2014-1294

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,

Plaintiffs-Appellants,

v.

EPIC PHARMA, LLC,

Defendant.

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.*)

BRIEF OF THE INTELLECTUAL PROPERTY LAW ASSOCIATION OF CHICAGO AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR REHEARING EN BANC

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2014-1296

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

Plaintiffs-Appellants,

v.

MYLAN PHARMACEUTICALS INC. AND MYLAN INC.,

Defendants-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,

Plaintiffs-Appellants,

v.

AMNEAL PHARMACEUTICALS, LLC,

Defendant-Appellee.

Appeals 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,

Plaintiffs-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 *Amicus Curiae* Intellectual Property Law Association of Chicago certifies the following:

1. The full name of every party of *amicus curiae* represented by me is:

   Intellectual Property Law Association of Chicago.

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

   Intellectual Property Law Association of Chicago.

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:

   Neal, Gerber & Eisenberg LLP: Kevin A. O'Connor, Kevin C. May

Date: April 15, 2016

Respectfully submitted,

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

RULES

INTEREST OF *AMICUS CURIAE*[1,2]

Amicus curiae Intellectual Property Law Association of Chicago ("IPLAC") submits this brief in support of Appellants' petition for rehearing *en banc* to address an improper restriction on the application of *Eibel Process*.

Founded in 1884, the Intellectual Property Law Association of Chicago is a voluntary bar association of over 1,000 members who practice in the areas of patents, trademarks, copyrights, trade secrets and the legal issues they present. Located in Chicago, a principal forum for U.S. patent litigation, IPLAC is the country's oldest bar association devoted exclusively to intellectual property matters. Its members include attorneys in private and corporate practices before federal bars throughout the United States, as well as the U.S. Patent and Trademark Office and the U.S. Copyright Office. IPLAC represents both patent holders and other innovators in roughly equal measure. In litigation, IPLAC's members are

[1] Pursuant to Federal Rule of Appellate Procedure 29(c)(5), amicus states that no counsel for a party authored this brief in whole or in part, no party or its counsel contributed money that was intended to fund preparing or submitting the brief, and no one but amicus and its counsel contributed financially to the brief's preparation and submission.

[2] In addition to the required statement of footnote 1, IPLAC adds that after reasonable investigation, IPLAC believes that (a) no member of its Board or Amicus Committee who voted to prepare this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation in this matter, (b) no representative of any party to this litigation participated in the authorship of this brief, and (c) no one other than IPLAC, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

split roughly equally between plaintiffs and defendants. As part of its central objectives, IPLAC is dedicated to aiding in the development of intellectual property law, especially in the federal courts.

SUMMARY OF ARGUMENT

The panel decision severely restricts *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923), such that *Eibel Process* cannot be applied to claims covering "end product[s]." In the context of this category of claims, the discovery of a previously unknown source of a problem could not be considered as part of the obviousness analysis. Such a restriction finds no support in the language or reasoning of *Eibel Process* and is contrary to the precedent of this Court and its predecessor. Finally, such a restriction violates well-settled principles of obviousness, and leads to unintended and undesirable consequences. This Court should grant *en banc* review of the panel decision in order to maintain uniformity of judicial decisions and to correct any deviation from the well-settled principles of obviousness.

ARGUMENT IN SUPPORT OF PETITIONER

The panel decision severely restricts the scope of *Eibel Process* by excluding claims covering "end product[s]," even when those claims also claim the source of the problem. The panel decision relies on the "end product" claim distinction in two places:

> But, here, Purdue did not claim the remedy of the problem of remaining 14-hydroxy in the oxycodone API—performing a second hydrogenation step. Instead, it claimed the ***end product***—an oxycodone API with low ABUK levels. (Slip Op. 13 (emphasis added).)
>
> But, again, Purdue claimed the ***end product***; it did not claim a particular method for creating that product, such as the use of hydrogenation after the salting step. (*Id.* at 14 (emphasis added).)

These statements improperly restrict *Eibel Process* for this category of claims, removing discovery of a previously unknown source of a problem from the obviousness analysis. The Supreme Court's decision in *Eibel Process* provides no support for such a restriction and the full Court should review to correct – or clarify – the panel decision.

I. A RESTRICTION ON *EIBEL PROCESS* IS CONTRARY TO THE RATIONALE OF *EIBEL PROCESS*.

Eibel Process addresses the non-obviousness of claims directed to a paper-making machine. The inventor, William Eibel, discovered that unequal speeds of paper stock and wire produced a defective paper product when the paper-making machine was operated at high speed. *Eibel Process Co.*, 261 U.S. at 67-68. Eibel's solution was to raise the pitch of the wire to equalize the speeds of the paper stock and wire by gravity. *Id*. at 64. The prior art taught that the pitch of the wire could be changed – albeit for a different purpose and to a different degree. *Id*. at 58.

The Supreme Court upheld the validity of the claims and characterized Eibel's invention as "the discovery of the source [of trouble] not before known and the application of the remedy." *Id*. at 68. Thus, *Eibel Process* established that the discovery of the previously unknown source of a problem can form the basis of a non-obvious invention – even if the ultimate solution to the problem is routine. *Id*.; *see also In re Sponnoble*, 405 F.2d 578, 585 (C.C.P.A. 1969) ("[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified.").

Eibel Process teaches that the discovery of a previously unknown source of a problem must be considered as part of an obviousness analysis: "The rationale of the *Eibel* case requires that we consider the unobvious cause of the problem solved, as well as the solution proposed, in arriving at a final determination of whether the invention claimed is 'obvious' within the meaning of section 103." *See In re Conover*, 304 F.2d 680, 684 (C.C.P.A. 1962). In such circumstances, the court has framed the obviousness inquiry as "whether the prior art recognized the cause of the problem." *In re Sponnoble*, 405 F.2d at 581 (emphasis in original); *see also In re Peehs*, 612 F.2d 1287, 1290 (C.C.P.A. 1980).

Eibel's claims were "an improvement on a machine." *Eibel Process Co.*, 261 U.S. at 70. And Eibel was entitled to patent his improved machine because he discovered the source of a problem associated with prior art machines. Similarly,

Purdue's claims are to an improved oxycodone product having low levels of the 14-hydroxy impurity, and Purdue also claimed the source of the reoccurring problem of the 14-hydroxy impurity – 8α produced during the manufacturing process. Yet, the panel held that the claimed discovery of this source of the problem could not be considered in an obviousness analysis.

There is no principled reason that the discovery of a previously unknown source of a problem, which must be considered in connection with all other types of claims, cannot be considered in connection with claims covering an improved "end product." *See Sponnoble*, 405 F.2d at 585. Indeed, prior to the panel decision, the principle espoused in *Eibel Process* has not been limited to claims that recite the remedy, nor has it been found inapplicable to "end product" claims. To the contrary, this Court and its predecessor have consistently applied the rationale of *Eibel Process* to uphold the validity of claims to an improved "end product."

II. A RESTRICTION ON *EIBEL PROCESS* IS CONTRARY TO THE PRECEDENT OF THIS COURT AND ITS PREDECESSOR.

Following *Eibel Process* and its progeny, including *Sponnoble* and *Conover*, the Court of Customs and Patent Appeals ("CCPA") held in *In re Roberts*, 470 F.2d 1399 (C.C.P.A. 1973), that a claim directed to an improved end product was not obvious where the inventors recognized the source of a problem with similar prior art products. Roberts' claims recited an end product – a "[c]orrugated polyethylene terephthalate film having a surface coefficient of friction of less than

about 0.40." *Id*. at 1400. The corrugated films of the prior art were difficult to store because they did not easily form rolls. *Id*. The inventors discovered that a high surface coefficient of friction was the source of the problem of poor roll formation. *Id*. The specification disclosed that the surface coefficient of friction could be lowered by (1) including a filler, (2) mechanically treating the film surface, or (3) applying a lubricant to the film surface. *Id*. None of these remedies, however, were recited in the end product claims. Nevertheless, the CCPA concluded that "[t]he unobvious aspect of this invention resides in the recognition of the source of the problem, i.e., that too high a surface coefficient of friction is responsible for poor roll formation." *Id*. at 1401. In stark contrast to the panel decision here, the CCPA did not require the patent claims to recite a particular method for creating the corrugated film product nor did it require the patent claims to recite any of the proposed remedies to the problem of poor roll formation.

Similarly, in *In re Tanczyn*, the CCPA held that claims directed to an improved end product – stainless steel products substantially free of surface defacing silicate inclusions – were not obvious. 202 F.2d 785, 787-788 (C.C.P.A. 1953). Earlier stainless steel products were susceptible to surface defects such as black spots, blisters, pits and inclusion lines. *Id*. at 785. Tanczyn discovered that these surface defects were caused by silicate inclusions and could be eliminated by minimizing the manganese content. *Id*. The CCPA used the rationale of *Eibel*

Process to reverse the agency's determination that the claims to the improved stainless steel products were unpatentable over the prior art: Tanczyn discovered the cause of a problem and the prior art had not "recognized that such a problem existed, [n]or . . . attempted to trace its source." *Tanczyn*, 202 F.2d at 787.

This Court has likewise applied the rationale of *Eibel Process* to claims to improved end products, including pharmaceutical compositions, without requiring that the steps to achieving the end product be claimed. *See, e.g., Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1356-57 (Fed. Cir. 2013). The claims in *Leo* recited a "pharmaceutical composition for dermal use" and included a vitamin D analog and a corticosteroid. *Leo Pharm.*, 726 F.3d at 1349. Though the prior art disclosed formulations including both of these compounds, the inventors discovered that the prior art formulations were not storage stable. *Id*. at 1354. As a result, this Court found that Leo's claimed improved pharmaceutical composition would not have been obvious to persons of ordinary skill in the art "because they would not have recognized the [storage stability] problem." *Id*. at 1356-1357.

The panel decision here conflicts with binding precedents, which establish that discovery of an unknown source of a problem is relevant to the obviousness inquiry not only for claims directed to a particular method, but also for claims directed to an end product. This Court should grant *en banc* review to correct – or clarify – the unnecessary limitation of *Eibel Process*.

III. A RESTRICTION ON *EIBEL PROCESS* IS CONTRARY TO WELL-SETTLED PRINCIPLES OF OBVIOUSNESS.

A. Rigid Rules for Obviousness Are Prohibited.

Restricting *Eibel Process*, such that it cannot be applied to end product claims, is not only incorrect and contrary to precedent, but contravenes the Supreme Court's prohibition on a rigid, inflexible approach to obviousness.

The Supreme Court consistently favors flexibility over rigidity, particularly in the obviousness analysis. *See KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 419-22 (2007). In *KSR*, the Supreme Court reviewed this Court's use of a rigid "teaching, suggestion, or motivation" test. 550 U.S. at 407. The Court observed that the obviousness analysis entails "an expansive and flexible approach" and, accordingly, rejected the "rigid rule that limits the obviousness inquiry." *Id*. at 415-419. This Court has acknowledged that it cannot "cling to formalistic rules for obviousness" in the face of *KSR*. *In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009). Yet, the panel decision does just that by creating a bright line rule that the principle of *Eibel Process* does not apply to end product claims.[3] The rigid, categorical disregard of the principle of *Eibel Process* is precisely the kind of approach that was emphatically rejected in *KSR*.

[3] This brief does not address product-by-process aspect of the panel decision. Nevertheless, the decision to disregard the process limitations as "immaterial to the obviousness analysis" further supports the idea that the panel decision could be read to create a rigid, inflexible rule that excludes consideration of the discovery of an unknown and unobvious source of a problem for end product claims.

B. The Claimed Invention As a Whole Must Be Considered.

Section 103 requires a determination as to whether the "claimed invention as a whole would have been obvious." *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363, 1372 (Fed. Cir. 2013) (emphasis added); *see also* 35 U.S.C. § 103(a). In *Sponnoble*, the CCPA stated:

> [A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the "subject matter as a whole" which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103.

405 F.2d at 585; *see also Peehs*, 612 at 1290.

Obvious analyses that fail to consider an unknown problem or an unknown cause of a problem have been repeatedly rejected. *See Tanczyn*, 202 F.2d at 787; *Leo Pharm.*, 126 F.3d at 1355 ("By brushing aside the storage stability issue, the Board erred by collapsing the obviousness analysis into a hindsight-guided combination of elements."). Thus, when an inventor discovers the cause of a problem and subsequently provides a solution, "the determinative question is whether that cause would have been recognized by one of ordinary skill in the art." *See Peehs*, 612 F.2d at 1290; *see also Sponnoble*, 405 F.2d at 586 ("The question here is whether the prior art recognized the cause of the problem.").

By excluding consideration of the discovery of an unknown and unobvious source of a problem for "end product" claims, the panel decision contravenes the

well-established principle that the obviousness inquiry must take into consideration the claimed invention as a whole.

IV. A RESTRICTION ON *EIBEL PROCESS* WOULD PRODUCE UNINTENDED AND UNDESIRABLE CONSEQUENCES.

A rigid rule that *Eibel Process* cannot be applied to end product claims would work significant damage on innovation by making it more difficult for innovators to protect significant advancements and improvements. The panel decision forecloses patentability for a vast number of improvement patents. The massive research and development to improve existing technologies, including pharmaceutical products, exemplifies the "progress of . . . useful Arts" that the patent system is intended to promote. The public derives great benefit from improvements that make pharmaceutical products safer (*e.g.*, by reducing levels of toxic impurities) or easier to administer (*e.g.*, oral versus intravenous). The ability of any innovator, not just the developer of the original product, to obtain a patent upon an improvement promotes innovation and competition. With the weakening of the patent incentive for improvements, the loser is the public.

CONCLUSION

The amicus supports the petitioner to the extent that it seeks rehearing *en banc* to clarify that that *Eibel Process* can be applied to end product claims.

Date: April 15, 2016

Respectfully submitted,

/s/ *Kevin A. O'Connor*

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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 2,521 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 2007 and 14-point Times New Roman font.

Dated: April 15, 2016

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CERTIFICATE OF SERVICE

I, Kevin A. O'Connor, hereby certify that on April 15, 2016, I electronically filed the foregoing BRIEF OF THE INTELLECTUAL PROPERTY LAW ASSOCIATION OF CHICAGO AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR REHEARING EN BANC with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the Court's CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the CM/ECF system.

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