NO. 2014-1294

IN THE

UNITED STATES COURT OF APPEALS

FOR THE FEDERAL CIRCUIT

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., AND RHODES TECHNOLOGIES,

Plaintiff-Appellants,

- vs -

EPIC PHARMA, LLC,

Defendant-Appellee.

Appeal from the United States District Court for the Southern District of New York in No. 1:13-cv-00683-SHS, Judge Sidney H. Stein

(Caption continued on inside cover.)

BRIEF OF AMICI CURIAE DONALD E. KNEBEL AND MARK D. JANIS IN SUPPORT OF PETITION FOR REHEARING EN BANC OF PURDUE PHARMA L.P., ET AL.

Mark D. Janis*
Center for Intellectual Property Research
Indiana Univ. Maurer School of Law
211 S. Indiana Avenue
Bloomington, IN 47401-7001
(812) 855-1205
mdjanis@indiana.edu

Donald E. Knebel
Center for Intellectual Property Research
Indiana Univ. Maurer School of Law
211 S. Indiana Avenue
Bloomington, IN 47401-7001
(317) 231-7214
dknebel@btlaw.com

**Attorney for Amici Curiae, Mark D. Janis and Donald E. Knebel In Support of Appellant Purdue Pharma, L.P.*

2014-1296

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., AND RHODES TECHNOLOGIES,

Plaintiff-Appellants,

- v -

MYLAN PHARMACEUTICALS INC. AND MYLAN INC.,

Defendant-Appellees.

Appeal from the United States District Court for the Southern District of New York in No. 1:12-cv-02959-SHS, Judge Sidney H. Stein

2014-1306, -1307

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., AND RHODES TECHNOLOGIES, AND GRÜNENTHAL GMBH

Plaintiff-Appellants,

- v -

AMNEAL PHARMACEUTICALS, LLC

Defendant-Appellee.

Appeal from the United States District Court for the Southern District of New York in No. 1:11-cv-08153-SHS, Judge Sidney H. Stein

(Caption continued.)

2014-1311, -1312, -1313, -1314

GRÜNENTHAL GMBH, PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., AND RHODES TECHNOLOGIES,

Plaintiff-Appellants,

- v -

TEVA PHARMACEUTICALS USA, INC.

Defendant-Appellee.

Appeals from the United States District Court for the Southern District of New York in No. 1:11-cv-02037-SHS and 1:12-cv-05083-SHS, Judge Sidney H. Stein

CERTIFICATE OF INTEREST

Counsel for the *Amici Curiae* certify the following:

1. The full name of every party or amicus curiae represented by me is: Donald E. Knebel and Mark D. Janis.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: same as above.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus curiae* represented by me are: none.

4. The names of all law firms and the partners or associates that appeared for the party or amicus curiae now represented by me in the trial court or agency or are expected to appear in this court are:

Donald E. Knebel
Center for Intellectual Property Research
Indiana University Maurer School of Law
211 S. Indiana Avenue
Bloomington, IN 47405-7001

Mark D. Janis
Center for Intellectual Property Research
Indiana University Maurer School of Law
211 S. Indiana Avenue
Bloomington, IN 47401-7001

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INTEREST OF *AMICI*

Amici curiae are professors at the Center for Intellectual Property Research of the Indiana University Maurer School of Law. Neither the individual *amici*, the Center, nor Indiana University has any interest in the outcome of this case. However, the Center, as part of its mission, has a strong interest in the sound development and administration of patent law. As a result, the Center and these *amici* have previously filed *amicus* briefs in this Court and in the United States Supreme Court on matters of patent law.

No one other than the undersigned wrote or funded any portion of this brief.

Pursuant to Rule 35(g), *amici* have filed herewith a Motion for Leave to file this brief. All parties in this case have consented to the filing of this brief.

ARGUMENT

This case presents the Court with an opportunity to decide whether judges should take into account process limitations when assessing the validity of product-by-process claims in litigation. The Court has already ruled that when construing claims as a predicate to an infringement determination, courts must treat product-by-process claims as being limited by the recited process terms. *Abbott Laboratories v. Sandoz, Inc.*, 566 F.3d 1282, 1291 (Fed. Cir. 2009) (en banc). However, *Abbott* did not present a corresponding validity issue, and the Court therefore did not address the logical consequence of its infringement ruling – namely, that the proper interpretation of product-by-process claims for validity determinations likewise requires courts to limit the claims to products made by the recited processes.

The panel opinion in this case ruled to the contrary. Specifically, the panel declined to apply the *Abbott* rule to an obviousness determination, holding that it had been proper for the trial court to disregard the process limitation in the product-by-process claims at issue en route to invalidating them for obviousness. Slip Op. at 15-16. The panel relied primarily on a prior panel decision of this Court, *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1370 (Fed. Cir. 2009), in which the panel refused to apply the *Abbott* rule to an anticipation analysis. *Accord Greenliant Systems v.*

Xicor LLC, 692 F.3d 1261, 1268 (Fed. Cir. 2012) (commenting on *Amgen* in the course of deciding an issue of recapture estoppel in a reissue matter). Thus, the panel opinion is the latest in a line of cases that has limited *Abbott* to the infringement context. The panel's ruling here has implications beyond the present dispute, making it appropriate for en banc review. Moreover, the fact that the general issue has now arisen in several cases suggests that the issue has percolated long enough at the panel level that it is ripe for en banc review.

The panel's rule for determining the validity of product-by-process claims warrants en banc reconsideration because it: (1) rests on a misconception about relevant Supreme Court precedent; (2) assumes without analysis that justifications that apply in the context of PTO administrative determinations of patentability necessarily must apply in judicial determinations of validity; (3) disregards the fundamental patent law axiom that courts are to construe claims the same way for both validity and infringement; and (4) threatens to render product-by-process claims valueless, contrary to this Court's express pronouncement en banc in *Abbott*. Moreover, the panel's rule that process terms can be disregarded in analyzing the validity of product-by-process claims materially affected its obviousness analysis in this case.

I. The Panel's Rule for Determining Validity of Product-by-Process Claims Rests on a Misconception About Relevant Supreme Court Precedent.

To justify its decision refusing to apply the *Abbott* rule to interpret a product-by-process claim in the context of anticipation, the panel in *Amgen* invoked the longstanding proposition that one should not be able to claim exclusive rights in an old product simply by making it by some new process. *See, e.g.*, *Amgen*, 580 F.3d at 1366 ("It has long been the case that an old product is not patentable even if it is made by a new process."), *citing Cochrane v. Basiche Anilin & Soda Fabrik*, 111 U.S. 293, 311 (1884) (hereinafter "*BASF*"); *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 373 (1938) ("[A] patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced.").

The present panel opinion's reliance on *Amgen* was flawed. The proposition from *BASF* and *General Electric* does not answer the claim construction question at issue here, but merely assumes it away. In the present case, as in *Amgen*, the court must determine whether in fact the claim should be construed to include the process limitation, or as a claim to the product "by whatever means produced." If the claim is limited by the process terms, as this Court held in *Abbott*, the premise for the

BASF/General Electric proposition disappears; there is no effort to claim an old product "by whatever means produced," and thus no need to trigger the *BASF/General Electric* proposition. In fact, *General Electric* noted that a claim could avoid a prior art product if "the claim uses language explicitly referring to the method of preparation, or describing the product in phrases suggestive of that process." 304 U.S. 374. That conclusion is inconsistent with *Amgen*, which holds that process limitations can be ignored in determining anticipation.

When it is evident that a line of Federal Circuit panel opinions is built on a misconception about relevant Supreme Court precedent, this Court should sit en banc to reexamine those opinions. The present case affords this Court an opportunity to do so.

II. The Panel's Rule Incorrectly Presumes That the Rules for Administrative and Judicial Determinations of Validity of Product-by-Process Claims Must be the Same, Contrary to a Prior Panel Decision.

In arriving at its conclusion that it was free to disregard the process limitations in the claims at issue despite *Abbott*, the panel relied in part on a prior Federal Circuit panel opinion involving an appeal from an ex parte patentability determination. *In re Thorpe*, 777 F.2d 695 (Fed. Cir. 1985). In that case, this Court ruled that "[i]f the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is

unpatentable even though the prior product was made by a different process." *Id.* at 697. *But cf.* MANUAL OF PATENT EXAMINING PROCEDURE 2113 (9th ed. Nov. 2015) (stating that even in ex parte examination, process limitations in a product-by-process claim should not always be disregarded.)

The *Amgen* panel opinion likewise invoked *Thorpe*. *Amgen*, 580 F.3d at 1366. Neither the present panel opinion nor the *Amgen* panel opinion explained why *Thorpe* should control judicial determinations of validity, especially after *Abbott*, although the *Amgen* panel opinion did make a remark in a footnote appearing to equate judicial determinations of validity with ex parte administrative determinations. *Amgen*, 580 F.3d at 1370 n.14.

However, this Court has already extensively explained why *Thorpe* should *not* control judicial determinations of validity or infringement in *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992). The *Atlantic Thermoplastics* panel recited arguments from prior cases suggesting that the PTO might have difficulty examining a product-by-process claim since the PTO had no capacity to carry out the process steps. *Id.* at 844 (*citing In re Brown*, 459 F.2d 531, 535 (C.C.P.A. 1972)).

As the *Atlantic Thermoplastics* court recognized, these rationales are peculiar to the context of ex parte examination. They do not carry over to judicial determinations of validity or infringement, as the *Atlantic Thermoplastics* panel explicitly pointed out:

> Thus, accommodating the demands of the administrative process and recognizing the capabilities of trial courts, the court treats claims differently for patentability as opposed to validity and infringement. The PTO's treatment of product-by-process claims as a product claim for patentability is consistent with policies giving claims their broadest possible interpretation. The same rule, however, does *not* apply in validity and infringement litigation.

Id. (emphasis added). *Amgen*, and the present panel opinion, are in direct conflict with *Atlantic Thermoplastics* on this point. This Court should intervene en banc to resolve the inconsistencies in its opinions.

III. The Panel's Rule Disregards the Patent Law Axiom That Courts are to Construe Claims the Same Way for Both Validity and Infringement.

The effect of the panel's ruling as to the treatment of product-by-process claims is to reject the principle that claims should be construed the same way for infringement as for validity, and the principle that a product that literally infringes if later, anticipates if earlier. In *Amgen*, the panel acknowledged that its approach to product-by-process claims contravened these principles, *Amgen*, 580 F.3d at 1369-70 (acknowledging that "[t]he impact of these different analyses is significant"), but offered no justification for the difference.

Respectfully, these principles should not be set aside so lightly. The principle that claim language must be interpreted the same way for determinations of validity and infringement is not simply a rule of convenience. It is, instead, a "fundamental tenet of patent law…." 5A

CHISUM ON PATENTS § 18.01 (2007). It also informs the famous symmetry principle: "That which [literally] infringes, if later, would anticipate, if earlier." *Peters v. Active Manufacturing Co.*, 129 U.S. 530, 53 (1889). This Court should intervene en banc to reconsider whether setting aside these deeply-embedded principles is justified in the present context.

IV. The Panel's Rule Threatens to Render Product-by-Process Claims Valueless, Contrary to this Court's Express Pronouncement En Banc in *Abbott.*

The patent statute mandates that patents include claims "particularly pointing out and distinctly claiming" the patented subject matter, but it does not prescribe particular claiming formats. 35 U.S.C. § 112 (b). This approach relieves Congress and the courts from the duty of micromanaging the formats of which claims, and leaves to the creativity of the patent drafter and the pressures of the marketplace the primary task of developing the best approaches to rendering inventions in words. Courts should be wary of adopting rules that single out particular claiming formats for condemnation.

Consistent with this approach, in *Abbott*, this Court stated that its en banc decision "in no way abridges an inventor's right to stake claims in product-by-process terms." *Abbott*, 566 F.3d at 1293. But the present panel decision, like that in *Amgen*, does just what *Abbott* sought to avoid: undercutting the viability of product-by-process claims so severely as to virtually eliminate any benefit to employing them. If the process limitations

in a product-by-process claim must be met for infringement, but can be ignored for validity determinations, there is little to be gained in pursuing such claims. An inventor would be better off simply omitting the process limitations and taking its chances on the product limitations being sufficiently novel to avoid invalidity. But it is precisely to avoid such situations that the Court of Custom and Patent Appeals decided to endorse the use of product-by-process claims beyond the traditional setting of "necessity" in *In re Hughes*, 496 F.2d 1216, 1219 (C.C.P.A. 1974) (Rich, J.) (speaking of product-by-process claims "as a hedge against the possibility that [the applicant's] broader product claims might be invalidated.").

Product-by-process claims also might be valuable in facilitating the pursuit of a direct infringement cause of action rather than relegating patentees to pursue inducement or contributory infringement actions. Even though the patent holder would still need to prove that the process limitations are satisfied in proving infringement, it may be able to avoid the need to prove the intent element of induced and contributory infringement. *Cf. In re Butler*, 37 F.2d 623, 625 (C.C.P.A. 1930) (product-by-process claims can avoid difficulties in proving infringement of process claims).

Neither the present panel decision nor the decisions on which it relies articulate any basis for rendering product-by-process claims essentially

valueless, regardless of the technology area or commercial setting. The Court should sit en banc to reconsider this outcome.

V. The Panel's Approach to the Product-by-Process Claims at Issue Materially Affected the Obviousness Analysis.

The panel's decision to disregard the process limitation in the claims at issue was material to its obviousness analysis. In particular, because the panel treated the claims as being directed to "the end product –an oxycodone API with low ABUK levels," Slip. Op. at 13, the panel concluded that the obviousness rule from *Eibel Process* "does not apply." *Id.*, *citing Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923) (holding that "where an inventor discovers a non-obvious source of a problem and then applies a remedy in response, the invention is nonobvious and worthy of a patent—even if the remedy, standing alone, would generally appear to be known in the art.") If the process limitations are properly taken into account, the applicability of *Eibel Process* must be reconsidered.

VI. Conclusion.

These amici believe that the panel decision in this case and the panel decisions on which it relies are inconsistent with this Court's en banc decision in *Abbott Laboratories v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009) and threaten the legitimate use of product-by-process claims. They therefore support the Petitioners' request for rehearing, en banc.

Respectfully submitted,

/s/Mark D. Janis

Donald E. Knebel
Mark D. Janis
Center for Intellectual Property Research
Indiana Univ. Maurer School of Law
211 S. Indiana Avenue
Bloomington, IN 47401-7001

CERTIFICATE OF SERVICE

I hereby certify that on April 15, 2016, a copy of the Brief of Amici Curiae Donald E. Knebel and Mark D. Janis in Support of Petition for Rehearing En Banc of Purdue Pharma, L.P., et al. was filed via operation of the Court's CM/ECF system. Copies of the Brief were served on counsel of record via electronic means on this day, April 15, 2016.

/s/Mark D. Janis
Mark D. Janis

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B).

The brief contains 2054 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

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 2010 and Times New Roman font set at 14pt font size.

Dated: April 15, 2016 */s/Mark D. Janis*

Mark D. Janis