

2018-1710, -1711

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

**PURDUE PHARMA L.P., P.F. LABORATORIES, INC., PURDUE
PHARMACEUTICALS L.P.,**

Appellants

v.

ANDREI IANCU, DIRECTOR, U.S. PATENT AND TRADEMARK OFFICE,
Intervenor.

Appeal from the United States Patent and Trademark Office, Patent Trial and
Appeal Board in Inter Partes Review Nos. IPR2016-01412 and IPR2016-01413

**CORRECTED RESPONSE TO PURDUE'S MOTION FOR REHEARING OR
REHEARING EN BANC OF INTERVENOR – DIRECTOR OF THE
UNITED STATES PATENT AND TRADEMARK OFFICE**

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The relevant dates in this case are as follows:

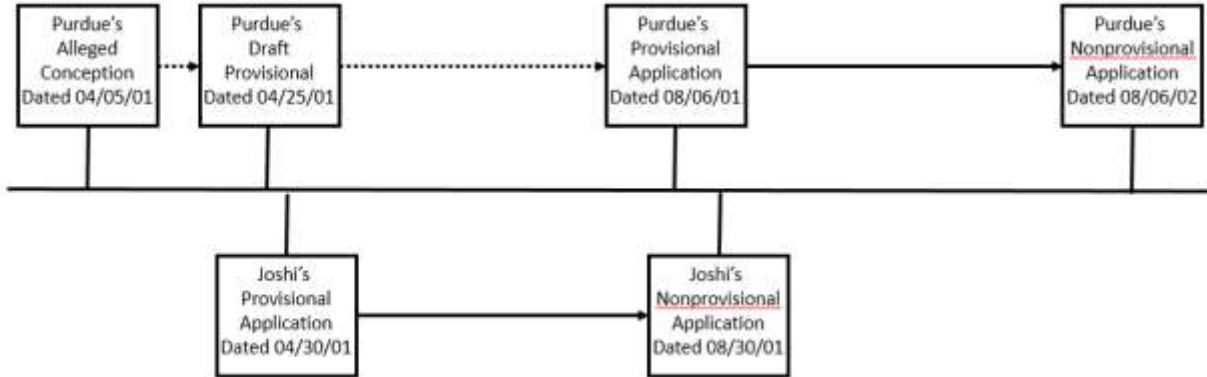


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I. INTRODUCTION

Purdue Pharma L.P., P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P. (Purdue) seeks rehearing or rehearing en banc of the Court's decision in *Purdue Pharma L.P. v. Iancu*, 767 Fed. Appx. 918 (Fed. Cir. 2019), on two grounds. First, Purdue argues that the Panel misapprehended this Court's precedent in *Dynamic Drinkware v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378-79 (Fed. Cir. 2015), by holding that Purdue had the burden of establishing that its patent was entitled to the benefit of its provisional application's filing date when – according to Purdue – Purdue's entitlement to this date was not disputed by Amneal. Second, Purdue argues that the Panel misapplied this Court's precedent to find that Purdue's provisional application did not contain adequate written support for its issued claims. Purdue's first argument fails because Purdue itself raised entitlement to its provisional application's filing date as an affirmative defense on which it bore the burden of production. And Purdue's second argument fails because the Panel correctly applied this Court's precedent – it just did not find in Purdue's favor. Thus, there is no basis for either en banc or panel rehearing.

II. BACKGROUND

Purdue is the owner of U.S. Patent No. 9,034,376 (the '376 patent). Amneal Pharmaceuticals, LLC (Amneal) petitioned for inter partes review of the '376 patent on the ground that its claims were unpatentable under 35 U.S.C. § 103

in view of three combinations of prior art. Each ground cited the Joshi patent publication as 35 U.S.C. § 102(e) prior art. (Appx7, Appx49.)

In its petition, Amneal explained that “the earliest possible effective filing date for the ’376 Patent is August 6, 2001,” the filing date of Purdue’s provisional application. (Appx109, Appc5423.) Amneal then contended that Joshi had priority extending back through its nonprovisional application, filed August 30, 2001, to its corresponding, “largely identical” provisional application, filed April 30, 2001. (Appx118; *see also* Appx365 ¶52, Appx632 n.5, Appx5439.)

Following the institution of inter partes review, Purdue raised the affirmative defense that Joshi was not § 102(e) prior art to the ’376 patent. As support, Purdue argued: (1) that Amneal “failed to establish that the subject matter of Joshi that it relies on is present in and supported by the Joshi provisional”; (2) that the ’376 patent is entitled to claim the benefit of its provisional application’s August 6, 2001 filing date; and (3) that the ’376 patent is entitled to claim the benefit of a prior conception based on a draft provisional application dated April 25, 2001, as well as laboratory notebooks dated between April 5 and April 12, 2001. (*See, e.g.*, Appx2719-2722, Appx2734-2735.) To support entitlement to its provisional application’s filing date, Purdue submitted a supplemental declaration by its expert, Dr. Stephen Byrn, averring that “the specifications of the ’376 patent and [Purdue’s provisional] application . . . are identical in all respects relevant to the

claims of the '376 patent,” and including a detailed claim chart purporting to show where “each element of the inventions in claims 1-13 and 16-19 of the '376 patent can be found in [Purdue’s] provisional application.” (Appx2907-2918 ¶55.)

In response, Amneal argued that Purdue was collaterally estopped from challenging Joshi’s right to the benefit of its provisional application’s filing date based on prior litigation. (Appx4288-4290, Appx9754-9756.) Amneal also argued that Purdue could not swear behind Joshi’s provisional application’s filing date because it had not established conception prior to Joshi’s provisional application’s filing date and, in fact, only realized that the claimed invention would work in November 2005. (Appx9757-9760.)

The Patent Trial and Appeal Board (Board) addressed Purdue’s affirmative defense regarding priority in its final written decision, and determined that Joshi was § 102(e) prior art to the '376 patent. In particular, the Board found that, although Amneal had met its initial burden of establishing that Joshi was prior art to the '376 patent, after Purdue challenged priority, Amneal had not carried its final burden of proof on Joshi’s entitlement to the benefit of its provisional application’s filing date. (Appx19, Appx62.) The Board nevertheless found that Purdue was collaterally estopped from challenging Joshi’s entitlement to its provisional application’s April 30, 2001 filing date. (Appx15-18, Appx58-61.) Alternatively, the Board found that, even if not estopped, Purdue’s challenge to

Joshi's status as prior art had failed to produce sufficient evidence that Purdue's provisional application (or its conception documents) supported the claims of the '376 patent, making Joshi prior art as of its non-provisional application's filing date. (Appx19-23, Appx63-65.) Having determined that Joshi was indeed prior art to the '376 patent, the Board determined that Amneal had set forth sufficient evidence that the claims of the '376 patent would have been obvious in view of each cited prior art combination. (Appx40, Appx83.)

On appeal, the Panel affirmed the Board's determination that Joshi is prior art to the '376 patent, as well as each of the Board's three obviousness determinations, in a nonprecedential opinion. *See Purdue*, 767 Fed. Appx. at 926. While the Panel decided that collateral estoppel did not prevent Purdue from challenging Joshi's right to the benefit of its provisional application's April 30, 2001 filing date, the Panel agreed with the Board that Amneal had satisfied its initial burden of production that Joshi is prior art to the '376 patent as of this date. *Id.* at 923-926. The Panel also agreed with the Board that the burden then shifted to Purdue to produce evidence that Joshi is not prior art to the '376 patent, and that the evidence Purdue produced in support of this affirmative defense failed to establish that the '376 patent is supported by and entitled to its provisional application's August 6, 2001 filing date. *Id.* at 923-926.

Purdue petitions for rehearing or rehearing en banc of the Panel's decision.

III. ARGUMENT

Federal Rule of Appellate Procedure 35(a)(1)-(2) provides that “en banc hearing or rehearing is not favored and ordinarily will not be ordered unless . . . necessary to secure or maintain uniformity of the court’s decisions; or . . . the proceeding involves a question of exceptional importance.” Fed. R. App. P. 35(a)(1)-(2). Federal Rule of Appellate Procedure 40 further provides that a petition seeking rehearing of a panel decision must “state with particularity each point of law or fact that the petitioner believes the court has overlooked or misapprehended.” Fed. R. App. P. 40. Purdue’s petition for rehearing or rehearing en banc fails to meet either standard.

A. Purdue fails to identify any conflict between the Panel’s decision and *Dynamic Drinkware* or provide any other reason why rehearing is required

Purdue asserts error in the Panel’s application of *Dynamic Drinkware*’s burden-shifting framework for establishing priority. The Panel correctly followed that framework.

Dynamic Drinkware made clear that, while the burden of proof remains with the petitioner to establish unpatentability during inter partes review, a traditional district court burden-shifting analysis governs the production of evidence during these proceedings:

In an inter partes review, the burden of persuasion is on the petitioner to prove “unpatentability by a preponderance of the evidence,” 35 U.S.C. § 316(e), and that burden never shifts to

the patentee. . . . A second and distinct burden, the burden of production, or the burden of going forward with evidence, is a shifting burden, “the allocation of which depends on where in the process of trial the issue arises.”

Dynamic Drinkware, 800 F.3d at 1378-79 (citations omitted). In practice, this means that, once a petitioner meets its initial burden of going forward with evidence that a prior art reference anticipates or otherwise renders unpatentable a patent owner’s claims, the patent owner has “the burden of going forward with evidence either that the prior art does not actually anticipate [or render unpatentable its claims], or . . . that [the reference] is not prior art because the asserted claim is entitled to the benefit of a filing date prior to the alleged prior art.” *Dynamic Drinkware*, 800 F.3d at 1379 (quoting *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008)). This Court has explained that a petitioner meets the initial burden of establishing that a reference is prior art – and shifts the burden to the patent owner – by producing evidence that the asserted reference meets one of the statutory requirements for prior art under 35 U.S.C. § 102 in relation to the earliest effective filing date available to the patent owner’s claims. *See Dynamic Drinkware*, 800 F.3d at 1379 (holding that *Dynamic Drinkware* satisfied its initial burden as petitioner “by arguing that Raymond anticipated the asserted claims of the ’196 patent under § 102(e)(2);” thereby shifting the burden to patent owner to produce evidence showing otherwise).

Once the burden of production shifts to the patent owner, the patent owner can satisfy its burden by, for example, “going forward with evidence that . . . the asserted claim is entitled to the benefit of a filing date prior to the alleged prior art.” *Dynamic Drinkware*, 800 F.3d 1375 at 1379 (citing *Tech. Licensing*, 545 F.3d at 1327). In that instance, the patent owner must “show not only the existence of the earlier application, but why the written description in the earlier application supports the [patentee’s] claim[s].” *Id.*

The Panel’s application of this burden-shifting framework to the facts of this case fully comports with applicable precedent. In its petition for inter partes review, Amneal asserted that Joshi qualifies as prior art under 35 U.S.C. § 102(e) because “the earliest possible effective filing date for the ’376 Patent is August 6, 2001” (i.e., the filing date of Purdue’s provisional application), whereas the earliest effective filing date for Joshi is April 30, 2001 (i.e., Joshi’s provisional application’s filing date) based on Amneal’s expert’s testimony. (Appx109, Appc5423.) The Panel – like the Board – correctly determined that Amneal had met its threshold burden of establishing that Joshi is prior art to the ’376 patent, thereby shifting the burden of production to Purdue to come forward with evidence that it is not. *Dynamic Drinkware*, 800 F.3d at 1379; *see also Purdue*, 767 Fed. Appx. at 925, Appx19, Appx62.

Purdue even acknowledges that “the burden did shift to Purdue to prove an earlier date of conception.” (Reh’g Pet. at 10.) However, Purdue argues that the Panel erroneously gave it the burden of coming forward with evidence that the ’376 patent was entitled to the benefit of its provisional application’s filing date. As shown below, the Panel correctly applied the burden-shifting framework based on the evidence submitted in Purdue’s Patent Owner Response.

1. Purdue had the burden of coming forward with evidence that the ’376 patent was entitled to the benefit of its provisional application’s filing date because it was both “at issue” and part of Purdue’s affirmative defense that Joshi is not § 102(e) prior art

According to Purdue, the burden of production shifts to the patent owner only on those priority matters the petitioner “affirmatively puts ‘at issue’ by satisfying its burden of production,” or on “new issues the patentee seeks to introduce, ‘effectively [as] an affirmative defense.’” (Reh’g Pet. at 11.) Purdue argues that the burden did not shift to Purdue to affirmatively prove entitlement to its provisional application’s filing date because Amneal used that date as its “chosen baseline” for asserting that Joshi was § 102(e) prior art and, thus, never placed entitlement to that date “at issue.” (Reh’g Pet. at 11.) Purdue also asserts that the burden did not shift on this point because it “had no need (or notice) to use the provisional application’s filing date as an ‘affirmative defense.’” (Reh’g Pet. at 10 (quoting *In re Magnum Oil Tools Int’l*, 829 F.3d 1364, 1376 (Fed. Cir. 2016).) Both of these burden-shifting arguments are belied by the record below.

On Purdue's first argument, Amneal did not admit or acknowledge that the '376 patent was entitled to the benefit of its provisional application's August 6, 2001 filing date. To meet its initial burden, Amneal needed only to assert that Joshi had an earlier effective filing date than Purdue's earliest possible effective filing date. In meeting this initial burden, Amneal merely acknowledged that "the earliest *possible* effective filing date for the '376 Patent" was August 6, 2001, not that this was, in fact, the effective filing date. (Appx109, Appc5423 (emphasis added).) The Panel correctly rejected Purdue's similar argument about Amneal's expert's use of the August 6, 2001 date for the same reason. *Purdue*, 767 Fed. Appx. at 926; *see also* Purdue's Opening Br. at 39. Thus, in contrast to Purdue's assertion, Amneal's use of the August 6, 2001 date as a baseline for establishing Joshi's status as § 102(e) prior art did not remove the '376 patent's entitlement to the benefit of that date as an issue.

Purdue's second argument also runs counter to the record below. Following institution of inter partes review, Purdue raised the following affirmative defense:

- (1) Amneal had not met its burden of establishing that Joshi was entitled to its provisional application's April 25, 2001 filing date,
- (2) the '376 patent was supported by and entitled to claim the benefit of its provisional application's August 6, 2001 filing date,

(3) the inventors had possession of the invention claimed in the '376 patent as of its April 25, 2001 draft provisional application

(See Appx2718-2722, Appx2734-2735, Appx8177.) If Purdue prevailed on point (1) but not on points (2) or (3), Joshi would still be prior art to the '376 patent as of its nonprovisional application's August 30, 2001 filing date. (See Appx20, Appx62.) Thus, in contrast to its assertions (Reh'g Pet. at 10), Purdue had a definite need to produce evidence that the '376 patent was entitled to the benefit of its provisional application's filing date as part of its affirmative defense.

Aware of this need, Purdue attempted to meet its burden of production. Purdue produced a supplemental expert declaration averring that the specifications of the '376 patent and Purdue's provisional application are identical in all relevant aspects to the claims of the '376 patent, along with a detailed claim chart purporting to show where "each element of the inventions in claims 1-13 and 16-19 of the '376 patent can be found in [Purdue's] provisional application." (Appx2907-2918 ¶55.)

Thus, Purdue's petition for rehearing fails to demonstrate any point of law or fact that the Panel overlooked or misapprehended in concluding that Purdue had the burden of going forward with evidence that the '376 patent was entitled to the benefit of its provisional application's filing date.

2. The Panel properly found that Purdue presented insufficient evidence to shift the burden of production back to Amneal

Before the Panel, Purdue not only acknowledged that it had the burden of production on its benefit claim, but also argued that it satisfied this burden:

Purdue satisfied any burden of production when it[] provided a detailed chart from its expert showing how the '534 provisional supports the '376 claims. At that point, **the burden of production shifted back to Amneal**

(Purdue Opening Br. at 40 (citations omitted; emphases added).)

Purdue satisfied its burden of production by submitting the provisional application, **expert testimony** stating that the provisional supports the '376 claims, **and a claim chart** **The burden then shifted to Amneal, which always bore the ultimate burden of persuasion. Because Amneal never contested the issue or Purdue's evidence – thus failing to meet its burdens of production and persuasion –** there was no reason for Purdue to exhaustively point out all of the provisional's many references to PEO and HPMC as preferred gelling agents. With no dispute or contrary evidence from Amneal, **there is no evidentiary basis for the Board's conclusion,** much less substantial evidence.

(Purdue Reply at 13 (citations omitted; emphases added).) According to Purdue, once it produced this evidence, “the burden of production shifted back to Amneal . . . to ‘convince’ the Board that Purdue ‘is not entitled to the benefit of the earlier filing date.’” (Purdue Opening Br. at 40 (quoting *Dynamic Drinkware*, 800 F.3d at 1379).)

The Panel, like the Board, concluded that Purdue had not produced sufficient evidence that the '376 patent was entitled to its provisional application's filing date to shift the burden of production back to Amneal:

Purdue never met its burden to show that the '376 patent is entitled to claim the benefit of the '534 application's filing date. It was therefore not necessary for Amneal to offer expert evidence to the contrary. *See Dynamic Drinkware*, 800 F.3d at 1379 (stating that **once the petitioner meets its initial burden of going forward with evidence that there is anticipating prior art, the patent owner has “the burden of going forward with evidence either that the prior art does not actually anticipate, or . . . that it is not prior art because the asserted claim is entitled to the benefit of a filing date prior to the alleged prior art.”** (quoting *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008))).

Purdue, 767 Fed. Appx. at 924-25 (emphases added).

Purdue mischaracterizes the Panel's decision as “plac[ing] on the patentee an initial burden to prove” that its patent is entitled to an earlier priority date. (Reh'g Pet. at 11-12.) When read in context, the Panel was properly stating that, once Amneal met its initial burden, the burden of production shifted to Purdue and Purdue did not produce sufficient evidence to shift its burden *back to* Amneal. The Panel did not legally or factually place the *initial* burden of production on Purdue, nor did it assign Purdue the final burden of proof.

3. Purdue's Petition fails to show either that the Board lacked authority to consider Purdue's benefit claim evidence, or that the Panel committed error by affirming the Board's findings on this issue

Purdue appears to argue that, when Amneal chose to rely on an estoppel argument rather than rebut its benefit claim evidence, that issue became moot and the Board lacked authority to consider it. (Reh'g Pet. at 12.) Purdue's petition fails to explain why the Panel's affirmance of the Board's findings on an allegedly moot issue are legal error.

As to mootness, this argument fails because the issue of the '376 patent's entitlement to its provisional application's August 6, 2001 filing date was still a "live" issue when the Board found that (1) Amneal had not carried its final burden of proof as to Joshi's entitlement to its provisional application's April 30, 2001 – thus leaving Joshi with an earliest effective filing date of August 30, 2001 – and (2) Purdue had not established entitlement to an April 25, 2001 conception date. Because there was no abuse of discretion by the Board, it follows that there was no legal error by the Panel in at least reviewing the Board's findings on this issue. Moreover, none of the cases Purdue cites in support of this argument manifests error by the Board or the Panel.

In particular, Purdue quotes the Supreme Court's decision in *SAS v. Iancu*, for the assertion that "the petitioner's contentions, not the Director's discretion, define the scope of [inter partes review]." (Reh'g Pet. at 12 (quoting *SAS Inst.*,

Inc. v. Iancu, 138 S. Ct. 1348, 1355 (2018)).) However, these statements concern the Director’s discretion to institute inter partes review on fewer than all of the unpatentability grounds raised in a petition for review. *SAS* says nothing about the Director’s ability to resolve issues raised as part of an affirmative defense following the institution of inter partes review.

Purdue’s reliance on *Magnum Oil* is similarly misplaced. Purdue cites *Magnum Oil* for the proposition that “the Board cannot rely on theories ‘never presented by the petitioner and not supported by record evidence’” (*See* Reh’g Pet. at 12 (quoting *Magnum Oil*, 829 F.3d at 1381).) In *Magnum Oil*, the Court held that the petitioner never satisfied its initial burden of production because its petition for inter partes review failed to include any argument or evidence regarding a motivation to combine the asserted prior art. *Magnum Oil*, 829 F.3d at 1377-1378. The Court also held that the Board lacked authority to supply a motivation-to-combine rationale on the petitioner’s behalf in its final decision on review. *Id.* at 1380.

Unlike the petitioner in *Magnum Oil*, Amneal satisfied its initial burden of production as to both unpatentability and the status of the prior art, shifting the burden of production to Purdue. *See Dynamic Drinkware*, 800 F.3d at 1379. Unlike the patent owner in *Magnum Oil*, Purdue raised an affirmative defense challenging the status of Joshi as prior art and attempted to discharge this burden

with evidence concerning entitlement to its provisional application's earlier filing date. And, unlike the tribunal in *Magnum Oil*, the Board did not supply an unpatentability argument on Purdue's behalf, it merely examined the evidence Purdue put forth as part of its affirmative defense. *Magnum Oil* does not address the Board or the Panel's ability to resolve such issues, let alone conflict with the Board and the Panel's resolution of those issues.

The decision in *Arctic Cat* also exposes no abuse of discretion by the Panel here. The patent owner in *Arctic Cat* raised two, distinct arguments that an asserted reference was not prior art to its patent. *Arctic Cat Inc. v. GEP Power Prod., Inc.*, 919 F.3d 1320, 1332 (Fed. Cir. 2019). After deciding in the patent owner's favor on one of these arguments, the Court decided not to address the other argument. *Id.* The *Arctic Cat* decision does not hold or even suggest that addressing the other argument would have been an abuse of discretion.

Finally, Purdue's contention (Reh'g Pet. at 12) that the Board's actions were not outside the Board's discretion because Purdue "never had an opportunity to address" the benefit claim issue willfully ignores that Purdue was the party that injected this issue into the proceedings in the first place.

B. Purdue fails to identify any conflict between the Panel's decision and this Court's written description case law

The Panel correctly affirmed the Board's factual finding that Purdue's provisional application did not support the '376 patent's claims. The Panel found

that substantial evidence supported the Board’s finding that Purdue’s claims to opioid dosage forms containing HPMC and PEO as gelling agents lacked written description support because Purdue’s provisional application merely included a “laundry list” of possible gelling agents without “specifically nam[ing] or mention[ing] the combination in any manner,” or providing blaze marks directing artisans to the claimed combination. (*See* Appx21-22, Appx64-65.) For example, the Board found that the passages in Purdue’s provisional application cited as evidence of written support describes xantham gum and pectin as the only “preferred” gelling agents, and none of the application’s examples use PEO or HPMC as a gelling agent. *Id.* The Panel also correctly found that Purdue had waived reliance on other passages by failing to cite them to the Board. *Purdue*, 676 Fed. Appx. at 925 (citing *In re Baxter Int’l, Inc.*, 678 F.3d 1357, 1362 (Fed. Cir. 2012)). Purdue’s petition does not explain how the Panel’s decision conflicts with binding legal precedent or present a question of exceptional importance. It is merely a complaint by Purdue about the Panel’s application of the correct legal standard to the facts of this case – an issue only of importance to Purdue.

VI. CONCLUSION

The Panel's non-precedential decision is consistent with this Court's precedent, and Purdue fails to identify a question of exceptional importance mandating the consideration of the full Court. Thus, Purdue's request for rehearing should be denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. Proc. 32(a)(7), I certify that the foregoing
CORRECTED RESPONSE TO MOTION FOR REHEARING OR REHEARING EN BANC FOR
INTERVENOR – DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
complies with the type-volume limitation required by the Court’s rule. The total
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authorities, is 3,899 words as calculated using the Microsoft Word® software
program.

/s/ Mary L. Kelly

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CERTIFICATE OF SERVICE

I certify that on August 7, 2019, I electronically filed the foregoing
CORRECTED RESPONSE TO MOTION FOR REHEARING OR REHEARING EN BANC FOR
INTERVENOR – DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
using the Court’s CM/ECF filing system. Counsel for the Appellants was
electronically served via e-mail per Fed. R. App. P. 25 and Fed. Cir. R. 25(e).

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