Appeal Nos. 2018-1976, 2018-2023

In the
United States Court of Appeals
for the Federal Circuit

GLAXOSMITHKLINE LLC, SMITHKLINE BEECHAM (CORK) LIMITED,

Plaintiffs – Appellants,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant – Cross-Appellant.

Appeal from the United States District Court
for the District of Delaware in Case No. 1:14-cv-00878-LPS-CJB,
Chief District Judge Leonard P. Stark.

**BRIEF OF *AMICUS CURIAE* APOTEX INC.
IN SUPPORT OF DEFENDANT – CROSS-APPELLANT'S PETITION FOR REHEARING EN BANC**

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 18-1976, 18-2023

Short Case Caption GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.

Filing Party/Entity Apotex Inc. (amicus curiae)

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I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

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Signature: /s/Andrew M. Alul

Name: Andrew M. Alul

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2).	3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Apotex Inc.		Apotex Pharmaceutical Holdings Inc.

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

TABLE OF ABBREVIATIONS

’000 patent	U.S. Patent No. RE40,000 (Appx31-45)
ANDA	Abbreviated New Drug Application pursuant to 21 U.S.C. § 355(j)
Apotex	*Amicus curiae* Apotex Inc.
Appx	Joint Appendix
CHF	Congestive heart failure
FDA	U.S. Food and Drug Administration
GSK	Plaintiffs-Appellants GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited
Hatch-Waxman or the Hatch-Waxman Act	Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at, *inter alia*, 21 U.S.C. § 355), as amended by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003)
Dr. McCullough	GSK’s expert, Dr. Peter McCullough
Section viii statement	Statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii)
Skinny label phase	Teva’s commercial marketing of its carvedilol ANDA product without the CHF indication in its generic label (September 2007 - April 2011 (Appx6-7))
Teva	Defendant-Cross-Appellant Teva Pharmaceuticals USA, Inc.

INTEREST OF THE *AMICUS CURIAE*

Amicus curiae Apotex Inc. ("Apotex")[1] is a global generic drug company that frequently files ANDAs seeking approval from the FDA to market its drugs, and frequently "carves out" from its drug labels indications covered by patents that Apotex is not seeking FDA approval for, and submits with its ANDAs Section viii statements for those patents. In the last fifteen (15) years, Apotex has filed approximately thirty-nine (39) ANDAs with carve outs and Section viii statements, with approximately a dozen of those currently pending. Annually, Apotex is engaged in dozens of patent lawsuits under the Hatch-Waxman Act.

Apotex has a significant interest in issues central to Teva's October 7, 2021 Petition for Rehearing En Banc (ECF No. 195). Years of jurisprudence from the Supreme Court and this Court have made clear that liability for induced infringement of a method patent under 35 U.S.C. § 271(b) requires an accused infringer to "encourage[], recommend[], or promote[]" the claimed method. *Grunenthal GmbH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1339 (Fed. Cir. 2019) (citing *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015)).

[1] Pursuant to Fed. R. App. P. 29(b)(3) and Federal Circuit Rule 35(g), Apotex files contemporaneously herewith its unopposed motion for leave to file this *amicus* brief. No counsel for any party authored this brief in any part, and no party, counsel, or person other than Apotex and its counsel contributed money to fund the preparation and submission of this brief. FED. R. APP. P. 29(a)(4)(E).

Moreover, Congress intended for generic drug manufacturers to avoid infringement liability for method patents that claim uses the generic is not seeking FDA approval for. 21 U.S.C. § 355(j)(2)(A)(viii); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012).

As explained below, the panel majority's rehearing decision in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021) ("*GSK II*") conflicts with years of precedent by finding substantial evidence that Teva induced infringement of the '000 patent during the skinny label phase of Teva's commercial marketing of its carvedilol ANDA product (September 2007 - April 2011 (Appx6-7)[2]). When objectively assessed in accordance with this Court's inducement precedent, the evidence the panel majority relied on did not rise to the level of legally cognizable proof of inducement, throwing into disarray this Court's inducement jurisprudence. Furthermore, when assessing Teva's intent to induce, the panel majority disregarded the Hatch-Waxman Act's statutory and regulatory structure by refusing to take into consideration what GSK told FDA in a sworn declaration about what the '000 patent claims covered in the brand label (*see* 21 C.F.R. § 314.53(c)(2)(O))—which did not include the post-MI LVD indication that GSK claims satisfies the congestive heart failure limitation of the '000 patent claims,

[2] All "Appx__" citations are to 18-1976 ECF Nos. 88-1 and 88-2, Corrected Non-Confidential Joint Appendix Volume Nos. I and II.

GSK II, 7 F.4th at 1331—rendering the carve out statute (21 U.S.C. § 355(j)(2)(A)(viii)) nearly impossible to comply with.

The ramifications for the generic drug industry and consumers are enormous—many generic drug companies, like Apotex, will now forgo filing ANDAs for off-patent drugs that carve out patented indications and only seek approval for off-patent uses. This is simply not what Congress intended, *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1359-62 (Fed. Cir. 2003), and will drastically undercut the goal of Hatch-Waxman: "to speed the introduction of low-cost generic drugs to market." *Caraco*, 132 S. Ct. at 1676. Generic drug manufacturers like Apotex who routinely file ANDAs and carve out patented uses from their drug labels need this full Court to rehear this case and to restore this Court's longstanding inducement jurisprudence, which *GSK II* simply cannot be reconciled with.

ARGUMENT

I. *GSK II* IS IN DIRECT CONFLICT WITH PATENT INDUCEMENT CASE LAW AND HATCH-WAXMAN

A. The Panel Majority's Opinion Unsettles Years of Inducement Precedent

Apotex respectfully submits that the panel majority's finding of substantial evidence supporting the jury's inducement verdict during the skinny label phase is simply irreconcilable with this Court's decisions in at least *Takeda*, *Grunenthal*, and *HZNP Meds. LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680 (Fed. Cir. 2019). "To

prove inducement, a plaintiff must present evidence of active steps taken to encourage direct infringement; mere knowledge about a product's characteristics or that it may be put to infringing uses is not enough." *HZNP*, 940 F.3d at 701 (citing *Takeda*, 785 F.3d at 630-31). GSK failed to do this, but the panel majority nonetheless found substantial evidence based on Teva's label and certain Teva marketing materials, product catalogs, and press releases.

With respect to the Teva's label, the panel majority went beyond the Indications and Usage section—the portion of the label that actually instructs physicians on the approved uses for the drug, *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1323-1324 (Fed. Cir. 2012)—to find substantial evidence of inducement based on an expert's testimony that disparate portions of the label "showed" or "met" certain claim elements. *GSK II*, 7 F.4th at 1328-1330. Although no expert actually testified that Teva's label encouraged, recommended, or promoted infringement, the panel majority relied on testimony from GSK's expert (Dr. McCullough) to recast these disjointed references to certain claim elements in Teva's label as encouragement, recommendation, or promotion of the claimed methods. *GSK II*, 7 F.4th at 1329. This was improper: underlying this Court's decisions in *Bayer*, *Takeda*, and *HZNP* is a recognition that courts should undertake an objective inquiry into whether the generic's label actually encourages, recommends, or promotes infringement as a matter of law.

For instance, in *Takeda*, this Court held that "speculation about how physicians may act" concerning "vague label language" is insufficient to support a finding of inducement as a matter of law. *Takeda*, 785 F.3d at 632-33. As this Court explained, "[t]his would seem to too easily transform that which we have held is 'legally irrelevant,' *Warner-Lambert*, 316 F.3d at 1364—mere knowledge of infringing uses—into induced infringement." *Id*. at 632. In *Bayer*, this Court expressly rejected expert testimony suggesting that statements in the generic's label established that the drug was FDA-approved to induce two therapeutic effects beyond contraception, when an objective reading of the label by the Court made clear that the drug was only approved for contraception. *Bayer*, 676 F.3d at 1325-1326 (rejecting expert testimony contrary to the label). In *HZNP*, this Court rejected the patent owner's reliance on expert testimony to create disputed material fact issues precluding summary judgment of no inducement, because the face of the label indisputably revealed no encouragement, recommendation, or promotion of the claimed methods. *HZNP*, 940 F.3d at 702. The line between description and encouragement is a legal distinction that the Court has always maintained (*Takeda*, *HZNP*), but *GSK II* now calls that legal distinction into question by contradicting this Court's inducement precedent.

Brand drug companies like GSK will ***always*** be able to find experts who read generic labels the way they want them to—this Court implicitly recognized that in

cases such as *Bayer*, *Takeda*, and *HZNP*. To avoid transforming what is "legally irrelevant"—mere knowledge of infringement—into inducement liability, this Court has sanctioned courts to take an objective review of the documentary evidence a brand relies on to prove inducement. If the face of the generic's label (and any other documents the brand relies on) fails to turn up actual evidence of encouragement, recommendation, or promotion of the claimed methods, then the brand's inducement claim cannot lie, irrespective of what its experts might say, and the generic is entitled to dismissal or judgment as a matter of law. *Takeda*, 785 F.3d at 632-33; *HZNP*, 940 F.3d at 702. The panel majority in *GSK II* did not follow this precedent, and has, as a result, thrown inducement law in the Hatch-Waxman context into disarray.

Finally, none of the other documentary evidence the panel majority relied on to find substantial evidence even mentioned, let alone encouraged, recommended, or promoted, the claimed methods: there is no mention in any of these documents of decreasing mortality or the actual claimed method (co-administration plus dosing). *GSK II*, 7 F.4th at 1335-36. The panel majority's rehearing opinion simply cannot be reconciled with this Court's previously well-settled inducement case law requiring that a generic company actually encourage, promote, or recommend the claimed methods in order to be liable for inducement. Rehearing is warranted to restore this Court's prior inducement jurisprudence and clear up the massive confusion engendered by *GSK II*.

B. Now ***Every*** Inducement Claim Must Go to Trial

One real world ramification of the panel majority's rehearing decision in *GSK II* is that, from here on out, ***every inducement claim in the Hatch-Waxman context will need to go to trial***, because virtually every generic carve out label will contain language relevant to unpatented indications that could be combined to supposedly meet the elements of a brand's method patent claims. Thus, at either the pleadings stage on a motion to dismiss or for judgment on the pleadings, or in response to a motion for summary judgment, brands from here on out will argue that early resolution is improper—irrespective of whether the generic's label and any other documentary evidence the brand relies on actually promotes the claimed methods—because the brand will be able to present expert testimony at trial showing that physicians will subjectively "understand" (*GSK II*, 7 F.4th at 1337) the generic's label to "show[]" or "me[e]t" (*id*. at 1329-30) elements of the claimed methods, citing *GSK II*. Every ANDA case in which the generic's label merely describes a claimed method—but does not objectively encourage, promote, or recommend the claimed methods—will need to go to trial. This cannot be squared with *Takeda*, which found no inducement as a matter of law irrespective of what the brand's expert might say, and especially *HZNP*, which affirmed summary judgment of no inducement over the brand's pleas that it should be given a chance to present expert

testimony at trial proving promotion of the claimed methods. *Takeda*, 785 F.3d at 632-33; *HZNP*, 940 F.3d at 702.

Rehearing en banc here is also critical because *GSK II* has provided brands with a blueprint for securing crippling damages awards against generics who carve out patented methods to avoid Hatch-Waxman litigation. Brands can simply lie in wait to sue on their method patents, as GSK did. *GSK II*, 7 F.4th at 1324-25. Then, after a generic has been on the market for years, the brand can sue, alleging a less than perfect carve out in the generic's label and, as explained above, every one of those suits will need to go a jury, potentially subjecting the generic to hundreds of millions of dollars in damages. *Id*. at 1340. And, after *GSK II*, the generic will not be able to rely on JMOL to correct a jury finding of inducement where its label objectively (on its face) does not promote the claimed methods. This simply cannot be what Congress intended, and does not comport with decades of Supreme Court and Federal Circuit case law. Indeed, the whole purpose of the carve out statute was for generics to avoid inducement claims by carving out patented methods. 21 U.S.C. § 355(j)(2)(A)(viii); *Caraco*, 132 S. Ct. at 1677.

C. The Panel Majority's Opinion Renders the Carve Out Statute Nearly Impossible to Comply with

Finally, the panel majority disregarded the statutory and regulatory structure of Hatch-Waxman and the carve out statute, in particular, to hold that what GSK told FDA in a sworn declaration about what the '000 patent claims covered in the brand

label—which ***did not*** include the post-MI LVD indication that GSK claims satisfies the congestive heart failure limitation of the '000 patent claims, *GSK II*, 7 F.4th at 1331—did not negate Teva's specific intent to induce infringement. This renders the carve out statute nearly impossible for generics to comply with. Under FDA regulations, brands are required to identify for the FDA what portions of the brand label are covered by the method patent the brand is listing in the Orange Book. 21 C.F.R. § 314.53(c)(2)(O); *GSK II*, 7 F.4th at 1331 (discussing GSK's FDA form 3542 submission). FDA relies on that information to provide generics with a template for carve out of the claimed methods, which the generic complies with in order to secure approval and avoid litigating the method patent. *GSK II*, 7 F.4th at 1333.

While certainly generics "have a separate obligation to analyze the scope of the [brand] patents themselves," *GSK II*, 7 F.4th at 1332, generics must rely on what brand drug companies tell FDA, under penalty of perjury, their method patents cover in the approved label. 21 C.F.R. § 314.53(c)(2)(O). This removes any guess-work on the part of the generic, leading to the orderly implementation of the carve out statute. Because of *GSK II*, brands have every incentive to identify less that all "of the specific section(s) and subsection(s) of the proposed labeling for the drug product that describes the method of use claimed by the patent submitted," 21 C.F.R. § 314.53(c)(2)(O)(2), reserving the ability to later sue generics who modified their

label in accordance with what the brand told FDA—something Congress clearly never intended, and that frustrates the orderly implementation of the carve out statute. Rehearing is desperately needed to rectify this problem.

II. *GSK II* WILL BE DEVASTATING TO THE GENERIC DRUG INDUSTRY

Left uncorrected, the skinny label portion of panel majority's decision in *GSK II* will devastate the generic drug industry. Apotex and other generic companies will now curtail efforts to file ANDAs for unpatented uses of off-patent drugs, eliminating generic competition for many drugs, with the end result being higher prescription drug prices for consumers. Because of *GSK II*, generics like Apotex now know that every inducement claim will need to go to trial, and that a brand can always find an expert to recast a generic label that merely "show[s]" or "me[e]t[s]" claim elements (*GSK II*, 7 F.4th at 1328-30) as promoting the claimed method, potentially subjecting the generic to crippling damages. Moreover, the generic now cannot effectively rely on the carve out statute, because *GSK II* absolves brands from having to accurately inform FDA of what their method patents cover—which is what generics rely on to effectively carve out claimed methods to comply with the carve out statute. Apotex respectfully requests that this Court grant Teva's petition for rehearing en banc to correct at least the skinny label portion of *GSK II*.

Respectfully submitted,

Dated: October 20, 2021

/s/ Andrew M. Alul____

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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