer have a specific intent to cause acts that constitute infringement, an affirmative act that induces others to infringe the patent, and that an act of direct infringement of the patent occur.[12] It also requires that the alleged inducer have actual knowledge of the patent and knowledge that its affirmative act to induce others would lead to such direct infringement.[13] The determination of whether each element has been met is currently a question of fact determined in many cases by a jury.[14] This Note will argue that the determination of whether a

7 SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc., 211 F.3d 21, 23–24 (2d Cir. 2000). SmithKline Beecham would later merge with Glaxo Wellcome to form GlaxoSmithKline. Alison Abbott, *Merger of Glaxo Wellcome and SmithKline Beecham Creates Pharmaceutical Giant*, 403 NATURE 232 (2000).

8 *SmithKline Beecham*, 211 F.3d at 28–29 ("Our point here is not only that Congress would have provided explicitly that the Hatch-Waxman Amendments trump the copyright laws had it foreseen the statutory conflict exposed by the present action, although we firmly believe that to be obvious."); *see also id.* ("If copyright law were to prevail, producers of generic drugs will always be delayed in—and quite often prohibited from—marketing the generic product, results at great odds with the purposes of the Hatch-Waxman Amendments.").

9 *See* FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 1 (Jan. 2010).

10 Preston K. Ratliff II, Mi Zhou & Mark Russell Sperling, *Federal Circuit Provides Additional Guidance for Induced Infringement in Hatch-Waxman Cases*, PAUL HASTINGS (Nov. 13, 2017), https://www.paulhastings.com/insights/client-alerts/federal-circuit-provides-additional-guidance-for-induced-infringement-in-hatch-waxman-cases [https://perma.cc/29CR-L6GC].

11 KIMBERLY PACE MOORE, PAUL R. MICHEL & RAPHAEL V. LUPO, PATENT LITIGATION AND STRATEGY 19–24 (1999).

12 *Id.*

13 Commil USA, LLC v. Cisco Sys., Inc., 575 U.S. 632, 640 (2015); Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 765–66 (2011); DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1304 (Fed. Cir. 2006).

14 James A. Johnson, *Induced Patent Infringement*, N.Y. STATE BAR ASS'N (Apr. 7, 2020), https://nysba.org/induced-patent-infringement/ [https://perma.cc/PT7M-253A] ("Moreover, the low threshold of the scienter requirement that can be established by inference and circumstantial evidence creates a fact question for a jury to decide.").

party actually intended to induce another to infringe the patent should instead be a question of law.

The influence of induced infringement on the generic manufacturer landscape and its interactions with skinny labels is best evidenced by the August 5, 2021, Federal Circuit decision of *GlaxoSmithKline v. Teva* (also referred to herein as "*GSK v. Teva*").[15] In that case, the Federal Circuit largely affirmed its October 2, 2020, decision,[16] which held that a jury had ample support to find induced infringement even during periods where Teva had used a skinny label that carved out the allegedly infringed-upon patent.[17] This resulted in an order that Teva pay GlaxoSmithKline $234 million in damages, though Teva only sold $74 million worth of the generic drug.[18] Criticism to this decision was swift, with many commentators indicating it was a death knell to the reliance of generic manufacturers on the safety provided by the practice of skinny labeling.[19] In late 2021, Teva

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

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

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

18 *GSK v. Teva – Induced Infringement Liability Despite Skinny Label*, COOLEY (Oct. 6, 2020), https://www.cooley.com/news/insight/2020/2020-10-06-gsk-v-teva-induced-infringement-liability-despite-skinny-label [https://perma.cc/4BES-FQ4L].

19 Paul A. Braier, GlaxoSmithKline v. Teva*: Federal Circuit Broadens Induced Infringement to Preclude Marketing Generics for Off-Patent Indications*, 17 J. GENERIC MEDS. 97, 98 (2021); 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://www.natlawreview.com/article/wide-ranging-effects-federal-circuit-s-assault-skinny-labels [https://perma.cc/2X8Y-8FZC] ("The U.S. Federal Circuit Court of Appeals recently issued an opinion that effectively strips generic drug manufacturers of the ability to avoid inducement lawsuits through the use of skinny drug labels. The opinion may have a significant negative effect on the generic drug industry because it seemingly creates new liability exposure where none previously existed."); Dani Kass, *GSK Redo Doesn't Cure Generics' 'Skinny Label' Uncertainty*, LAW360 (Aug. 9, 2021), https://www.law360.com/articles/1410679/gsk-redo-doesn-t-cure-generics-skinny-label-uncertainty [https://perma.cc/66Z9-ZQ77] ("Attorneys said it was hard to see what else Teva could have done to comply with the law, and that uncertainty could scare generic-drug makers from bothering with skinny labels. Teva only sold about $74 million of the drug it now owes $235 million for infringing."); Matthew Lane, *Federal Circuit Should Restore Generics 'Skinny Label' Process*, BLOOMBERG L. (Jan. 12, 2021), https://news.bloomberglaw.com/ip-law/federal-circuit-should-restore-generics-skinny-label-process [https://perma.cc/2YCN-JEVV] ("The Federal Circuit's decision in *GlaxoSmithKline v. Teva* undermines this skinny label framework by holding that a generic manufacturer who uses a skinny label can still be liable for induced infringement merely by accurately describing its product as therapeutically equivalent to the branded drug. This equivalency, a requirement for FDA approval of generic medicines, is essential safety information for doctors and pharmacists treating their patients."); Allie Nawrat, *Skinny Labelling of Generics: The Beginning of the End for This Practice?*, PHARM. TECH. (Feb. 15, 2021), https://www.pharmaceutical-technology.com/features/skinny-labelling-generics-lawsuits/ [https://perma.cc/QR6Z-J8RJ] ("The industry is now faced with a 'precedent finding' that even a full carve out of the patented

filed a petition for rehearing en banc before the Federal Circuit arguing the prior decision would "have a 'seismic' impact on the drug industry," but a sharply divided Federal Circuit announced in February 2022 that it would not take up the en banc petition.[20] While GlaxoSmithKline contends that Teva is overly alarmist, Teva announced plans to seek Supreme Court review, and commentators believe a congressional correction or Supreme Court hearing may be forthcoming.[21]

Although the Federal Circuit considered *GSK v. Teva* to be a "narrow, case-specific"[22] decision, it is nonetheless clear that the generic drug manufacturing industry is concerned that this will serve as a basis for similar arguments in the future, and that it will be further broadened outside the scope of that specific case.

A notable concern of *GSK v. Teva* was that a jury found induced infringement to exist where there was little evidence of such, and substantial evidence suggesting the contrary. The district court judge granted a motion for JMOL because the judge felt the evidence failed to support a finding of inducement.[23] Notwithstanding the sparse evidence, the Federal Circuit reversed the motion for JMOL, relying almost entirely on the supremacy of the jury's decision and the categorization of this issue as a question of fact.[24] There is, however, no statutory requirement or instruction from the Supreme Court indicating that the determination of all elements of inducement are actually questions of fact. In patent law, what is considered a question

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use can lead to induced infringement . . . [and] this case gives brand manufacturers a 'roadmap' to challenge generic drugs relying on skinny labelling."); *see also* Dennis Crouch, GSK v. Teva*: Skinny Label Approval Is Not a Patent Safe Harbor*, PATENTLYO (Aug. 5, 2021), https://patentlyo.com/patent/2021/08/skinny-approval-patent.html [https://perma.cc/RC7G-N9Y5].

20 Dani Kass, *Teva Says GSK Skinny Label Win Will Have 'Seismic' Impact*, LAW360 (Oct. 7, 2021), https://www.law360.com/articles/1429343 [https://perma.cc/NXS4-LX25] (discussing Teva's en banc filing); Dani Kass, *Sharply Split Full Fed. Circ. Won't Eye Skinny Label Ruling*, LAW360 (Feb. 11, 2022) [hereinafter Kass, *Sharply Split*], https://www.law360.com/articles/1464381/ [https://perma.cc/RL67-M8YY] (reporting the February 11, 2022, denial).

21 Crouch, *supra* note 19; Susan Decker, Christopher Yasiejko & Ian Lopez, *Glaxo's Win in Case Against Teva Lifts Other Drugmakers*, BLOOMBERG (Aug. 5, 2021), https://www.bloomberg.com/news/articles/2021-08-05/glaxo-wins-revival-of-235-million-case-against-teva-over-coreg [https://perma.cc/XEY2-QCYK]; Britain Eakin, *Full Fed. Circ. Told Teva Overreacting in Skinny Label IP Case*, LAW360 (Dec. 7, 2021), https://www.law360.com/articles/1446435/ [https://perma.cc/EMY5-95S4]; Kass, *Sharply Split*, *supra* note 20 ("'We are disappointed in this decision and plan to . . . seek Supreme Court review of this decision . . . ,' Teva said in a statement Friday.").

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

23 *Id.* at 1325.

24 *Id.* at 1330.

of fact and what is considered a question of law can appear a haphazard mix with no significant substance or reasoning to guide the wayward practitioner.[25]

This Note proposes a novel argument for improving the application of induced infringement by splitting its elements into separate questions of fact and law, incorporating the relevant perception and reasoning of both judge and jury. Part I provides a primer of the Hatch-Waxman Act and interactions (and lack thereof) between the USPTO and FDA in regulating pharmaceutical compositions. Part II assesses the historical landscape that led to the codification of induced infringement. Part III concludes by proposing an alternate approach by treating an element of induced infringement as a question of law, rather than a question of fact, and sets forth the groundwork enabling the courts to consider it as such.

Although it is important that researching companies recoup costs in their endeavors to develop novel pharmaceutical agents and methods of treatment, the finding of induced infringement in *GSK v. Teva* took the application of induced infringement too far. Induced infringement should be found only in those cases where the alleged perpetrator *actually intended* to induce such infringement, which is an understanding more aligned with the fundamentals of patent law and the protection of intellectual property rights. Expanding the theory of induced infringement to cover any generic pharmaceutical that has a new method of treatment will have a chilling effect on the industry, allowing the brand manufacturer to essentially re-monopolize a composition that would otherwise be available to the public.

I. A BRIEF HISTORY OF ANDAS AND SKINNY LABELS

In order to sell a pharmaceutical moiety in the United States, it must be proven effective for its intended use and safe for human consumption.[26] The process of developing a novel pharmaceutical from concept to FDA approval will typically cost over $1 billion over the course of twelve years.[27] There is a remarkably high amount of

25 *See* Paul R. Gugliuzza, *Law, Fact, and Patent Validity*, 106 IOWA L. REV. 607, 609–10 (2021) ("[T]he distinction between law and fact is one of the most perplexing concepts in all of law. Some deride the distinction as a myth, and not unreasonably so. . . . The uncertainty surrounding the law-fact distinction is particularly acute in patent litigation . . . ." (footnote omitted)).

26 *Development & Approval Process: Drugs*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/development-approval-process-drugs [https://perma.cc/ZKF4-D94J] (Oct. 28, 2019).

27 Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 20 (2016) ("The estimated average out-of-pocket cost per approved new compound is $1395 million (2013

failure that comes with drug development, with more than 90% of potential drugs failing at some point during the process—the vast majority meeting failure when issues are found with efficacy or safety—leading to large losses for the unfortunate drug developer that fails to get to market.[28] Pioneer drug developers argue that a strong patent system should ensure that researchers recoup their expenses in bringing a drug to market, as well as money lost in developing drugs that could not make the cut, as total losses in research and development.[29]

The Hatch-Waxman Act of 1984 recognized the importance of pioneer drug manufacturers' research and development, and sought to allow them to recoup such costs. It does so by providing "patent term restoration" to restore up to five years of time lost during the FDA approval process, extending patent coverage of the drug.[30] The Act also balances the interests of generic drug manufacturers by allowing them to enter the drug market so long as their compound does not infringe a brand manufacturer's patent.

In seeking to lower costs of pharmaceuticals by providing less expensive generic products, the Act expedites generic drug approval through the FDA.[31] A generic company can rely on the safety and efficacy information provided by the original manufacturer of the drug by filing an Abbreviated New Drug Application (ANDA), resulting in accelerated FDA approval whereby the drug can be placed on the market as soon as the original patent on the drug expires.[32] Generic

dollars)."); Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs*, 1 JACC: BASIC TO TRANSLATIONAL SCI. 170, 171 (2016) ("[T]he drug development takes on average 12 years from concept to market . . . .").

28 Derek Lowe, *The Latest on Drug Failure and Approval Rates*, SCI. (May 9, 2019), https://www.science.org/content/blog-post/latest-drug-failure-and-approval-rates [https://perma.cc/9BHS-EA6M].

29 *See generally* Marcia Angell & Arnold S. Relman, *Patents, Profits & American Medicine: Conflicts of Interest in the Testing & Marketing of New Drugs*, DÆDALUS, Spring 2002, at 102.

30 Philip S. Johnson, *Hatch Amendment Would Preserve Balanced Incentives for Pharmaceutical Innovation and Drug Affordability*, HEALTH AFFS. BLOG (Nov. 9, 2018), https://www.healthaffairs.org/do/10.1377/hblog20181106.217086/full/ [https://perma.cc/2LUJ-PU7P]; *see* WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RSCH. SERV., R41114, THE HATCH-WAXMAN ACT: A QUARTER CENTURY LATER 1 (2012) ("The Hatch-Waxman Act established several practices intended to facilitate the marketing of generic drugs while permitting brand name companies to recover a portion of their intellectual property rights lost during the pharmaceutical approval process.").

31 SCHACHT & THOMAS, *supra* note 30, at 1; Baker et al., *supra* note 19.

32 SCHACHT & THOMAS, *supra* note 30, at 1; *Abbreviated New Drug Application (ANDA)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda [https://perma.cc/84K5-FYN7] (Nov. 15, 2021); Baker et al., *supra* note 19 ("Instead of proving the drug's safety, the generic manufacturer only needs to prove to the FDA that its product is bioequivalent to the brand-name drug."); *see also* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) (2018).

manufacturers are additionally incentivized to promptly file an ANDA because the first manufacturer to file an ANDA that results in approval is eligible to receive a 180-day period of exclusivity, during which all other generic manufacturers are barred from entering the market, leading to a sizable competitive advantage that continues years following the approval.[33]

If a chemical moiety is no longer under patent, and absent any additional exclusivity period provided by the FDA, then the composition of matter belongs to the public.[34] As described in the Introduction, pharmaceutical companies will frequently extend the life of their patent coverage by including additional patented subject matter beyond the mere drug itself, including formulations and methods of treatment. In some cases a composition has numerous therapeutic uses that have been approved by the FDA, but some of those uses are not covered by a patent. In such instances, a generic manufacturer producing the nonpatented drug for a nonpatented use may not be infringing any patent rights of the brand manufacturer.

The Hatch-Waxman Act provided guidance regarding noninfringing uses. When a pharmaceutical composition is no longer patented and it has unpatented uses approved by the FDA, then an ANDA can be filed by using the brand manufacturer's previously approved drug label as a basis before "carv[ing] out" any patented subject matter.[35] The resulting "skinny labels" have *carved out* methods of treatment covered by any remaining patents, allowing a generic manufacturer to quickly sell a competing product without infringement.[36] Codified in 21 U.S.C. § 355(j)(2)(A)(viii), this

33 *First Generic Drug Approvals*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals [https://perma.cc/L9Q2-ZN53] (Nov. 17, 2021); *First Generic Launch Has Significant First-Mover Advantage over Later Generic Drug Entrants*, DRUGPATENTWATCH, https://www.drugpatentwatch.com/blog/first-generic-launch-has-significant-first-mover-advantage-over-later-generic-drug-entrants/ [https://perma.cc/V7QP-HK46] ("[T]he first generic entrant into a market has an 80% market share advantage over the second entrant, and a 225% market share advantage over the third entrant. Moreover, these advantages last for at least three years.").

34 *See Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity [https://perma.cc/HG73-6SPT] (Feb. 5, 2020).

35 Petition for Rehearing En Banc at viii, GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320 (Fed. Cir. 2021) (No. 18-976, 18-2023); 21 U.S.C. § 355(j)(2)(A)(viii) (2018) ("[I]f with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.").

36 21 U.S.C. § 355(j)(2)(A)(viii) (2018); Abraxis Bioscience, Inc. v. Navinta LLC, 625 F.3d 1359, 1362 (Fed. Cir. 2010) ("As a general rule, the label associated with the generic

practice of generating a skinny label is also known as a "section viii carveout."[37]

The FDA publishes the Orange Book, which serves to identify drugs that have been deemed safe and effective.[38] While the FDA will not approve a generic drug that infringes a patent, the Administration doesn't determine this itself—it relies on the brand manufacturer to register any patents that cover a compound or method of use so that the FDA may incorporate this information into the Orange Book.[39] In turn, generic manufacturers should be able to rely on the Orange Book and can seek FDA approval by notifying the FDA it will not infringe any of the patents listed therein.[40]

The incentives provided by Hatch-Waxman to spur the generic market have been effective. Prior to the Hatch-Waxman Act, only approximately 35% of top-selling drugs would get competition from generic manufacturers once their patents expired; in contrast, nearly all drugs now face competition from generic manufacturers upon patent expiration.[41] In 2019 alone, more than one thousand ANDAs were approved or tentatively approved—107 of which were "[f]irst generic drugs" that would be eligible to receive generic market exclusivity.[42] As of 2018, a full 90% of outpatient prescriptions were for generic versions of drugs, leading to substantial decreases in prescription drug costs within the United States.[43]

Brand drug manufacturers will continue to seek means of ensuring their market dominance in the face of potential generic competitors. One common practice is the "pay-for-delay" strategy of

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version of a drug must be exactly the same as the label of the branded drug approved in the original New Drug Application . . . . One exception to the rule under the Hatch-Waxman Act is if a generic manufacturer makes a 'Section viii Statement,' seeking FDA approval for a use not covered by a method patent listed in the Orange Book, along with a proposed label that 'carves out' the patented method." (citations omitted)).

37 *GlaxoSmithKline LLC*, 7 F.4th at 1327.

38 *Approved Drug Products with Therapeutic Equivalence Evaluations: Orange Book*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book [https://perma.cc/QNZ4-UNT8] (Dec. 10, 2021).

39 ERIN H. WARD, KEVIN J. HICKEY & KEVIN T. RICHARDS, CONG. RSCH. SERV., R46679, DRUG PRICES: THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES 31 (2021).

40 GlaxoSmithKline LLC v. Teva Pharms., 976 F.3d 1347, 1360 (Fed. Cir. 2020) (Prost, J., dissenting).

41 SCHACHT & THOMAS, *supra* note 30, at 5, 15.

42 OFF. OF GENERIC DRUGS, U.S. FOOD & DRUG ADMIN, 2019 ANNUAL REPORT 2.

43 Steven M. Lieberman, Paul B. Ginsburg & Kavita K. Patel, *Balancing Lower U.S. Prescription Drug Prices and Innovation—Part 1*, HEALTH AFFS. BLOG (Nov. 24, 2020), https://www.healthaffairs.org/do/10.1377/hblog20201123.804451/full/ [https://perma.cc/GW4Z-FRJR]; *see also* AM. ACAD. OF ACTUARIES, PRESCRIPTION DRUG SPENDING IN THE U.S. HEALTH CARE SYSTEM: AN ACTUARIAL PERSPECTIVE 6 (2018).

offering patent settlements to generic manufacturers in return for a commitment to not compete with them in the market.[44] As discussed in the Introduction, another common strategy is to sue the generic manufacturer by alleging induced infringement.

II. A PRIMER ON INDUCED INFRINGEMENT AND APPLICATION TO *GLAXOSMITHKLINE V. TEVA*

Part II serves as a primer to induced infringement and analyzes the court's application of this doctrine to *GSK v. Teva*. Section II.A analyzes the historic roots of induced infringement and delves into the evolution of the doctrine as it is applied by the courts today. Section II.B provides a summary of how courts currently apply induced infringement and the elements required for showing the same. Section II.C looks into the decision and reasoning of the court in *GSK v. Teva* and indicates some potential flaws with the current system for determining induced infringement.

A. A Brief History of Indirect Infringement

U.S. law recognizes two general categories of patent infringement: direct infringement and indirect infringement. A patent grants the right to the patent owner to "exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States."[45] If a party makes, uses, offers for sale, sells, or imports the invention within the United States, then they may be liable for *direct* patent infringement.[46] In contrast, if a party conducts any other actions that lead to a third party directly infringing a patent, that initial party may be liable for *indirect* patent infringement, either under the doctrine of contributory infringement or the doctrine of induced infringement.[47]

Induced infringement is a relatively recent development in the field of patent law. To understand the evolution of induced infringement, it is beneficial to look behind the veil of how the broader doctrine of indirect infringement came into being. Historically, the only ground a patent owner could sue under in seeking relief was an action of direct infringement. This changed with the 1871 decision of

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44 *Pay for Delay*, FED. TRADE COMM'N, https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay [https://perma.cc/AWQ7-DDHR].

45 35 U.S.C. § 154 (2018).

46 35 U.S.C. § 271(a) (2018); 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.02 (2012).

47 35 U.S.C. § 271(b)–(c); 5 CHISUM, *supra* note 46, § 17.04; W. Keith Robinson, *Only a Pawn in the Game: Rethinking Induced Patent Infringement*, 32 SANTA CLARA HIGH TECH. L.J. 1, 4 (2015).

Wallace v. Holmes, which is the earliest known case recognizing the tort of indirect infringement.[48] In *Wallace*, the doctrine of indirect infringement was invoked "to protect patent rights from subversion by those who, without directly infringing the patent themselves, engage in acts designed to facilitate infringement by others."[49] Indirect infringement thus provided a common-law "cause of action when more than one party was involved in the infringement of a patent."[50]

It has been recognized that the historical foundations of indirect infringement included an equitable element, since the issue was "an expression both of law and morals."[51] Circuit Judge Lourie—a revered member of the Federal Circuit for over thirty years and having a background in chemistry[52]—delved into the historical aspects of indirect infringement before his appointment to the Federal Circuit, and also found that the foundational matters of indirect infringement should consider an assessment of equity.[53] For over eighty years following the *Wallace* decision, indirect infringement continued as a matter of common law. In 1952, indirect infringement was finally codified in two subcategorizations: induced infringement and contributory infringement.[54] This codification sought to reduce the "[c]onsiderable doubt and confusion as to the scope of" indirect infringement that resulted from "a number of decisions of the courts."[55] In codifying contributory and induced infringement, Congress recognized the moral and equitable aspects of such infringement, and did not indicate that codification would remove

48 Wallace v. Holmes, 29 F. Cas. 74 (1871); RICHARD T. HOLZMANN, INFRINGEMENT OF THE UNITED STATES PATENT RIGHT: A GUIDE FOR EXECUTIVES AND ATTORNEYS 32 (1995) ("In 1871 appeared the first case clearly recognizing that a person can be held to infringe by making or selling an unpatented element for use in a patented combination or process.").

49 Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 188 (1980) (discussing *Wallace*, 29 F. Cas. 74).

50 Robinson, *supra* note 47, at 7.

51 Mercoid Corp. v. Mid-Continent Inv. Co., 320 U.S. 661, 677 (1944) (Frankfurter, J., dissenting).

52 *Judge Alan D. Lourie to Receive the 2020 American Inns of Court Professionalism Award for the Federal Circuit*, BUSINESSWIRE (May 5, 2020), https://www.businesswire.com/news/home/20200505005101/en/Judge-Alan-D.-Lourie-to-Receive-the-2020-American-Inns-of-Court-Professionalism-Award-for-the-Federal-Circuit [https://perma.cc/6MHG-UHEP].

53 Alan D. Lourie, *Contributory and Active Inducement of Infringement in Wake of* Rohm and Haas Company v. Dawson Chemical Company, *in* INFRINGEMENT OF PATENTS 165, 167, 172, 182, 184 (PLI Pats., Copyrights, Trademarks & Literary Property, Course Handbook Ser. No. 132, 1981). Judge Lourie was working as corporate counsel for a large pharmaceutical corporation at the time, providing a practical viewpoint in analyzing induced infringement. *Id.* at 167; *Lourie, Alan David*, FED. JUD. CTR., https://www.fjc.gov/history/judges/lourie-alan-david [https://perma.cc/A46L-TSJV].

54 S. REP. NO. 1979, at 6 (1952).

55 *Id.*

these considerations.[56] Nevertheless, interpretation of the statutes around indirect infringement has resulted in an apparent removal of such equitable considerations (as evidenced by the *GSK v. Teva* decision, relying entirely upon the jury's evaluation of factual matters). This is not to say the interpretation of the statute is clear—indeed, "[e]ven the Supreme Court has acknowledged that the inducement statute is ambiguous."[57]

The 1952 codification of indirect infringement clearly split the grounds of indirect infringement—which "recites in broad terms that one who aids and abets an infringement is likewise an infringer"—and contributory infringement—"which is concerned with the usual situation in which contributory infringement arises" and controls, for example, the sale of components that are a material part of a patented invention.[58] The Federal Circuit has recognized that:

> The legislative history of the Patent Act of 1952 indicates that no substantive change in the scope of what constituted "contributory infringement" was intended by the enactment of § 271. However, the single concept of "contributory infringement" was divided between §§ 271(b) and 271(c) into "active inducement" (a type of direct infringement) and "contributory infringement," respectively.[59]

The statutes concerning indirect infringement have not undergone substantive changes since 1952.[60]

B. Finding Induced Infringement

When a party conducts "activity that 'aids and abets' infringement" of a patent, it is an indication of induced infringement.[61] A showing of induced infringement requires that three elements are met: (i) direct infringement by a third party has occurred; (ii) the inducing party had a specific intent to cause said direct infringement; and (iii) the inducing party does an affirmative act that so induces the third party to infringe.[62] The Supreme Court

56 *Id.*

57 Robinson, *supra* note 47, at 5.

58 S. REP. NO. 1979, at 6; 35 U.S.C. § 271(b) (2018) (the recent codification of induced infringement); *id.* § 271(c) (the recent codification of contributory infringement).

59 Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990) (citations omitted).

60 Patent Act of 1952, Pub. L. No. 82-593, § 271, 66 Stat. 792, 811 (enacting 35 U.S.C. § 271).

61 MOORE ET AL., *supra* note 11, at 19.

62 *Id.*; *see also* Corrected Non-Confidential Joint Appendix Volume I of II at Appx168, GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 976 F.3d 1347 (Fed. Cir. 2020) (No. 18-

recently held that the specific intent parameter further requires the alleged inducer have actual knowledge of the patent and knowledge that its induced act would lead to direct infringement.[63]

With respect to induced infringement, the United States Code states that "[w]hoever actively induces infringement of a patent shall be liable as an infringer."[64] Some logical questions for a practitioner would be: what constitutes active inducement of infringement, and what evidence is required for such a showing?

In generic drug manufacturing cases, the Federal Circuit previously established that, when the brand manufacturer relied on a generic's drug label's instructions along with advertising and marketing to show intent to actively induce infringement, "[t]he question is not just whether [those] instructions describ[e] the infringing mode, . . . but whether the instructions teach an infringing use *such that* we are willing to infer from those instructions an affirmative intent to infringe the patent. *The label must encourage, recommend, or promote infringement.*"[65] With respect to evidence showing such active inducement, the Federal Circuit is "of the opinion that proof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement."[66]

C. Active Inducement in GlaxoSmithKline v. Teva

Tying this understanding of active inducement into the *GSK v. Teva* decision, that court noted that "[e]vidence of active steps taken to encourage direct infringement [sic] such as advertising an infringing use or instructing how to engage in an infringing use, show

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1976, -2023) (jury instructions outlining the requirements for a showing of induced infringement in *GlaxoSmithKline v. Teva*).

63 Commil USA, LLC v. Cisco Sys., 575 U.S. 632, 632 (2015); Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 765–66 (2011). The Federal Circuit has held that inducement requires encouragement of another's infringement, and it's not sufficient to show an alleged inducer only had knowledge of the direct infringer's activities. DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1306 (Fed. Cir. 2006).

64 35 U.S.C. § 271(b) (2018).

65 Eli Lilly & Co. v. Teva Parenteral Meds., Inc. 845 F.3d 1357, 1368 (Fed. Cir. 2017) (alterations in original) (second emphasis added) (citation omitted) (quoting Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp., 785 F.3d 625, 631 (Fed. Cir. 2015)); GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320, 1327 (Fed. Cir. 2021) ("When a plaintiff relies on a drug's label accompanying the marketing of a drug to prove intent, '[t]he label must encourage, recommend, or promote infringement.'" (alteration in original) (quoting *Takeda*, 785 F.3d at 631)); *see also* MOORE ET AL., *supra* note 11, at 19 ("Examples of such active steps include: providing instructions and plans through labels or advertising that enable the buyer to use the product in an infringing manner.").

66 Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990).

an affirmative intent that the product be used to infringe."[67] In the written opinion, however, there was little critical assessment of whether Teva's skinny label instructed a third party how to engage in an infringing use—instead, the court felt it "*must presume the jury* found that Teva" provided "a label that instructed physicians to use it in an infringing manner."[68]

It appears the Federal Circuit is putting the full weight of its decision on the jury members' backs, both holding them up as the ultimate decisionmakers when it comes to the analysis of induced infringement, as well as the scapegoat upon whom any blame shall lie. In finding allegedly "substantial evidence support[ed] that Teva actively induced by marketing a drug with a label encouraging a patented therapeutic use"[69] the court relied on Teva press releases that predated the '000 patent (the patent at issue) and advertising materials which merely noted that Teva's compound was equivalent to GlaxoSmithKline's Coreg (the brand drug at issue).[70] The court also faulted Teva for failing to take down these old press releases once the '000 patent reissued.[71] Equipped with this haphazard assortment of evidence glued together with GlaxoSmithKline's expert witness testimony, the majority feel there is substantial evidence that the jury could have relied upon to find induced infringement.[72]

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67 GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320, 1333–34 (Fed. Cir. 2021) (quoting Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 915 (2005)).

68 *Id.* at 1334 (emphasis added) (describing also that in forming its decision, "[w]e assume, as we must, that the jury found the post-MI LVD use infringes the '000 patent, and that Teva's label contained instructions encouraging prescribing carvedilol in a manner that infringes the '000 patent").

69 *Id.* at 1326 (emphasis omitted). The court stated that the "patented use was on the generic label at all relevant times . . . therefore, Teva failed to carve out all patented indications." *Id.*

70 *Id.* at 1335 (noting as evidence Teva's product catalogs describing the generic tablets as the "therapeutic equivalent" to the brand compound, and citing to "two relevant press releases" located in the Joint Appendix); Corrected Non-Confidential Joint Appendix Volume I of II at Appx6347, GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 976 F.3d 1347 (Fed. Cir. 2020) (No. 18-1976, -2023) (a press release dated 2004 stating the generic tablets "are the AB-rated generic equivalent of GlaxoSmithKline's Coreg® Tablets and are indicated for treatment of heart failure and hypertension"); *id.* at Appx6353 (a press release dated 2007 stating the FDA granted approval of the ANDA to market the generic version "of GlaxoSmithKline's cardiovascular agent Coreg®"); U.S. Patent No. RE40,000 (showing the patent reissued January 8, 2008).

71 *GlaxoSmithKline*, 7 F.4th at 1337.

72 *Id.* at 1337–38.

In her dissent, Circuit Judge[73] Prost recognized the substantial lack of evidence that the jury purportedly relied on. She noted that:

> [GlaxoSmithKline] alleged that, even though Teva's skinny label carved out the very use—indeed, the *only* use—that GSK said was patented, the label showed that Teva intended to encourage an infringing use. GSK also supported its inducement case by pointing to two cursory, pre-patent press releases that announced Teva's drug's approval (or "tentative" approval) and called it the generic equivalent of GSK's brand drug Coreg. The evidence of inducement—i.e., that Teva had culpable intent to encourage infringement and that its skinny label or press releases caused doctors' prescribing practices—was thin to nonexistent. But a jury found Teva liable all the same. This sometimes happens. And when it does, there is a remedy: a court will reverse a jury's verdict if there is insufficient evidence to support it. The experienced trial judge sensibly did just that.[74]

This split decision is notable in part for the ardency with which Circuit Judge Prost expounds her opinion that the court should not have upheld the jury's verdict due to the lack of substantial evidence. It is clear that both Circuit Judge Prost and District Judge Stark—the judge having the most proximate relationship to the factual information provided to the jury throughout the case—feel there is insufficient evidence for a jury to find induced infringement in this case.[75] There is also a clear concern that this case will lead to follow-along cases in the future, since GlaxoSmithKline may have provided the groundwork for brand manufacturers to pursue induced infringement where there is any combination of a generic skinny label with any vague indication that said generic is equivalent to the brand compound.[76]

In contrast, it appears that Chief Judge Moore and Circuit Judge Newman stand behind the jury, showing hesitance to overturn the jury's decision, but without seeking to reevaluate the weight of the evidence themselves.[77] They also believe the district court judge overreached by reevaluating *de novo* whether Teva's actions actively

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73 Though previously Chief Judge of the Federal Circuit, Circuit Judge Prost vacated the position on May 21, 2021, prior to the rendering of the *GlaxoSmithKline v. Teva* decision. *Id.* at 1323 n.**.

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

75 *Id.*; GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 313 F. Supp. 3d 582, 589–90 (D. Del. 2018).

76 *GlaxoSmithKline*, 7 F.4th at 1359 (Prost J., dissenting) (Judge Prost criticizing "the majority's weakening of intentional encouragement (where describing an infringing use piecemeal—or simply calling a product a 'generic version' or 'generic equivalent'—is now enough)").

77 *Id.* at 1331 (majority opinion) ("The district court erred in reweighing the evidence and finding against GSK following the jury's verdict in its favor.").

induced others to infringe, since the opinion of the court is that this aspect—like all other aspects of induced infringement—is a question of fact.[78]

As discussed further in Part III, there is no requirement that all elements of induced infringement be treated as questions of fact. If a judge is in a better position to evaluate certain aspects of inducement, it can enable a more balanced approach to deciding matters of induced infringement. This would not be the first time the patent litigation landscape has turned a practiced question of fact for the jury into a question of law for the judge's evaluation. Applying this line of thinking to *GSK v. Teva*, it would have been well within the district judge's realm to evaluate the evidence of the generic skinny label and Teva's marketing materials to determine whether Teva had actively induced others to infringe on GlaxoSmithKline's patent.

III. INDUCED INFRINGEMENT AS A MIXED QUESTION OF FACT AND LAW

The *Markman* decision discussed further herein invites the judicial system to consider whether elements of patent law are better evaluated by the court, and also suggests some issues may be split such that some factors are evaluated by the jury and others are evaluated by the court. Part III will argue that the court—not the jury—should decide whether there has been a sufficient showing that the alleged inducer had the requisite intent that the acts it induced would actually lead to direct patent infringement. Section III.A sets forth the groundwork and introduces the argument that determining whether a party had actual intent to induce others to infringe a patent should be a question of law. Section III.B walks through the *Markman* decision and maps a similar analysis to the issue at hand to evidence that the Supreme Court's prior considerations can result in finding that the issue of intent to induce should be a question of law. Section III.C provides a brief summary of the analysis from Section III.B and responds to potential criticisms of this proposal.

A. Induced Infringement's Partial Question of Law

One manner of resolving the issue of wayward juries having a disproportionate impact on decisions of induced infringement would be for the courts to treat portions of inducement as a question of law rather than a question of fact. The notion that controversies in patent

78 *Id.* at 1330 ("Critically, the district court erred by treating this fact question—whether the post-MI LVD indication instructs a physician to prescribe carvedilol for a claimed use—as though it were a legal one for it to decide *de novo*.").

law ought to be treated as a mixed combination of fact and law is not novel,[79] and the concept of taking something that has been treated as a question of fact for juries from their purview and giving it to the courts is not a radical idea.[80] While patent infringement is generally a question of fact, there is an underlying question of law. For example, where "there is no dispute as to the evidentiary facts . . . the question of infringement resolves itself into one of law," depending on comparisons between the patent claims, the accused device, and the application of the rule of equivalency.[81] Where "facts are not in dispute, infringement becomes a matter of law."[82]

This is not to say that the jury ought not be involved in deciding questions of induced infringement. It is not doubted that to determine whether infringement occurred is a question of fact that should be resolved by a jury,[83] nor is it contested that, with induced infringement specifically, there are factual issues that should be considered by the factfinder. There exist, however, certain aspects within the determination of induced infringement that are best resolved by the court, and in patent law there is a long history of mixing questions of law and questions of fact.[84] Elements of induced infringement may be treated akin to obviousness in patent law, which is a question of law with a consideration of underlying factual bases.[85]

Because Congress has failed to provide clear guidance with respect to the manner in which induced infringement is determined, it is well within the Court's power to provide the boundaries.[86] Taking any one element for determining induced infringement away from the jury and giving it to the court would result in a more balanced inquiry and uniform results, incorporating the default reverence given to the jury while also considering the insights from the experienced and knowledgeable court. The next logical step is evaluating whether any

79 Gugliuzza, *supra* note 25, at 607.

80 *See* Markman v. Westview Instruments, Inc., 517 U.S. 370, 388 (1996).

81 Kemart Corp. v. Printing Arts Rsch. Lab'ys, Inc., 201 F.2d 624, 627 (9th Cir. 1953); *see also* Del Francia v. Stanthony Corp., 278 F.2d 745 (9th Cir. 1960); Hansen v. Colliver, 282 F.2d 66 (9th Cir. 1960).

82 Perkin-Elmer Corp. v. Computervision Corp., 680 F.2d 669, 671 (9th Cir. 1982), *aff'd on reh'g*, 732 F.2d 888 (Fed. Cir. 1984).

83 Gugliuzza, *supra* note 25, at 634 ("Under longstanding Supreme Court precedent, infringement is a question of fact for the jury." (citing *Markman*, 517 U.S. at 384)).

84 *See id.* at 607.

85 Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

86 *Markman*, 517 U.S. at 376 (holding "the interpretation of claim terms to be the exclusive province of the court"); Marbury v. Madison, 5 U.S. (1 Cranch) 137, 177 (1803) ("It is emphatically the province and duty of the judicial department to say what the law is.").

of the elements of induced infringement would better be decided by the court rather than the jury.

As discussed in Section II.B, there are three elements to be considered in evaluating whether induced infringement exists: (i) an affirmative act by the alleged inducer that actually causes a direct act of infringement;[87] (ii) a specific intention to induce another party to infringe the patent;[88] and (iii) that the infringement by the other party actually occurs.[89] Currently, a finding of a specific intention to induce another party to infringe a patent requires the alleged inducer have actual knowledge of the patent and knowledge that the induced acts would result in patent infringement.[90] This Note recognizes that the determination of whether a direct act of infringement actually occurred is a question of fact that belongs to the jury.[91] Similarly, it seems the determination of whether the alleged inducer's affirmative act actually caused a direct act of infringement is best determined by the jury weighing evidence provided by the parties.

However, this Note suggests that the question of whether the alleged inducer *intended* and had knowledge that its induced act would lead to infringement has underlying tones of maliciousness, and may best be characterized as an issue that should rightly be determined by the court. It is not sufficient to show that the alleged inducer had

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> [T]he legislative history of § 271(b) indicates that Congress did not intend to impose liability on persons for activities not actually resulting in direct infringement. . . . Since the term "actively induce infringement" is not clearly in derogation of the common law of contributory infringement, this court must conclude that Congress intended this term to cover situations in which actual infringement results from "active inducement."

Hautau v. Kearney & Trecker Corp., 179 F. Supp. 490, 492–93 (E.D. Mich. 1959).

88 Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 760 (2011) ("Although the text of § 271(b) makes no mention of intent, we infer that at least some intent is required. The term 'induce' means '[t]o lead on; to influence; to prevail on; to move by persuasion or influence.' Webster's New International Dictionary 1269 (2d ed. 1945). The addition of the adverb 'actively' suggests that the inducement must involve the taking of affirmative steps to bring about the desired result, see *id.*, at 27. When a person actively induces another to take some action, the inducer obviously knows the action that he or she wishes to bring about.").

89 MOORE ET AL., *supra* note 11, at 19; *see also infra*, Section II.B. Induced infringement under 35 U.S.C. § 271(b) cannot be found unless an act of direct infringement under 35 U.S.C § 271(a) occurs. Limelight Networks, Inc. v. Akamai Techs., Inc., 572 U.S. 915, 917 (2014).

90 *Global-Tech*, 563 U.S. at 765–66.

91 To determine otherwise would be to directly conflict with the Supreme Court's teaching that whether or not infringement has occurred under 35 U.S.C. § 271(a) is the purview of the jury. Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996) ("[W]hether infringement occurred . . . 'is a question of fact, to be submitted to a jury.'" (quoting Winans v. Denmead, 56 U.S. (15 How.) 330, 338 (1854)).

knowledge that some of its users may end up infringing the patent; induced infringement requires *intent* to cause such action.[92] Under this proposed construction, as with the *Markman* decision, the statutory right of trial by jury in patent infringement would still exist—it would still be for the jury to decide whether or not infringement actually occurred,[93] and the jury would decide numerous of the other elements of inducement as well.

With this novel evaluation of induced infringement, one of the more contentious issues of *GSK v. Teva* could be determined by the court and would be a question of law reviewable *de novo*. The judges disagreed as to whether sufficient evidence existed for a jury to find that Teva had knowledge its actions (i.e., providing a skinny label and marketing materials) would actually lead to inducement to infringe GlaxoSmithKline's '000 patent.[94] By accepting this issue as a question of law, decisions of induced infringement would become more equitable and consistent.

B. Basis in Precedent: Markman

The Supreme Court has not yet considered if courts may determine, as a matter of law, whether an alleged inducer intended that its induced act would lead to infringement.[95] However, this would not be the first time the judiciary took an issue that had previously been

92 Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1365 (Fed. Cir. 2003) ("[I]ntent to induce infringement cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent.").

93 5 DONALD R. CHISUM, CHISUM ON PATENTS § 17.04, Lexis (database updated March 2022) ("[T]he Supreme Court confirmed that a person may not 'be liable for inducing infringement of a patent under 35 U.S.C. § 271(b) when no one has directly infringed the patent under § 271(a) or any other statutory provision.'" (quoting *Limelight Networks, Inc.*, 572 U.S. at 917)).

94 GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320, 1339–40 (Fed. Cir. 2021) (Chief Judge Moore and Circuit Judge Newman supporting the per curium decision that there was sufficient evidence of causation to establish inducement); *id.* at 1342 (Prost, J., dissenting) (Circuit Judge Prost arguing "[t]he evidence of inducement—i.e., that Teva had culpable intent to encourage infringement and that its skinny label or press releases caused doctors' prescribing practices—was thin to nonexistent . . . a court will reverse a jury's verdict if there is insufficient evidence to support it."); GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 313 F. Supp. 3d 582, 591 (D. Del. 2018) (District Judge Stark finding "that neither sufficient nor substantial evidence supports the jury's finding of inducement. . . . Without proof of causation, which is an essential element of GSK's action, a finding of inducement cannot stand").

95 *See* Timothy R. Holbrook, *The Supreme Court's Quiet Revolution in Induced Patent Infringement*, 91 NOTRE DAME L. REV. 1007, 1007, 1011–25 (2016) (describing that only four Supreme Court decisions have considered induced infringement—three generally dealing with the mental state of knowingly inducing infringement, and one declining to expand the scope of the statute to include divided infringement).

considered a question of fact to be resolved by juries and gave it to the courts as a question of law. In patent infringement, the interpretation of patent claim terms had for a period of time been the duty of the jury, but this practice was reversed in 1996 when the Supreme Court unanimously held that "judges, not juries, are the better suited to find the acquired meaning of patent terms" in *Markman v. Westview Instruments*.[96] *Markman* invites a similar analysis in other avenues of patent law to determine whether something may better be considered by courts, not juries.

Although there is a right to have a jury consider certain factual questions—as codified in the Seventh Amendment—*Markman* evidences the Supreme Court may characterize issues as questions of law rather than fact.[97] The judicial system has the power to resolve this issue since Congress has not yet provided guidance.[98] This Note concerns only such evaluation of a single element of induced infringement, not the broader catalogue of indirect infringement. That analysis will be left to others who may be interested in such an approach.

In assessing whether elements of an alleged inducer's intent can be analyzed as a question of law, this Note proposes evaluating the matter in much the same manner that the Court did in *Markman*. Subsection III.B.1 evaluates the Seventh Amendment right to a jury trial, the "historical test" for determining whether such right exists for a given matter, and the Court's analysis in finding that a jury trial was not necessary in questions of claim construction. Subsection III.B.2 mimics the evaluation of *Markman* by reviewing the application of the historical test to the issue at hand. Subsection III.B.3 evaluates additional factors described by the *Markman* decision in evaluating whether an issue is a question of fact or a question of law.

1. The "Historical Test" and *Markman*'s Evaluation

The Seventh Amendment encapsulates the constitutional right to a jury in certain civil cases.[99] The Supreme Court has recognized that,

96 517 U.S. 370, 388 (1996).

97 U.S. CONST. amend. VII ("In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.").

98 "It is emphatically the province and duty of the judicial department to say what the law is." Marbury v. Madison, 5 U.S. (1 Cranch) 137, 177 (1803).

99 U.S. CONST. amend. VII ("In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.").

"[s]ince Justice Story's day" in the early 1800s, the Court has "understood that '[t]he right of trial by jury thus preserved [by the Seventh Amendment] is *the right which existed* under the English common law *when the Amendment was adopted*.'"[100] Where such right to a jury trial did not exist under English common law when the Seventh Amendment was ratified in 1791, there is no constitutional requirement that a jury hear the issue:

> Omission of provision for a jury has been upheld . . . on the ground that the suit in question was not a suit at common law within the meaning of the Amendment, or that the issues raised were not particularly legal in nature. Where there is no direct historical antecedent dating to the amendment's adoption, the court may also consider whether existing precedent and the sound administration of justice favor resolution by judges or juries.[101]

Determining whether such jury right exists is called the "historical test."[102] To apply the "historical test," the Court first determines whether the cause of action was directly or analogously tried at law at the time of the passage of the Seventh Amendment, then the Court evaluates "whether a particular issue occurring within a jury trial . . . is itself *necessarily* a jury issue, the guarantee being *essential* to preserve the right to a jury's resolution of the ultimate dispute."[103]

With regard to the first step of the historical test, *Markman* recognized that the broader issue—patent infringement—was a matter to be tried before a jury at the time the Seventh Amendment was adopted.[104] However, in looking to the second step of the historical test, the *Markman* Court noted that "when, as here, *the old practice provides no clear answer* . . . we are forced to make a judgment about the scope of the Seventh Amendment guarantee without the benefit of any foolproof test."[105] When past practice does not provide an obvious answer, the Court must consider whether a jury trial is fundamental to preserve a common-law right for that particular issue by looking at historical context.[106] In *Markman*, the Court—after evaluating the

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100 *Markman*, 517 U.S. at 376 (second alteration in original) (emphasis added) (quoting Balt. & Carolina Line, Inc. v. Redman, 295 U.S. 654, 657 (1935)).

101 *Amdt7.1.2.1 Identifying Cases Requiring a Jury Trial*, CONST. ANNOTATED (footnote omitted), https://constitution.congress.gov/browse/essay/amdt7_1_2_1/ [https://perma.cc/P5RD-2HPG].

102 *Markman*, 517 U.S. at 376 (citing Charles W. Wolfram, *The Constitutional History of the Seventh Amendment*, 57 MINN. L. REV. 639, 640–43 (1973)).

103 *Id.* at 376–77 (emphasis added).

104 *Id.* at 377 ("[T]here is no dispute that infringement cases today must be tried to a jury, as their predecessors were more than two centuries ago.").

105 *Id.* (emphasis added).

106 *Id.* at 377–78 ("[T]he answer to the second question 'must depend on whether the jury must shoulder this responsibility as *necessary to preserve the "substance of the common-law*

practice of courts at the time the Seventh Amendment was adopted—held that "evidence of common-law practice at the time of the framing does not entail application of the Seventh Amendment's jury guarantee to the construction of the claim" and thereafter evaluated other parameters.[107]

This is not to say that there was no historical evidence that juries were somehow involved in claim construction—to the contrary, there are historical documents that suggest juries had some say in claim construction arguments in some circumstances. What the *Markman* decision highlights, however, is that where the past participation of jury involvement is confusing or haphazard, *the historical test is not dispositive.*[108]

The lack of clear historical precedent is a particular issue with matters involving patent litigation. The *Markman* Court noted:

> Although by 1791 more than a century had passed since the enactment of the Statute of Monopolies, which provided that the validity of any monopoly should be determined in accordance with the common law, *patent litigation had remained within the jurisdiction of the Privy Council* until 1752 and hence *without the option of a jury trial.* Indeed, the state of patent law in the common-law courts before 1800 led one historian to observe that "the reported cases are destitute of any decision of importance. . . . At the end of the eighteenth century, therefore, the Common Law Judges were left to pick up the threads of the principles of law without the aid of recent and reliable precedents." Earlier writers expressed similar discouragement at patent law's amorphous character, and, as late as the 1830's, English commentators were irked by enduring confusion in the field.[109]

Overall, the *Markman* Court found that there was a lack of evidence of jury involvement in claim construction predating the Seventh Amendment.[110] Where there is a lack of historical clarity, "the

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right of trial by jury." Only those incidents which are regarded as fundamental, as inherent in and of the essence of the system of trial by jury, are placed beyond the reach of the legislature.'" (citations omitted) (quoting Tull v. United States, 481 U.S. 412, 426 (1987)).

107 *Id.* at 384.

108 *Id.* at 388 ("Where history and precedent provide no clear answers, functional considerations also play their part in the choice between judge and jury to define terms of art."); *id.* at 380 ("Few of the case reports even touch upon the proper interpretation of disputed terms in the specifications at issue and none demonstrates that the definition of such a term was determined by the jury. This absence of an established practice should not surprise us, given the primitive state of jury patent practice at the end of the 18th century, when juries were still new to the field." (footnote omitted) (citations omitted)).

109 *Id.* at 380–81 (emphasis added) (footnote omitted) (citations omitted) (quoting E. Wyndham Hulme, *On the Consideration of the Patent Grant, Past and Present*, 13 L. Q. REV. 313, 318 (1897)).

110 *Id.* at 384.

fact/law distinction at times has turned on a determination that, as a matter of the sound administration of justice, one judicial actor is better positioned than another to decide the issue in question."[111] Finding that neither history nor precedent provided a clear answer, the *Markman* Court relied on its assessment of the interpretive skills of both judge and jury and the policies that would be furthered by allocating the responsibility, ultimately recognizing that, for claim construction, "judges, not juries, are the better suited to find the acquired meaning of patent terms."[112]

The fact that the construction of claims may require a consideration of factual evidence, such as expert witness testimony, did not dissuade the Court from its decision—the Court felt a judge is in a better position to consider the patent document and construe the claims.[113] Finally, as a matter of practical considerations, the Court found it desirable to ensure uniformity in the interpretation of claims and application of judgments.[114]

2. The Historical Test and Precedent, as Applied to Induced Infringement

An application of the *Markman* methodology to the matter of induced infringement suggests that the judge, not the jury, is in a better position to decide whether an alleged inducer intended that its induced act would lead to infringement. As with *Markman*, the first step in evaluating this issue should be a consideration of the historical test.[115]

As noted in subsection III.B.1, applying the historical test begins by determining whether the broader cause of action was directly or analogously tried at law in 1791.[116] In induced infringement, as with *Markman*'s claim construction, the cause of action is patent infringement, and "there is no dispute that infringement cases today must be tried to a jury, as their predecessors were more than two centuries ago."[117] Thus the overall conclusion of whether infringement exists should be tried before a jury.

Having reached a similar conclusion as the *Markman* Court here, the "conclusion raises the second question, whether a particular issue occurring within a jury trial . . . is itself *necessarily* a jury issue, the

111 Miller v. Fenton, 474 U.S. 104, 114 (1985).

112 *Markman*, 517 U.S. at 384, 388.

113 *Id.* at 389–90.

114 *Id.* at 390–91.

115 *Id.* at 376 (citing Charles W. Wolfram, *The Constitutional History of the Seventh Amendment*, 57 MINN. L. REV. 639, 640–43 (1973)).

116 *See id.* at 376.

117 *Id.* at 377.

guarantee being *essential* to preserve the right to a jury's resolution of the ultimate dispute."[118] As discussed in Section II.A, there was no established historical practice, when the Seventh Amendment was ratified, that the analysis of inducement was "a guaranteed jury issue."[119] This finding is unsurprising considering "the primitive state of jury patent practice at the end of the 18th century, when juries were still new to the field,"[120] and is compounded by the fact that the first recognized case of indirect infringement was decided in 1871—a full eighty years after the Seventh Amendment was ratified. Accordingly, common-law practice at the time the Seventh Amendment was ratified didn't require the interpretation of inducement by a jury, nor is there any indication of a jury's involvement with an equivalent analysis.

Turning to the more relatively recent precedent, the first decision concerning indirect infringement—*Wallace v. Holmes*—is enlightening. There, Circuit Judge Woodruff unilaterally determined that where a party has acted with "the express purpose of assisting, and making profit by assisting, in a gross infringement of the complainants' patent" while not technically infringing themselves, they will nevertheless be held liable for such infringement.[121] The decision does not mention any consideration of a jury, and Judge Woodruff consistently relies upon his personal ascertainment of the situation.[122] Thus the first known case concerning indirect infringement did not involve a jury, indicating this was not "a guaranteed jury issue."[123] Akin to *Markman*, here, when the first actual practice of indirect infringement analysis was brought about, it was the judge that analyzed the action.[124]

As with *Markman*, application of the historical test and looking to precedent do not clearly guarantee that the jury should determine whether an alleged inducer intended other parties to infringe the patent. There is no suggestion that juries had the responsibility during the 18th century of analyzing inducement of infringement, and the first example of any indirect infringement was assessed unilaterally by the judge, not a jury. Therefore here, "common-law practice at the

118 *Id.* (emphasis added).

119 *Id.* at 380; *see supra* Section II.A.

120 *Markman*, 517 U.S. at 380.

121 Wallace v. Holmes, 29 F. Cas. 74, 79–80 (D. Conn. 1871).

122 *Id.* at 78–80. Judge Woodruff invokes his personal opinion six times, such as noting that it is "in my judgment" that "defendants have no protection . . . against the charge of infringement" and "I apprehend, that . . . the want of all the parties would be no defence. Each is liable for all the damages." *Id.*

123 *Markman*, 517 U.S. at 380.

124 *Id.* at 382 (placing importance on the fact that cases that "first reveal[ed] actual practice" of claim construction evidenced it was "the judge construing the patent").

time of the framing does not entail application of the Seventh Amendment's jury guarantee to the" analysis of inducement.[125]

3. Additional Factors, as Applied to Induced Infringement

The *Markman* Court, finding no evidence of a jury guarantee from the historic test and precedents turned to the consideration of "the relative interpretive skills of judges and juries and the statutory policies that ought to be furthered by the allocation" to evaluate whether claim construction was to be determined by the judge or the jury.[126] This Note follows suit, and turns to functional considerations.

The question of whether one party *intended* to induce another party to infringe a patent is an equitable issue. It has historically been recognized that patent suits are an issue of equity as well as law.[127] Specifically, the historical foundations of indirect infringement considered it to be an issue that was "an expression both of law and morals."[128] Past patent litigation practice provided that patent owners who sought to sue in equity for the collection of both damages and an injunction would not have a right to a jury trial, thus it was the judge's purview to render decisions concerning equitable matters.[129] It wasn't until 1938 that questions concerning equity and law merged, enabling patent owners seeking damages for infringement to bring their cases before a jury.[130]

Where there is an equitable issue, it should be determined by the judge rather than the jury, even if there are underlying issues concerning fact.[131] Though the power of traditional equity has

125 *Id.* at 384.

126 *Id.*; *see also id.* at 388 ("Where history and precedent provide no clear answers, functional considerations also play their part in the choice between judge and jury . . . ."); Miller v. Fenton, 474 U.S. 104, 114 (1985) (noting that where there is a lack of historical clarity, "the fact/law distinction at times has turned on a determination that, as a matter of the sound administration of justice, one judicial actor is better positioned than another to decide the issue in question").

127 Patent Act of 1836, ch. 357, § 17, 5 Stat. 117, 124.

128 Mercoid Corp. v. Mid-Continent Inv. Co., 320 U.S. 661, 677 (1944) (Frankfurter, J., dissenting); Lourie, *supra* note 53, at 167, 172, 182, 184.

129 *See* Gugliuzza, *supra* note 25, at 616.

130 *Id.* at 617.

131 *See* Philippe Signore, *On the Role of Juries in Patent Litigation (*Part 1*)*, 83 J. PAT. & TRADEMARK OFF. SOC'Y 791, 797 (2001):

> Certain questions of fact are part of an overall issue that is deemed to be "equitable in nature." An example of such an equitable issue is whether the patentee committed inequitable conduct in front of the USPTO. This issue involves questions of fact, such as whether the patentee intended to deceive the USPTO, that would appear to be triable by a jury. The factual questions underlying inequitable conduct, however, are sometimes reserved for the judge *because of the equitable nature of the overall issue.*

decreased over time,[132] the federal courts nonetheless ought to exercise equitable power in certain cases to achieve better justice. The court is also better equipped to resolve ambiguities arising from piecing together aspects of evidence. It is the court who can find an explanation to "ambiguities arising from the description of external things, by evidence *in pais*" rather than the jury, by virtue of the court's "peculiar knowledge and education to understand them."[133] A judge presented with the evidence of both sides is better prepared than a jury to balance the issues and consider whether an alleged inducer actually *intended* that others infringe a patent, due to the training and experience required for the position.

Additionally, the statutory policies advanced by providing the judge with the power to make this determination are similar to those advanced by the *Markman* Court. In *Markman*, the emphasized policy matter was "the importance of uniformity in the treatment of a given patent."[134] Such uniformity is also valuable with the issue of inducement. When it is determined that intent to induce is not found in a case between a patent owner and one alleged inducer, a second case between the patent owner and a second alleged inducer should likely reach the same conclusion if the facts are sufficiently similar. A lack of uniformity results in more costly litigation and attempts to sway a jury's opinion concerning an aspect that should be an equitable issue for the judge to decide.

Therefore, when considering the advancement of policies and which member of the court is better equipped to determine the issue of intent with respect to induced infringement, it is the judge—not the jury—that ought to resolve this matter.

C. Intent to Induce Infringement: A Question of Law

The question of whether an alleged inducer actually *intended* to induce a third party to directly infringe a patent should be a question of law, determined by the judge rather than the jury. In treating the analysis of this issue in much the same way as the Court did in *Markman*, it is clear that there is no historical requirement or precedent guaranteeing that a jury need consider this element of

Id. (emphasis added) (footnote omitted).

132 *See* Andrew Kull, *Equity's Atrophy*, 97 NOTRE DAME L. REV. (forthcoming May 2022) ("[Traditional equity] was the power to modify and correct applicable *legal* rules, suitable as the first-order resolution of the general run of cases, so as to do better justice between particular parties in particular circumstances."). *See generally* Symposium, *The Nature of the Federal Equity Power*, 97 NOTRE DAME L. REV. (forthcoming May 2022) (discussing equity powers in the federal court system).

133 Bischoff v. Wethered, 76 U.S. (9 Wall.) 812, 815 (1869).

134 Markman v. Westview Instruments, Inc., 517 U.S. 370, 390–91 (1996).

inducement. Because indirect infringement is an equitable issue with an underlying moral analysis, and because allowing the more experienced judge to ascertain this matter will lead to more uniformity in patent litigation, the issue is best resolved by the court.

Some may contend that to remove a consideration from the jury and give it to the court is a high hurdle, and that a court cannot consider aspects that belong to said jury.[135] However, where it is at least disputed whether the Seventh Amendment would provide a guarantee of a jury trial to decide the issue, the judicial system ought to deliberate whether a judge may be in a better position to resolve it. From the above analysis, this Note recommends that the judiciary consider the merits of allowing a judge—rather than a jury—to decide whether an allegedly inducing party *intended* to induce another party to infringe a patent. This is not to say that the jury would be removed altogether. Indeed, the jury would still have the ultimate say of whether infringement of the patent had actually occurred, preserving the role that is traditionally reserved for the jury. This approach would simply give the judge a means of providing a viewpoint directed to equity within the specific issue of intent to induce.

Certain commentators are concerned that judges already wield too much power and that their influence should be reined in.[136] However, the decision of *GSK v. Teva* clearly shows it is the jury that currently has all the power with respect to determining induced infringement. This proposal—having the judge, rather than the jury, decide the issue of intent to induce—results in a sharing of power between the bodies. The jury continues to provide its insights with regard to factual matters while the judge resolves the equitable, moral, and legal issues; thus the judges are not being given too much power. This is, instead, a manner of balancing what is currently an imbalanced system.

Overall, the question of whether a party intended to induce infringement of a patent should be determined by a judge. The evolving understanding of patent law enables this consideration, and a judge's viewpoint would be beneficial to the determination of induced infringement. This would result in a more balanced inquiry with equitable and uniform results, allowing for the court to provide its insights from the experienced and knowledgeable judge. Ultimately, this approach would lead to the sound administration of justice.

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135 *See* Parsons v. Bedford, 28 U.S. (3 Pet.) 433, 446 (1830).

136 *See* Gene Quinn, *It May Be Time to Abolish the Federal Circuit*, IPWATCHDOG (July 9, 2019), https://www.ipwatchdog.com/2019/07/09/may-time-abolish-federal-circuit/id=111122/ [https://perma.cc/JVP5-J8X8].

CONCLUSION

This Note contends that within the overall analysis of induced infringement, a judge, rather than a jury, should decide as a matter of law whether an alleged inducer intended to cause others to infringe a patent. The *Markman* decision invites such reconsideration of elements within patent law, and the analysis conducted within that decision is informative with respect to induced infringement. Here, the historical test and precedent do not evidence any guarantee under the Seventh Amendment for a jury to consider the aspect of intent within induced infringement. Because indirect infringement is an equitable issue that judges—rather than juries—are better suited to decide, and since overall policies would be better served by enabling judges to do so, the determination of whether a party *actually intended* to induce infringement should be treated as a question of law.

This will reintroduce an element of equity and fairness into the considerations of looking at induced infringement, and will serve as a buffer to prevent brand manufacturers from tying together tenuous connections suggesting that generic manufacturers intended to induce others to infringe on their patents. By requiring a stronger case be brought against generic drug manufacturers, the application of skinny labels may be strengthened, decreasing the concerns raised by many following the decision of *GlaxoSmithKline v. Teva*.[137]

Would this proposal have any effect on the case of *GSK v. Teva*? Perhaps. In Circuit Judge Prost's dissent, she noted that "[t]he evidence of inducement—i.e., that Teva had *culpable intent to encourage infringement* and that its skinny label or press releases caused doctors' prescribing practices—was thin to nonexistent."[138] It seems that, at least in her opinion, there was not a sufficient showing of equitable intent. The opinions of Chief Judge Moore and Judge Newman are less discernable, but the majority opinion's reliance on the supremacy of the jury, rather than a reconsideration of the evidence, indicates that it's at least plausible the court would have come to a different conclusion if they had reviewed intent as a question of law.

While it is important that brand manufacturers are able to protect intellectual property rights to new methods of treatment, this should not come at the cost of suppressing generics from entering the drug market. The decision of *GSK v. Teva* could have a chilling effect on the important generic market if the issues discussed in this Note are not resolved.

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137 *See supra* note 19.

138 Glaxosmithkline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320, 1342 (Fed. Cir. 2021) (Prost, J., dissenting) (emphasis added).