No. 18-1976, -2023

United States Court Of Appeals
for the Federal Circuit

GLAXOSMITHKLINE LLC AND 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, CASE NO. 14-CV-878-LPS-CJB, DISTRICT JUDGE LEONARD P. STARK

GSK'S RESPONSE BRIEF TO PETITION FOR REHEARING *EN BANC*

Juanita R. Brooks
Jonathan E. Singer
Michael A. Amon
Fish & Richardson P.C.
12860 El Camino Real,
Ste. 400
San Diego, CA 92130
(858) 678-5070
brooks@fr.com;
singer@fr.com;
amon@fr.com

Michael J. Kane
William R. Woodford
Elizabeth M. Flanagan
Fish & Richardson P.C.
3200 RBC Plaza
60 South Sixth Street
Minneapolis, MN 55402
(612) 335-5070
kane@fr.com;
woodford@fr.com;
betsy.flanagan@fr.com

Douglas E. McCann
Nitika Gupta Fiorella
Fish & Richardson P.C.
222 Delaware Ave.,
17th Floor
Wilmington, DE 19899
302-652-5070
dmccann@fr.com
fiorella@fr.com

CERTIFICATE OF INTEREST

Counsel for Plaintiffs-Appellants certifies the following:

1. Provide the full names of all entities represented by undersigned counsel in this case.

   GlaxoSmithKline LLC and SmithKline Beecham (Cork) Ltd.

2. 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.

   Not applicable

3. 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.

   GlaxoSmithKline plc.

4. 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).

   Fish & Richardson P.C.: John Farrell, Phillip Goter, Jeremy Anderson, Robert M. Yeh*, Ryan O'Connor, Jeremy Saks, W. Chad Shear, Limin Zheng*, Santosh Coutinho*. * = No longer with firm.

5. 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).

   GlaxoSmithKline LLC, et al. v. Glenmark Pharmaceuticals Inc., USA, et al., Case No. 14-cv-877-LPS-CJB (D. Del.).

6. 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).

Not applicable

Dated: January 29, 2021

/s/ Michael A. Amon
Michael A. Amon

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

INTRODUCTION

This case does not implicate the fate of section viii carve-outs. Nor does it upset the legal framework for evaluating them. Instead, this case involves a typical review of a properly instructed jury's verdict. Specifically, the majority found substantial evidence supported the jury's factual finding that Teva's actions, as a whole, induced physicians to prescribe its generic to treat heart failure according to GSK's patented methods. There is no legal principle this Court need address, and thus no basis for en banc review.

The district court legally and factually erred by disturbing the jury's verdict. First, the district court substituted its judgment for the jury's when it concluded that Teva's partial (or "skinny") label did not encourage the patented use. GSK presented ample evidence from which the jury could, and did, conclude otherwise, including (1) Teva's partial label, which said its product "is indicated ***to reduce cardiovascular mortality***"[1] in a class of patients (post-MI LVD patients) of whom about half are symptomatic heart failure patients; (2) expert testimony showing how Teva's partial label instructed the patented method of treatment; and (3) Teva's promotional materials where Teva touted its generic as a complete replacement of Coreg®, which doctors used, according to the patented methods, to treat heart failure.

---

[1] All emphasis added.

Second, the district court applied the wrong law to these facts. At Teva's urging, it not only required ***direct*** evidence that Teva's activities caused doctors' infringement—when binding precedent says otherwise—but it used ***GSK's prior promotion*** of its branded product to ***rule out*** the conclusion that Teva caused infringement. Under that logic, virtually no copyists could be liable for induced infringement because they could always point to the innovator's prior product roll-out.

The majority righted these errors by reinstating the jury's verdict, over the dissent's objections. Central to the dissent's reasoning is a faulty premise Teva pushed: that Teva's partial label "included only the two unpatented indications and 'carved out' GSK's patented method." (Petition at 1.) Indeed, the dissent suggests this point was undisputed, saying Teva did "everything right," when in fact GSK presented substantial evidence that Teva's partial label instructed physicians to use the drug in an infringing manner. Once this error is remedied, any concern over proper section viii carve-outs should evaporate. What's left is a run-of-the-mill substantial evidence case, with no "exceptional circumstances" justifying en banc review.

BACKGROUND

I. GSK's Breakthrough Invention and Teva's Infringement

This case centers on GSK's revolutionary method of treating congestive heart failure. Heart failure stems from the heart's (specifically, the left ventricle's) inability to pump enough blood. (Appx10359-10360; Appx10601-10604; Appx11519.) The percentage of blood the left ventricle pumps out with each contraction is called the

"ejection fraction." A normal ejection fraction is 55%-70%, while heart failure patients' ejection fraction is typically less than 40%. (Appx10603; Appx11226.)

GSK's invention story is unique: GSK started with a hypertension drug, carvedilol, that doctors believed would ***kill*** heart failure patients, only to discover carvedilol was so effective in ***treating*** heart failure it decreased the risk of death by 65%. (Appx2996; Op. 4 n.2.) GSK changed the standard of care for these patients, meaning heart failure stopped being the "death sentence" it once was. (Appx10361-10362.)

The FDA approved carvedilol for heart failure in 1997,[2] which GSK marketed as Coreg®. (Op. 3.) GSK soon recognized its breakthrough discovery was not reaching all heart failure patients, including "post-MI LVD" patients. These are patients who recently suffered heart attacks (*i.e.* myocardial infarctions (MI)), and have left ventricular dysfunction (LVD), meaning their ejection fraction is ≤ 40%. While these patients have "an early form of heart failure," they were not treated with Coreg® until later in the disease's progression because the original clinical studies had excluded patients experiencing a major cardiovascular event within three months. (Appx2997; Appx10381-10382; Appx10602-10606.) GSK thus sought to market Coreg® for "post-MI LVD" (Op. 4), during which it explained to FDA that LVD and

[2] The FDA had previously approved carvedilol for the treatment of hypertension. (Op. 3.)

heart failure "are part of a single disease continuum," and that the "post-MI LVD" indication addressed "the beginning" of that continuum. (Appx11963-11965; Appx11968-11969.) Upon approval, GSK added indication 1.2 to the Coreg® label for reducing the risk of death in post-MI patients who have an "ejection fraction of ≤ 40% (with or without symptomatic heart failure)." (Appx7665; Appx5548 (47% of patients with symptoms of heart failure).)

During this time, GSK obtained U.S. Patent No. 5,760,069 for its method of treating heart failure with carvedilol. But, in response to invalidity allegations in Teva's paragraph IV letter, GSK obtained the reissue patent central to this appeal, RE40,000. (Op. 4-5.) The '000 patent claims cover treating *all* Class II-IV heart failure patients. (*See* Appx44 (describing patient classifications).)

In March 2002, Teva submitted its ANDA for generic carvedilol to treat heart failure and hypertension. (Op. 4; Diss. Op. 8.) Two years later, Teva announced its ANDA had received FDA "tentative approval" "for treatment of ***heart failure*** and hypertension" and that it "anticipated" final approval when the patent on the carvedilol molecule expired in 2007. (Appx6347; Op. 13.) Weeks before its launch date, Teva hastily decided to go with the partial label instead. Teva amended its label by removing some of the language regarding heart failure, but, critically, it ***left in*** the indication for post-MI LVD:

> Carvedilol is indicated to ***reduce cardiovascular mortality*** in clinically stable patients who have survived the acute phase of a myocardial

> infarction and ***have left ventricular ejection fraction of ≤ 40%*** (***with*** or without ***symptomatic heart failure***).

(Op. 5 (quotation marks omitted).) Even Teva's expert ***agreed*** this indication encompassed treating patients with congestive heart failure. (Appx11226.) Teva then issued another press release stating it had received FDA final approval to market a generic of GSK's "cardiovascular" agent, Coreg®. (Op. 13 (quotation marks omitted).)

In 2011, Teva amended its label to be identical to Coreg®'s label, adding the separate congestive heart failure indication (the "full label").[3] (Op. 6.)

II. The Jury Sides with GSK

At trial, Teva argued it had carved-out the heart failure indication from its partial label, so it could not have induced infringement with its partial label. It also contended GSK failed to prove Teva directly communicated with prescribing physicians and "caused" them to infringe the '000 patent, during either the partial or full label period. (Op. 6-7.)

GSK showed Teva was wrong on both points. GSK presented substantial evidence Teva's partial label was not a true section viii carve-out because it left in language that instructed infringement via the post-MI LVD indication. GSK also

---

[3] The congestive heart failure indication states the drug is "for the treatment of mild-to-severe chronic heart failure of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitors, and digitalis, to increase survival and, also, to reduce the risk of hospitalization." (Appx5532.)

presented substantial evidence Teva encouraged physicians to use its generic in the claimed manner. (Op. 12-16.) After a 7-day trial, a properly instructed jury agreed with GSK, finding Teva induced infringement during both the partial and full label periods. (Op. 7.)

III. The District Court Takes Away the Jury Verdict but the Majority Reinstates It

The district court upended the jury's carefully considered verdict at JMOL. The district court performed its own fact-finding and credibility determinations to conclude that physicians already knew how to use Coreg® to treat heart failure—from GSK's promotion of Coreg®, Coreg®'s label, and other available information—and that "these alternative non-Teva factors were what caused the doctors to prescribe generic carvedilol for an infringing use." (Op. 8.) The district court also rejected the jury's finding that Teva's partial label containing the post-MI LVD indication encouraged physicians to infringe. (Appx15-16 at n.9)

A majority panel of this Court disagreed. Recognizing this Court does "not find facts afresh," the majority found "ample record evidence of promotional materials, press releases, product catalogs, the FDA labels, and testimony of witnesses from both sides, to support the jury verdict." (Op. 16-17.) The panel further recognized that the district court applied an improper, heightened causation requirement for inducement, when the Supreme Court has made clear that even "advertising an infringing use or instructing how to engage in an infringing use" is sufficient. (Op. 11

(quoting *MGM Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005)).) Under the proper standard, the panel found substantial evidence supports the jury's verdict. (Op. 17.)

Chief Judge Prost dissented, primarily based on a pivotal, incorrect premise Teva advanced: that Teva's partial label properly carved out the patented use. (Diss. Op. 2-3, 13, 15, 18, 20, 22, 27-28.) Even more, the dissent suggests GSK conceded this at trial. (Diss. Op. 13, 15, 18.) Respectfully, that is wrong. GSK presented substantial evidence, including expert testimony, showing that, by leaving in language from the post-MI LVD indication, Teva's partial label instructed the patented use. (Appx10622-10631; Appx5506-5530; Oral Arg. at 8:20-8:32, 21:56-23:45.[4]) The jury credited GSK's evidence, as it was authorized to do.

REASONS FOR DENYING THE PETITION

No "exceptional circumstances" exist here to justify en banc review. The majority applied prevailing law to review a properly instructed jury's resolution of a factual dispute and found substantial evidence supported the jury's verdict. That is precisely what this Court is supposed to do.

Teva tries to make this case sound exceptional with doomsday rhetoric about the death of section viii carve-outs, but the majority's holding signals no such thing.

---

[4] Oral Argument, GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc. (No. 18-1976), http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2018-1976.mp3.

The majority merely reaffirmed that section viii is not a get-out-of-jail-free card for generics who do not fully carve out the patented use from their labels. Section viii carve-outs are still readily available; generics need only employ them properly. The jury reasonably found Teva failed to do so here, so the panel correctly reinstated the verdict.

I. The Majority Applied Settled Law to Properly Conclude Substantial Evidence Supports the Jury's Verdict

A. Teva encouraged doctors to prescribe its drug in an infringing manner

The majority carefully considered the evidence presented and concluded a reasonable jury could, and did, find Teva encouraged doctors to use its product in an infringing manner. (Op. 12-16.) The majority thus properly reinstated the jury's verdict.

GSK presented the jury with Teva's partial label, which itself provides substantial support for the jury's verdict. Teva's partial label instructed doctors to use Teva's product "to reduce cardiovascular mortality" in post-heart attack patients who have an "ejection fraction of ≤40% (with or without symptomatic heart failure)." (Op. 5.) Critically, both experts agreed this patient population ***encompassed those suffering from symptomatic heart failure***, i.e., those covered by '000 patent. (Appx10602-10606; Appx10622-10623; Appx11226.) The jury was free to credit this undisputed testimony and find Teva's partial label encouraged the infringing use.

Beyond that, the majority walked through Teva's promotional materials—including press releases, product catalogs, Teva's Generic Product Reference Guide, and two editions of Teva's Monthly Prescribing Reference—where Teva consistently, over nine years, touted that its carvedilol tablets were "AB rated equivalents of the Coreg® tablets." (Op. 12-13.) The majority also looked to GSK's expert, Dr. McCullough, who explained what this information communicates to doctors. The jury heard Dr. McCullough explain that:

- doctors are "completely reliant" on information from generic manufacturers;
- doctors receive Teva's product catalogs, visit its website, and read its product guides and press releases;
- he saw Teva's 2004 press release and understood it to communicate to doctors that Teva expected to sell a generic of Coreg® that would be indicated to treat heart failure;
- Teva's 2007 press release referencing GSK's "cardiovascular agent, Coreg®" (Appx6353) encouraged doctors to prescribe Teva's product for heart failure;
- Teva's Spring 2008 catalog listing Teva's product next to Coreg® tablets and using the phrase "AB rating" would lead a doctor to believe "they're therapeutically interchangeable"; and

- doctors had "lots of information . . . that indicated that [Teva's product] was a complete replacement" for Coreg®.

(Op. 13-14.)

There was more. The jury heard from Professor Lietzan, who explained the significance of Teva's use of the AB rating and testified to FDA's "general position . . . that if you compare one product to another by name"—as Teva did in its product catalogs—"you are implying the use of the product." (Op. 15.) And Teva's Director of New Products said Teva "still expect[ed] to get sales" from doctors using its generic to treat heart failure, even though it had supposedly carved out that indication. (Op. 14.) Based on all the above, the majority properly found substantial evidence supported the jury's verdict.

Teva largely ignores the majority's thorough analysis, except to half-heartedly argue the majority's reliance on press releases pre-dating the '000 patent conflicts with *Nat'l Presto Indus. Inc. v. West Bend Co.*, 76 F.3d 1185 (Fed. Cir. 1996). Not so. As the majority explained, "[t]he jury was correctly instructed that it could find inducement if Teva 'continued to take an action that began before the '000 patent issued, after the '000 patent was issued on January 8, 2008, intending to cause the physicians to directly infringe by administering Teva's carvedilol product.'" (Op. 15 (citation omitted).) Teva did not object to that instruction, so it cannot complain now that the jury followed it. Further, neither Teva nor the dissent cite any precedent suggesting Teva's decision to keep its 2007 press release live on its commercial website, which it

regularly updates and maintains, is "passive" and not "active" inducement. (Petition at 15; Diss. Op. 23.) A jury could thus reasonably find the press releases constituted Teva's initial promotion of its drug as AB equivalent to Coreg®, and Teva affirmatively continued this promotion after the '000 patent's issuance through other marketing materials. The majority properly considered the press releases as one of many pieces of the substantial evidence supporting the verdict.

B. The majority applied the correct test for induced infringement

The majority also properly applied the test established by the Supreme Court to find a jury could infer from the record evidence that Teva took "active steps . . . to encourage direct infringement." (Op. 11 (quoting *Grokster*, 545 U.S. at 936).) The standard Teva advocates for is contrary to this well-established precedent, and, if adopted, would fundamentally cripple practicing entities' ability to show inducement.

In *Grokster*, the Supreme Court held that "advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe." *Grokster*, 545 U.S. at 936. It further explained that "inducement to infringe is not negated when the direct infringers already knew of the infringing subject matter." *Id.* Consistent with these principles, this Court has "affirmed induced infringement verdicts based on circumstantial evidence of inducement (*e.g.*, advertisements, user manuals) directed to a class of direct infringers (*e.g.*, customers, end users) without requiring hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material." (Op. 11 (quoting

Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 843 F.3d 1315, 1335 (Fed. Cir. 2016).) That is what we have here. This Court has also applied these principles to pharmaceutical cases, finding inducement where, as here, the defendant's label instructs the infringing use. (Op. 11-12.)

Based on these cases, the majority properly concluded that the district court applied the wrong test when it reasoned Teva could not have "caused" physicians to infringe because "physicians already knew how to use carvedilol for treating CHF." (Op. 16.) That is because "precedent makes clear that when the provider of an identical product knows of and markets the same product for intended direct infringing activity, the criteria for induced infringement are met." (*Id.*)

Tellingly, neither Teva, the district court, nor the dissent even mention *Grokster,* much less try to show the majority's analysis is at odds with it. Instead, Teva advocates for a heightened inducement standard that requires not only proof an alleged infringer advertises or instructs an infringing use—which *Grokster* says is enough—but also ***direct evidence*** that such advertising or instruction caused direct infringement, as opposed to other factors. Not only is that counter to *Grokster* and other cases the majority cited, it also conflicts with the instruction given to the jury:

> GSK is not required to present hard proof of any direct infringer physician stating, for example, that she read Teva's labels or other Teva materials and that these labels or other Teva materials caused her to prescribe Teva's generic carvedilol in an infringing manner. GSK must prove that Teva's actions led physicians to directly infringe a claim of the '000 patent, but GSK may do so with circumstantial – as opposed to direct – evidence.

(Op. 7.) Importantly, Teva did not object to this instruction. Nor could it have, because, as the majority's recitation of the law makes clear, inducement ***does not*** require the specific and direct proof of causation Teva now advances. Indeed, not even the cases Teva cites support its new test; they merely require, as Teva says (at 16), proof that "the [inducement] defendants' action led to direct infringement." *Grokster* tells us what is required to meet that proof: active steps to encourage infringement, which includes "advertising an infringing use or instructing how to engage in an infringing use." *Grokster*, 545 U.S. at 936.

Beyond that, Teva's version of inducement would lead to absurd results and essentially end inducement liability in cases involving practicing entities. According to Teva and the district court, because GSK promoted its own drug and taught physicians how to use it, a jury could not find Teva encouraged infringement even during the full label period, ***when Teva's label included the separate heart failure indication***. In every case involving an innovator, that innovator will have told the world about its invention before the accused product comes to market. In all those cases, regardless of how egregious the defendants' actions, the defendant could avoid infringement by pointing to the success and recognition of the innovator's product as "causing" direct infringement. That cannot be, and is not, the law.

Ironically, with all of Teva's focus on the supposed sweeping effects of the majority's opinion, it's Teva's advancement of a new standard for induced

infringement that would upend Hatch-Waxman law and have devastating effects for innovators.

II. The Panel's Opinion Does Not Spell the End of Section VIII Carve-outs

The doomsday scenario for carve-outs Teva's petition (and amici's briefs) portrays falls apart for a simple reason: the jury found Teva's partial label ***did not*** properly carve out GSK's patented use.[5] This case thus follows *AstraZeneca LP v. Apotex, Inc.*, where this Court concluded that because the generic's partial label did not actually carve out the patented use, it would cause doctors to infringe. 633 F.3d 1042, 1056 (Fed. Cir. 2010). The partial label framework did not collapse after *AstraZenenca*, and it will not after this case either.

Far from being undisputed, as Teva, the amici, and the dissent posit, GSK presented substantial evidence Teva's partial label included instructions to treat heart failure according to the patented methods in its post-MI LVD indication. (Appx10622-10631.) We know the jury understood GSK's arguments regarding the partial label's instructions from its verdict: it evaluated each claim and only found a subset of them infringed by the partial label. (Appx204-213.)

---

[5] GSK appreciates Congressman Waxman's perspective, but his conclusion also ignores this finding. Because Teva's partial label was not a proper "skinny label," the majority contravened none of the "skinny label" protections with its decision. (Waxman Br. 9-12.)

That is why this case is not the end of carve-outs. As long as generics fully carve out the patented use, they can continue to enjoy the carve-out statute's protection. This Court has recognized as much. It has found no infringement in cases where generics used the carve-out statute as intended. *See, e.g.*, *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631-32 (Fed. Cir. 2015). Conversely, as Teva acknowledges (at 14 n.8), in cases where generics didn't carve out enough, this Court has found they could not use section viii as a shield against liability. *See, e.g. AstraZeneca*, 633 F.3d at 1056. This case falls in the latter bucket.

Teva tries to side-step *AstraZeneca* by saying (at 8, n.6) the majority did not hold Teva's partial label instructed the patented method. But that finding is implicit in, and necessary to, its decision. For example, the majority quoted from Teva's partial label, noted the label provided evidence from which a jury could conclude Teva encouraged the patented use, and cited numerous cases where the content of the product label constituted inducement. (Op. 6, 11-12, 16-17.) Further, the majority reversed the district court's grant of JMOL, which was premised on finding Teva's partial label fully carved-out the patented use, and reinstated the infringement verdict for both the partial and full label periods. (Op. 18; Appx15-16 at n.9.) This means the majority recognized Teva's insufficient carve-out as a basis on which the jury could find induced infringement, and upheld the jury's verdict accordingly.

Teva is thus wrong (at 10) that the majority "uph[eld] massive liability for distributing an unpatented product, even *without* having encouraged the patented

method." The opposite is true: the majority found there was substantial evidence Teva *did* encourage the patented method, including through its partial label.[6] For the same reason, Teva is wrong (at 13) that the decision "eviscerates" any active-inducement requirement; instead, the panel properly held Teva's partial label "was evidence of liability," precisely because a jury could and did find it actively induced doctors to infringe. Nor does the decision hold, as Teva suggests (at 14), that Teva's description of its product as the AB-rated generic equivalent of Coreg® was alone "enough for inducement liability." Notably, the jury was instructed that Teva's AB-rating was "***not*** by itself" sufficient to find liability, and Teva provides no reason to believe the jury disregarded this instruction. (Appx171.) Instead, as the majority properly found, GSK presented the jury with substantial evidence in addition to Teva's AB-rating description, including Teva's partial label and other advertising, to support its verdict.

Finally, the majority's decision will have no chilling effect on generics entering the market with partial labels. (Petition at 18.) All this decision does is reiterate that

---

[6] In doing so, the majority did not, as Teva suggests (at 11), "equate[]" Teva's witness's testimony that Teva expected to get sales from the carved-out indication with encouraging direct infringement. The majority simply, and properly, identified that testimony as one of many pieces of evidence from which the jury could reasonably conclude that Teva encouraged doctors to prescribe its generic for the patented use.

generics who wish to do so must comply with section viii by completely carving out the patented use. Notably, Teva relies on the *Amarin* case to show the supposed onslaught of litigation that will befall generic carve-outs, but there the generic expressly recognized that the majority's "fact-specific" decision here ***did not*** overrule any precedent, including the cases Teva cites as warranting en banc review. Hikma's Motion to Dismiss, at 19-20, *Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.*, No. 20-cv-1630 (D. Del. Jan 27, 2021), ECF No. 12.

Simply put, the panel's decision is limited to the facts of this case and does not bind any future panel from coming to a different conclusion based on different facts of another carve-out case. The Court should thus deny Teva's petition.

CONCLUSION

For the foregoing reasons, Teva's petition should be denied.

Dated: January 29, 2021

Respectfully submitted,

/s/Michael A. Amon
Michael A Amon

Attorneys for Plaintiffs-Appellants

CERTIFICATE OF SERVICE AND FILING

I certify that I electronically filed the foregoing document using the Court's CM/ECF filing system on January 29, 2021. Counsel was served via CM/ECF on January 29, 2021.

/s/ Michael A. Amon
Michael A. Amon

CERTIFICATE OF COMPLIANCE

The undersigned attorney certifies that GSK'S RESPONSE BRIEF TO PETITION FOR REHEARING *EN BANC* complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B). The relevant portions of the brief, including all footnotes, contains 3,894 words, as determined by Microsoft Word.

Dated: January 29, 2021

/s/ Michael A. Amon
Michael A. Amon

Attorneys for Plaintiffs-Appellants