18–1976, –2023

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

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

BRIEF OF *AMICI CURIAE* NOVARTIS PHARMACEUTICALS CORPORATION AND SANDOZ INC. IN SUPPORT OF REHEARING EN BANC

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December 16, 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 18-1976, -2023

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

Filing Party/Entity Novartis Pharmaceuticals Corporation

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

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

Date: 12/16/2020

Signature: /s/Jane M. Love, Ph.D.

Name: Jane M. Love, Ph.D.

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
Novartis Pharmaceuticals Corporation		Novartis AG

☐ 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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GlaxoSmithKline LLC v. Glenmark Pharmaceuticals Inc., USA, No. 1:14-cv-877 (D. Del.)		

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

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Signature: /s/Dan L. Bagatell

Name: Dan L. Bagatell

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Sandoz Inc.		Novartis AG

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☐ None/Not Applicable ☐ Additional pages attached

Perkins Coie LLP	Dan L. Bagatell	Andrew T. Dufresne

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TABLE OF CONTENTS

Table of Authorities iii

Table of Abbreviations v

Introduction and Interest of *Amici* 1

Argument 3

I. The majority's confusing analysis leaves both generics and originators in the dark regarding the limits on marketing generic drugs for non-patented indications 3

II. To the extent the majority opinion suggests that carved-out labels or references to FDA equivalence ratings alone can induce infringement, it is legally erroneous 5

A. A carved-out label alone cannot support liability for inducing infringement of a patent limited to the carved-out indications 5

B. Promotional materials that merely refer to FDA therapeutic-equivalence ratings cannot induce infringement of a method patent limited to one of multiple therapeutic uses 6

III. The uncertainty created by the majority's opinion will inhibit informed decisionmaking by both innovators and generics and risks upsetting the careful balance that Congress established 7

A. *All* pharmaceutical companies need clear and predictable legal frameworks to guide their product-development decisions 7

B. The majority opinion creates uncertainty that will only worsen as courts struggle to reconcile it with longstanding precedent and apply it to different facts 8

C. The majority's ruling risks upsetting the balance that Congress struck to promote carved-out labels and enable timely access to off-patent medicines while preserving incentives to invest in new therapeutic uses 10

Conclusion 12

Certificate of Compliance 13

Certificate of Authority 13

TABLE OF AUTHORITIES

Cases **Pages**

AstraZeneca LP v. Apotex, Inc.,
633 F.3d 1042 (Fed. Cir. 2010) 4, 5

Bristol-Myers Squibb Co. v. Shalala,
91 F.3d 1493 (D.C. Cir. 1996) 10

Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,
566 U.S. 399 (2012) 10

Eli Lilly & Co. v. Teva Parenteral Meds., Inc.,
845 F.3d 1357 (Fed. Cir. 2017) 5

Global-Tech Appliances, Inc. v. SEB S.A.,
563 U.S. 754 (2011) 5

HZNP Meds. LLC v. Actavis Labs. UT, Inc.,
940 F.3d 680 (Fed. Cir. 2019),
cert. denied, No. 20-88 (U.S. Nov. 2, 2020) 6

Kimble v. Marvel Ent., LLC,
576 U.S. 446 (2015) 12

Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.,
545 U.S. 913 (2005) 5, 11

Sigma-Tau Pharms., Inc. v. Schwetz,
288 F.3d 141 (4th Cir. 2002) 11

Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.,
785 F.3d 625 (Fed. Cir. 2015) 4, 6, 10

Warner-Lambert Co. v. Apotex Corp.,
316 F.3d 1348 (Fed. Cir. 2003) 6

Statutes, Rules, and Regulations **Pages**

21 U.S.C. § 355(j)(2)(A)(viii) 1, 9, 10, 11

21 C.F.R. § 314.3(b) 6

Other Authorities **Pages**

Compl., *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, No. 20-cv-1630 (D. Del. filed Nov. 30, 2020) 9

H.R. Rep. No. 98-857(I) 11

United States Food and Drug Administration, *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* § 1.7 (40th ed. 2020), *available at* https://www.fda.gov/media/71474/download 6

TABLE OF ABBREVIATIONS

ANDA	Abbreviated New Drug Application
Dissent *xx*	page *xx* of Chief Judge Prost's dissenting opinion
FDA	the United States Food and Drug Administration
GSK	plaintiffs–appellees GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited
Majority Op. *xx*	page *xx* of the majority's opinion
Novartis	*amicus curiae* Novartis AG
Orange Book	FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*
R&D	research and development
Sandoz	*amicus curiae* Sandoz Inc.
Section viii	21 U.S.C. § 355(j)(2)(A)(viii)
Teva	defendant–cross-appellant Teva Pharmaceuticals USA, Inc.

INTRODUCTION AND INTEREST OF *AMICI*[*]

As explained in the accompanying motion for leave to file, Novartis AG operates across the spectrum of the pharmaceutical industry. Its Innovative Medicines division, including *amicus* Novartis Pharmaceuticals Corporation, is a world leader in developing new pharmaceuticals and new methods of pharmaceutical treatment. Its Sandoz division, including *amicus* Sandoz Inc., develops and markets quality generic and biosimilar alternatives to branded pharmaceuticals.

All of Novartis shares the common goal of discovering new ways to improve and extend people's lives. And the entire company urges this Court to rehear this case because the panel's decision injects uncertainty into a body of law upon which innovators and generics alike rely when deciding to invest in the complex technical and regulatory efforts needed to bring medicines to market. *Amici* take no position on the ultimate outcome of this case.

In 21 U.S.C. § 355(j)(2)(A)(viii), Congress endorsed carved-out labels as a way to market generic versions of drugs for off-patent indications when other uses remain patented-protected. Until this case, branded and generic pharmaceutical companies understood the ground rules. Generics *could* be held liable for actively inducing infringement if they marketed a drug with a label describing a patented

[*] No party's counsel authored any part of this brief, and no one other than *amici* and their counsel contributed money to fund its preparation or submission.

therapeutic use or if they took active steps to encourage doctors or patients to use the drug in an infringing manner. But generics generally could *not* be held liable for merely marketing and selling under a "skinny" label omitting all patented indications, or for merely noting (without mentioning any infringing use) that FDA had rated a product as therapeutically equivalent to a brand-name drug. That balanced legal regime promoted timely access to medicines for off-patent uses while preserving incentives to invest in researching and developing new applications.

The panel decision risks upsetting that careful balance by sending ambiguous signals based on ambiguous facts about what activities may result in liability for induced infringement when a generic employs a carved-out label. The decision is unclear and may suggest that carved-out labels or references to therapeutic equivalence with no mention of any infringing use may—without more—support liability for inducing infringement. That would contradict this Court's precedent, and the uncertainty that this decision has introduced will encourage inefficient litigation and discourage use of the carved-out labels that Congress sought to promote.

Both branded and generic drug companies need clear, predictable legal frameworks to guide their investment, R&D, and marketing decisions. Generics need to know when their actions may give rise to liability so they can adjust their conduct or decline to proceed with investments and development plans.

Conversely, originators need a clear picture of when they can expect generics to enter the market, and when and how to monitor generic marketing activities and enforce their patent rights. Unless clarified, the majority's decision will inject uncertainty into these dynamics, and the situation will only worsen as lower courts attempt to apply it to other facts. Indeed, the decision is already being cited in other cases, adding to the urgency of en banc review.

The Court should grant rehearing to re-settle the law and clarify that active steps *beyond* merely a using a carved-out label or referring to an FDA equivalence rating are necessary to support inducement liability. The stakes are too high and the issues too important to defer to another day.

ARGUMENT

I. The majority's confusing analysis leaves both generics and originators in the dark regarding the limits on marketing generic drugs for non-patented indications

The majority opinion relies (at 11) on the premise that a plaintiff can prove the intent necessary for inducement through circumstantial evidence. The majority then identifies (at 16) various forms of evidence offered by GSK, including "promotional materials, press releases, [and] product catalogs" referring to Teva's AB equivalence rating, "the FDA labels" of Teva's generic product, and the "testimony of witnesses from both sides." But the opinion never explains which of those sources of evidence sufficed to support the infringement verdict. As a result, it can

be read as suggesting that evidence from any of those categories alone may suffice to establish inducement liability.

The majority introduced further uncertainty by failing to distinguish between the periods when Teva used full and carved-out labels. Between 2008 and 2011, Teva sold carvedilol under a label that omitted the FDA-approved indication for congestive heart failure covered by GSK's patent. But Teva's label included the patented indication from 2011 until the patent expired in 2015. The majority opinion does not differentiate between the skinny-label and full-label periods when analyzing infringement. Majority Op. 16-17.

The distinction is important because the full-label and skinny-label periods are critically different. As this Court has made clear, a label that itself encourages an infringing use constitutes evidence of active inducement, while a label that omits all infringing uses may not. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) ("The pertinent question is whether the proposed label instructs users to perform the patented method."); *see Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015) (to induce infringement, "[t]he label must encourage, recommend, or promote infringement"). The majority's analysis blurs this critical distinction by generally referring (at 16) to "the FDA labels" as substantial evidence supporting inducement liability for the entire 2008-2015 timeframe.

II. To the extent the majority opinion suggests that carved-out labels or references to FDA equivalence ratings alone can induce infringement, it is legally erroneous

Generic drug companies may be liable for actively promoting or instructing others to use generic drugs in an infringing manner—whether through a product label or otherwise. *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1368-69 (Fed. Cir. 2017); *AstraZeneca*, 633 F.3d at 1056-61. But the majority upsets settled expectations and legally errs to the extent it holds that a carved-out label or a reference to FDA therapeutic equivalence ratings alone suffices to establish inducement.

A. A carved-out label alone cannot support liability for inducing infringement of a patent limited to the carved-out indications

Inducement requires an affirmative act that specifically encourages infringement. *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011); *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936-37 (2005). Teva's carved-out label did not mention treating congestive heart failure, much less discuss the precise methods for treating that disease claimed in GSK's patent. And this Court has stressed that every step of a claimed method must be considered when analyzing inducement. *HZNP Meds. LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019), *cert. denied*, No. 20-88 (U.S. Nov. 2, 2020).

To the extent the majority was suggesting (at 16) that Teva's carved-out label by itself supported the infringement verdict, that suggestion contravenes settled precedent including *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364-65 (Fed. Cir. 2003), which held that a label omitting all reference to a method of use *cannot* induce infringement of a patent on that method, and *Takeda*, 785 F.3d at 631-32, which held that that a label can induce infringement of a patented method *only* if it specifically encourages, recommends, or promotes infringement.

B. Promotional materials that merely refer to FDA therapeutic-equivalence ratings cannot induce infringement of a method patent limited to one of multiple therapeutic uses

An AB equivalence rating indicates that FDA has determined that a generic drug is therapeutically equivalent to a reference drug. *Orange Book* § 1.7 (40th ed. 2020). But that determination applies only when the product is used under the conditions "specified in its labeling." *Id.*; *see also* 21 C.F.R. § 314.3(b). Referring to a therapeutic-equivalence rating for a generic product's approved non-infringing indications thus says nothing to promote its use for an off-label patented indication. Indeed, as the dissent observed (at 26), GSK's counsel admitted in closing argument that establishing liability required "more than just the AB rating" and that "the fact that Teva said [the accused products] were AB rated isn't enough to prove inducement …." The situation should remain the same after this case.

III. The uncertainty created by the majority's opinion will inhibit informed decisionmaking by both innovators and generics and risks upsetting the careful balance that Congress established

A. *All* pharmaceutical companies need clear and predictable legal frameworks to guide their product-development decisions

Both branded and generic pharmaceutical companies require stable, predictable legal environments to operate effectively. Patent litigation inherently entails some uncertainty, but the governing legal framework should be as predictable as possible and consistent with Congress's intent.

In making investments and product-development and marketing decisions, originators and generics need a clear picture of when generics may legally enter the market and how they may legally market their products. Originators need to plan ahead when setting their R&D and business plans because developing new drugs and new therapeutic uses for existing drugs typically requires many years and high levels of investment. Knowing what the market will look like is critical, among other things, to decide where to focus R&D expenses. Legal ambiguity over carved-out labeling would cloud forecasts and lead to more litigation with unpredictable outcomes, potentially creating disincentives to investment. Originators also frequently partner with smaller companies and help commercialize their inventions, and uncertainty about the extent and duration of patent protection may deter those investments.

For their part, generics need to know when they may launch and what marketing techniques are permitted. Developing generic medicines and obtaining regulatory clearance is a lengthy and expensive process with uncertain returns, that often must be planned for many years in advance of a product launch. And, like originators, generics base their R&D roadmaps on assumptions about what patent rights will remain in force and how they will be permitted to market their products in different time-periods.

All pharmaceutical companies suffer when the governing law is uncertain.

B. The majority opinion creates uncertainty that will only worsen as courts struggle to reconcile it with longstanding precedent and apply it to different facts

The majority's opinion injects harmful uncertainty into the law of inducement liability. For example, consider a scenario in which patents covering a compound and one therapeutic indication for using the compound expire in 2021, while a patent on using the compound for another indication expires in 2024. Until this decision, everyone understood that FDA-approved generics could enter the market in 2021, assert therapeutic equivalence with the branded product, and use a label that carves out the remaining patented indication—without fear of inducing infringement of the remaining indication patent, absent active steps to induce infringement outside the label and AB-rating. Originators could foresee the 2021 expirations and develop their plans accordingly. At the same time, generics could

time their development and regulatory efforts to be ready to launch in 2021 and then make sure to use only carved-out labels and avoid taking any affirmative steps to promote the still-patented use until 2024.

The majority opinion unsettles those expectations. It is now unclear whether mere marketing using a carved-out label or FDA therapeutic-equivalence ratings may constitute inducement of patent infringement. In the example above, neither originators nor generics would know whether generics may enter the market in 2021 or instead must wait until all patent coverage expires in 2024. The uncertainty will only grow as litigants and courts struggle to apply the decision to new sets of facts.

Indeed, some patentees are already attempting to take advantage of and extend the ruling in this case. A recent complaint involving another Section viii ANDA is illustrative: the defendant's efforts to match the plaintiff's label (apart from the carve-out) allegedly demonstrate the defendant's specific intent to induce infringement, and the defendant's description of its product as AB-rated to the plaintiff's product likewise allegedly shows the defendant's intent to have its product substituted for the branded product for all uses, including the carved-out use. Compl., ¶¶ 93-95, 110-112, *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc*., No. 20-cv-1630 (D. Del. filed Nov. 30, 2020) (also citing other categories of evidence analogous to the evidence here). Other patentees are similarly reading this

decision broadly and asserting it aggressively in court and settlement negotiations. Clarification is needed.

C. The majority's ruling risks upsetting the balance that Congress struck to promote carved-out labels and enable timely access to off-patent medicines while preserving incentives to invest in new therapeutic uses

If the majority's opinion stands, the resulting uncertainty is likely to dissuade generics from availing themselves of Section viii as broadly as Congress intended.

Section viii was designed to strike a balance: Congress aimed to enable timely access to lower-cost generic medicines while preserving incentives for originators to invest in developing those medicines for new therapeutic uses, which represent important lifesaving innovations. Carved-out labels work by allowing the launch of generic versions of off-patent medicines for all uses except those still covered by patents. Congress specifically allowed and encouraged carved-out labeling when it adopted Section viii, and Section viii provides a crucial path for generic drug companies to bring low-cost products to market for approved uses "as soon as patents allow." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405, 424-26 (2012); *see also Takeda*, 785 F.3d at 631 (explaining that "the statute was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses"); *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1500 (D.C. Cir. 1996) (holding that FDA may approve

generic drugs with labels that carve out patented indications); H.R. Rep. No. 98-857(I), at 14-15, 22.

Section viii also serves the broader public policy of "premis[ing] liability on purposeful, culpable … conduct" and not "discouraging the development of technologies with lawful and unlawful potential" or "compromis[ing] legitimate commerce or discourag[ing] innovation having a lawful promise." *Grokster*, 545 U.S. at 937; *see also Sigma-Tau Pharms., Inc. v. Schwetz*, 288 F.3d 141, 147-48 (4th Cir. 2002) (rejecting, in the related context of orphan-drug approval, the assertion that "foreseeable off-label use" should "bar the approval of generic drugs, even for unprotected indications").

If not clarified and corrected, the majority's opinion is likely to discourage generics from invoking Section viii. As discussed above, predictable legal frameworks are necessary to enable both innovative and generic companies to make the decisions needed to develop and launch their products. If the timing and conditions under which a generic medicine can be launched without risking inducement liability are unclear, both kinds of companies may choose not to develop certain products or to delay their development and launch. In some cases, such as this one, a patent on a new therapeutic use issues only after decisions to start generic product development have been made. Uncertainty may delay or cause abandonment of product launches in such cases, hampering future R&D investments

potentially to the detriment of patients. More generally, by deterring use of Section viii in some cases, the majority's opinion threatens to undermine public access after patents covering a drug compound and some of its approved indications have expired. *See Kimble v. Marvel Ent., LLC*, 576 U.S. 446, 451-53 (2015) (noting the public policy against "measures that restrict free access to formerly patented … inventions").

CONCLUSION

The Court should grant rehearing and vacate the panel's decision. At a minimum, the panel should revise the decision to clarify the bases for Teva's liability in each period and confirm that marketing under a carved-out label and promotion of FDA bioequivalence ratings for a drug cannot, without more, induce infringement of a patent covering a particular use of that drug.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Circuit Rule 35(g)(3). The brief contains 2600 words, excluding the portions exempted by rule, as counted by the word-processing software used to prepare it.

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft® Word and 14-point Times New Roman type.

Dated: December 16, 2020 /s/Dan L. Bagatell
Dan L. Bagatell

CERTIFICATE OF AUTHORITY

I certify that I have the authority of Jane M. Love, Ph.D., counsel for Novartis Pharmaceuticals Corporation, to file this document with her electronic signature.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: December 16, 2020

/s/Dan L. Bagatell
Dan L. Bagatell