**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 TEVA'S PETITION FOR REHEARING *EN BANC*

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## 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*, William Woodford*. * = 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: December 6, 2021

*/s/ Michael A. Amon*
Michael A. Amon

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## INTRODUCTION

As before, this appeal involves review of a jury's verdict for substantial evidence, not a sea change in the law of induced infringement or a death knell for the "skinny" label. The majority has now twice applied black letter law to conclude that substantial evidence supported the jury's factual findings. Namely, that Teva's actions induced physicians to prescribe its generic drug to treat heart failure according to GSK's patented methods, and therefore the district court's JMOL was erroneous. In reversing, the majority made no legal pronouncements that will bind any panel of this Court from concluding, in a different case, on different facts, that a properly executed skinny label strategy and marketing campaign does not create inducement liability. There are thus no exceptional circumstances or contrary precedents warranting en banc review.

Contrary to Teva's assertion that somehow its current predicament is GSK's fault, the jury verdict, now twice reinstated, is based squarely on Teva and its actions. As the majority held, the jury had overwhelming testimony and documentary evidence from which to conclude that Teva's own actions, representations, and motivations led to where Teva now finds itself, i.e., owing $235 million for willfully encouraging and instructing physicians to use its generic to carry out GSK's patented method of treating congestive heart failure.

Unable to counter the majority's holding that "substantial evidence in this case supports the jury's determination that Teva's partial label contained information

encouraging each claimed step and the preamble," and that "Teva's partial label was evidence Teva instructed physicians to use its carvedilol in an infringing way," Teva rephrases it. (Op. 17, 24.)

The majority did not hold, as Teva wrongly claims, that "because snippets of language in disparate portions of the label could 'satisfy' each claim term if a doctor read them together, Teva can be held liable for inducement." (Pet. 2.) Rather, the majority read the same label as the jury, where "[a]ll of the claim limitations were contained in the Indications section (which amounted to a single sentence), the Clinical Study section (to which doctors were directly referred by the Indication section), and the Dosage and Administration section (which immediately follows the Indication section and which says how much and how often to give the carvedilol)." (Op. 15-16.)

Knowing that substantial evidence supports the jury's verdict, Teva tries to pique the en banc Court's interest in other ways, but each falls flat. Even though it is well-settled that inducement verdicts may be supported by circumstantial evidence, Teva advocates for an about-face exception when it comes to proving causation. Precedent provides no room for this. Further, Teva's refrain that the panel's rehearing decision is the Armageddon for skinny label generics is belied by the dearth of cases mirroring this one that have been filed in its wake. History shows that generic manufacturers by-and-large know how to execute proper skinny labels. That Teva is on the wrong side of history is no reason to rewrite it now.

Simply put, Teva did not get it right, the jury and majority did (twice.) There is no need for this Court to revisit the jury's verdict a third time.

## BACKGROUND

This case centers on GSK's revolutionary, patented method of using carvedilol to treat congestive heart failure and Teva's intentional, unapologetic, and enterprising profit from it.

### I. Congestive Heart Failure and GSK's Breakthrough Invention

The jury heard significant evidence about GSK's breakthrough invention that resulted in the '000 patent. GSK started with a drug, carvedilol, that doctors believed would kill heart failure patients, only to discover it was so effective in treating heart failure it decreased the risk of death by 65%. (Appx2996; Appx10363-10364.) As inventor Dr. Ruffalo testified, the clinical results were so good FDA ***stopped*** the trial so all patients would obtain carvedilol's life-saving benefits. (Appx11282, Appx10372-10373.)

For this discovery, FDA approved Coreg® (carvedilol) tablets for treating heart failure. Because of Coreg®, heart failure stopped being the "death sentence" it once was. (Appx10361-10362.)

The jury also learned all about what "congestive heart failure" is. (Appx10359-10360; Appx10601-10604; Appx11519.) Both side's experts agreed that when the heart's left ventricle can't pump more than 40% of the blood it contains in a single

contraction (an "ejection fraction" ≤40%), that "left ventricular dysfunction," or **LVD**, constitutes "congestive heart failure." (Appx10603; Appx11132; Appx11226.)

The jury also heard GSK kept innovating after Coreg®'s initial approval by studying it in recent heart attack patients (post-myocardial infarction, or ***post-MI***) that have LVD. The jury heard from inventor Dr. Lucas and GSK's expert Dr. McCullough that these patients have "an early form of heart failure" given their ≤ 40% ejection fraction (i.e., LVD). (Appx2997; Appx10381-10382; Appx10602-10606; Appx11132; Appx11226; Appx11522-11523.) FDA awarded Coreg® an approval for reducing the risk of death in this early heart failure, "post-MI LVD" population, too.

These two approvals are reflected in Coreg®'s label as indications 1.1 and 1.2:

**1 INDICATIONS AND USAGE**

**1.1 Heart Failure**

COREG is indicated 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 *[see Drug Interactions (7.4) and Clinical Studies (14.1)]*.

**1.2 Left Ventricular Dysfunction Following Myocardial Infarction**

COREG is indicated to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of ≤40% (with or without symptomatic heart failure) *[see Clinical Studies (14.2)]*.

(Appx7665.)

## II. GSK's Reissue Patent and Teva's Infringement

The jury learned GSK obtained U.S. Patent No. 5,760,069 for its method of treating heart failure with carvedilol (Appx10373-10374), and that a host of generic

companies, including Teva, sought to market copies of Coreg® before that patent expired. In response to the generics' arguments, GSK sought a reissue to address any invalidity concerns. (Appx10373-10374; Appx10530; Appx10968.)

Teva tried to convince the jury it thought those reissue proceedings resulted in a "gap" in patent coverage, meaning Teva could launch its generic without concern. (Appx10324, Appx10343.) But the jury was instructed there was no "gap" (Appx166; Appx11832-11833), and heard Teva's motivations in launching its product were manifestly otherwise.

For example, the jury heard that Teva always intended to market its carvedilol for all of Coreg®'s indications, including heart failure. Teva's label included the heart failure indication back in 2002, and still in 2004 when its ANDA received "tentative" approval. (Appx10453; Appx10457; Appx10488; Appx10530.) Teva's 2004 press release announced this "tentative approval" from FDA "for treatment of ***heart failure*** and hypertension" and said Teva "anticipated" final approval in 2007. (Appx6347; Appx7437; Appx10530-10531; Appx11239-11241; Appx11655-11660.)

After telling the world for years its generic would be approved for all indications, the jury heard that, just weeks before Teva launched in 2007, it decided to switch course and adopt its partial label. (Appx6347; Appx7437; Appx10457.) The jury learned Teva did so knowing this was "a legal strategy, not a commercial strategy" because Teva intended it would nonetheless get sales for the carved-out indication. (Appx10488; Appx10491; Appx10458.)

Notably, the jury heard ***no evidence*** that Teva tried to take back its prior communications despite this change in indications. Rather, the jury saw a second Teva press release about its final approval to market a generic of GSK's "cardiovascular" agent, Coreg®. (Appx6353.) The jury heard GSK's expert interpret this as a missive to use Teva's generic just like Coreg®, including for treating heart failure. (Appx11659-11660.)

The jury ***never heard*** that Teva received or viewed GSK's Orange Book patent-listing forms, or that those forms or GSK's use codes were considered—let alone played any role in Teva's decisions. What the jury *did hear* from both parties' regulatory experts was that, even though FDA provided a "mock-up" label, Teva had an independent obligation to ensure its partial label did *not* instruct GSK's patented method. (Appx10584; Op. at 21-23.)

The jury heard substantial evidence from GSK's expert that Teva failed to fulfill that obligation. While Teva removed some of the language regarding heart failure from its partial label, critically, it left in the indication for treating post-MI LVD patients. (Op. 7-8.) Teva's expert ***agreed*** this post-MI LVD indication, which instructs treating patients with ≤ 40% ejection fraction (i.e., LVD), ***encompassed*** treating patients with congestive heart failure. (Appx11226.)

The jury also saw Teva's marketing materials over the years. This included a website and product catalogs describing Teva's generic as an AB rated therapeutic equivalent to Coreg®, and Prescribing References emphasizing the importance of

reading and relying on labels. (Appx6196; Appx10611; Appx10991-10992; Appx4245-4246.)

GSK's expert tied all of this together. Dr. McCullough testified doctors read generic labels, he personally read Teva's label, doctors receive and read generics' product catalogs, product guides, press releases, and are, in fact, "completely reliant" on information from generic manufacturers. (Appx11660–11664.) He explained to the jury what a physician would think from all this: that Teva's generic was indicated to treat heart failure and that Teva was encouraging physicians to prescribe Teva's product as "a complete replacement" for Coreg®, including for heart failure. (*Id.*)

The jury also learned that, in 2011, Teva added the separate heart failure indication onto its label (the "full label"), now expressly copying the Coreg® label in full. (Appx10465; Appx10569.)

## III. The Jury's Liability Verdict and the District Court's JMOL

After a 7-day trial, a properly instructed jury agreed with GSK, finding Teva willfully induced infringement by selling its generic with both the partial and full labels, and awarding GSK $235 million. (Op. 8-9.)

The district court upended the jury's verdict at JMOL. The district court performed its own fact-finding and credibility determinations to conclude that physicians already knew how to use carvedilol to treat heart failure—from GSK's promotion of Coreg®, Coreg®'s label, and other sources—and that "these alternative non-Teva factors were what caused the doctors to prescribe generic carvedilol for an

infringing use." (Appx18-21; Op. 9.) The district court also substituted its own judgment for the jury's and found, as a factual matter, that Teva's partial label did not encourage infringement. (Appx15-16 at n.9; Op. 9.)

## IV. The Majority Reinstates The Jury's Verdict, Twice

A majority panel of this Court reversed the district court's decision. 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 of inducement to infringe [the asserted claims]." (2020 Op. 16-17.) The majority 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. (*Id.* 11 (quoting *MGM Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005)), 16.) Under the proper standard, the majority concluded substantial evidence supports the jury's verdict and reinstated it. (Op. 18.)

Teva sought rehearing, with amici, treating the majority's decision as the end for section viii carve outs. (*Id.* 9-10.) But a common, incorrect premise fueled this claim: that Teva's partial label had actually carved out the patented use. (*See id.* 13.) The majority granted the petition for panel rehearing "to make clear how the facts of this case place it clearly outside the boundaries of the concerns expressed by *amici*." (*Id.* 10.)

In its second opinion, the majority emphasized that "[t]his is a case in which substantial evidence supports a jury finding that ***the patented use was on the generic label at all relevant times*** and that, therefore, Teva failed to carve out all patented indications." (*Id.* (emphasis added).)

This time the dissent characterized Teva's partial label as not including an infringing use at all, based on GSK's statements to FDA about what uses were patented, or, at most, ***describing*** the patented use, but not ***encouraging*** it. (Dissent 18, 30.)

Teva uses this second dissent as its new roadmap for relief. But the dissent overlooks the jury had evidence from both sides on these points, including expert testimony on the nature of GSK's submissions to FDA, FDA's refusal to decide infringement, how a physician would understand Teva's partial label and concluded that Teva's partial label ***did*** encourage the patented use. Because substantial evidence supports that finding, the majority properly reinstated the verdict a second time.

## REASONS FOR DENYING THE PETITION

No "exceptional circumstances" exist 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.

Because the majority's "narrow, case-specific review of substantial evidence does not upset the careful balance struck by the Hatch-Waxman Act regarding section

viii carve-outs" (Op. 10-11), or otherwise conflict with existing precedent on inducement, causation, or anything else, this Court should deny Teva's petition.

## I. The Majority Properly Applied Settled Law

### A. The Majority's Substantial Evidence Holding Complies With Inducement Precedent

The majority carefully and methodically walked through the extensive evidence outlined above. It then applied settled inducement law to these facts, under the right standard of review, to conclude a reasonable jury could find Teva encouraged doctors to use its product in an infringing manner. (Op. 11-34.)

Quoting the leading Supreme Court case on inducement, the majority concluded that a jury could infer from the evidence that Teva took "active steps . . . to encourage direct infringement" through its partial label. (Op. 24-25 (quoting *Grokster*, 545 U.S. at 936).) It also noted that under this Court's precedent, "when a product is sold with an infringing label or an infringing instruction manual, such a label is evidence of intent to induce infringement." (Op. 24-25.)

Further, the majority found all of the non-label evidence GSK presented (i.e., Teva's marketing and sales efforts, including catalogs, press releases, and its website), provided additional evidence from which the jury could conclude Teva encouraged and promoted infringement. (Op. 26-32.)

Teva's chief argument for rehearing misstates the majority's holding. The majority did not sustain Teva's liability based on "snippets of language in disparate

portions" of Teva's partial label that "could 'satisfy'", "mention", "meet" or "describe" the claim limitations. (Pet. 2, 11-13, 17.) Rather, the majority repeatedly stated there was substantial evidence supporting the jury's conclusion that the partial label ***instructed and encouraged*** infringement, for example:

- "In contrast, substantial evidence in this case supports the jury's determination that Teva's partial label contained information encouraging each claimed step and the preamble." (Op. 17)
- "We conclude substantial evidence supports the finding that Teva's partial label was evidence Teva instructed physicians to use its carvedilol in an infringing way." (Op. 24.)
- "Dr. McCullough did not testify that Teva's actions merely describe infringement; he testified Teva's actions encouraged infringement." (Op. 24.)

This case is thus like those in which infringement followed where a product was not merely "capable of" infringing, but was sold with instructions recommending infringement. *See Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1365-66 (Fed. Cir. 2012) (collecting cases and discussing the difference between describing versus recommending infringement); *see also Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630-31 (Fed. Cir. 2015) (invoking *Toshiba* to reiterate an inducing drug label must suggest following the infringing mode, not just describe it).

The majority also addressed Teva's "cobbl[ing] together" argument and rejected that, too. (Op. 15-17.) The majority reviewed evidence showing all the claim limitations were contained in three, interrelated sections of Teva's partial label: Indications; Clinical Studies (referenced by the Indications); and Dosage and

Administration. Notably, it is the Indications section that GSK's expert said satisfied the critical claim limitation—"decreasing mortality caused by congestive heart failure"—the very section ***Teva*** advocates should be the "focus." (Pet. 12.) Its verdict shows that is exactly what the jury found—Teva's post-MI LVD indication explicitly instructs using the product to treat heart failure—and that finding was supported by substantial evidence. *See also Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 645-46 (Fed. Cir. 2017). Teva's disagreement[1] is no basis for upending the verdict or for en banc review.

Teva's cited cases are inapposite, as the majority already explained. In *Bayer Schering Pharma AG v. Lupin, Ltd.*, a Hatch-Waxman case, the patented method covered three effects, but not even the branded label had indications for all three effects. 676 F.3d 1316, 1324 (Fed. Cir. 2012). That is not this case. (Op. 16.) In *HZNP Medicines LLC v. Actavis Laboratories UT, Inc.*, the claimed method required three steps, while the label only required the first step, and did not otherwise encourage the other two steps. 940 F.3d 680, 702 (Fed. Cir. 2019). Here, by contrast,

[1] Teva continues to ignore the jury's factual finding that the post-MI LVD indication encouraged physicians to use Teva's drug for heart failure, suggesting that it is "expressly agnostic about whether patients even *had* heart failure." (Pet. 13.) But as the majority noted, while the jury heard some conflicting evidence on this point, it is undisputed that Teva's expert, Dr. Zusman, agreed that post-MI LVD indication encompasses heart failure patients, and the jury was thus free to credit that testimony. (Op. 16.)

the jury heard Dr. McCullough's testimony that Teva's partial label instructed using its product according to every claim limitation. (Op. 17.) The jury was free to credit that testimony and conclude that the partial label ***instructed*** and ***encouraged*** physicians to infringe, not merely described an infringing use.

### B. The Majority's Holding Respects the Causation Requirement

No one disputes the jury was properly instructed on causation and, applying that law, the majority concluded substantial evidence supports the jury's verdict that Teva's actions actually caused doctors to infringe. (Op. 35-37.) According to Teva, however, the fact no one testified that a particular doctor actually read and relied upon Teva's label in prescribing its product precludes a finding of causation. In other words, Teva demands direct evidence to prove inducement. (Pet. 15-16.) This ignores that the jury was instructed GSK did not need to prove causation with a physician's statement "that she read Teva's label other Teva materials and that these labels or materials caused her to" infringe. (Appx173.) Teva's contrary take is not only at odds with this instruction, but conflicts with precedent.

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." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315,

1335 (Fed. Cir. 2016). As recounted by the majority, the jury heard exactly this type of circumstantial evidence accompanied by expert testimony. (Op. 35-37.)

Beyond being demonstrably wrong, Teva's take on causation would improperly heighten the burden on patentees and essentially end inducement liability in cases involving practicing entities. According to Teva, the supposedly "uncontroverted evidence" that showed Teva's actions did not influence doctors, was the evidence that GSK promoted Coreg® and taught physicians how to use it. (Pet. 15.) Because of that, Teva contends a jury could not find Teva's actions encouraged infringement even during the full label period, *when Teva's label included the separate "heart failure" indication*. But in every case involving an innovator, that innovator will have told the world about its invention before the accused product comes to market. Under Teva's reasoning, in those cases, regardless of how egregious the defendant's actions, it 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. Indeed, as the majority already expressed, the Supreme Court rejected this in *Grokster*: "inducement to infringe is not negated when the direct infringers already knew of the infringing subject matter." (2020 Op. 11 (citing *Grokster*, 545 U.S. at 936).)

## 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 and the majority concluded substantial evidence supports that finding. 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, 1056-61 (Fed. Cir. 2010).

The partial label framework did not collapse after *AstraZenenca*, and it will not here. That much is clear, since the majority's original opinion came out over a year ago. While Teva and amici predicted an onslaught of litigation befalling the generic carve-out, the *Amarin v. Hikma* case is ***still*** the only litigation they cite. (Pet. 3, 17.) 2021 WL 3396199 (D. Del. Aug. 3, 2021).

Teva's and the dissent's suggestions otherwise are again premised on a faulty assertion: that "the background facts here will seemingly persist in most skinny-label cases." (Pet. 17 (quoting Dissent 35).) Not so. This is a unique case in which a properly instructed jury found the generic's label was *not* a true skinny label, a host of other materials encouraged infringement, and Teva's specific intent to earn sales for the supposedly carved-out patented use was crystal clear. Thus, as long as generics actually omit the patented use from their labels, they can continue to enjoy the carve-out statute's protection.

This distinction is nothing new; the Court has previously found no infringement in cases where generics used the carve-out statute as intended, *see, e.g.*,

*Takeda*, 785 F.3d at 631-32, but has upheld liability where generics did not carve out enough, *see, e.g. AstraZeneca*, 633 F.3d at 1061.

Teva's suggestion that the majority's decision creates an unworkable regime for FDA is similarly flawed. Teva blames GSK for its failure to fully carve out the patented use from its partial label, based on the use codes GSK submitted to FDA. (Pet. 5 (citing Dissent 11), 18.) Tellingly, Teva ***never*** made this point to the jury. Instead, the jury heard evidence from both parties that (1) FDA is not an expert in patent law and doesn't determine the scope of patent rights; (2) use codes "are not meant to substitute for the applicant's review of the patent and approved labeling"; and thus (3) the obligation remains on the ANDA applicant "to analyze the scope of the patents listed in the Orange Book to determine how to prepare their Section viii carve-out label." (Op. 20-22; Appx10584.) This case thus signals no change in FDA practice; the onus was and remains on the generic to fully carve out the patented use in order to obtain section viii protections.

Simply put, the majority's decision is limited to the facts of this case and does not bind any future panel from coming to a different conclusion in a carve-out case with different facts.

## CONCLUSION

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

Dated: December 6, 2021

Respectfully submitted,

*/s/Juanita R. Brooks*
Juanita R. Brooks

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 December 6, 2021. Counsel was served via CM/ECF on December 6, 2021.

*/s/ Juanita R. Brooks*
Juanita R. Brooks

## 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. 35(b)(2)(A). The relevant portions of the brief, including all footnotes, contains 3,889 words, as determined by Microsoft Word.

Dated: December 6, 2021

*/s/ Michael A. Amon*
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