2013-1306

United States Court of Appeals for the Federal Circuit

BRISTOL-MYERS SQUIBB COMPANY,

Plaintiff-Appellant,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellee.

Appeal from the United States District Court for the District of Delaware in No. 10-CV-0805, Magistrate Judge Christopher J. Burke.

BRIEF OF INTELLECTUAL PROPERTY OWNERS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF BRISTOL-MYERS SQUIBB COMPANY'S PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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July 28, 2014

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Bristol-Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc., 2013-1306

CERTIFICATE OF INTEREST

Counsel for the Amicus Curiae, Intellectual Property Owners Association, certifies the following (use "None" if applicable; use extra sheets if necessary):

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

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None

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:

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

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July 28, 2014

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The Intellectual Property Owners Association (IPO) submits this brief as an amicus curiae pursuant to Fed. R. App. P. 29 and Rule 29 of this Court. IPO takes no position on the underlying merits of the appeal. IPO supports the petition for rehearing en banc filed by Bristol-Myers Squibb Company (BMS) to seek clarity on the important legal issues discussed herein affecting the validity of issued patents and pending patent applications.

INTEREST OF AMICUS CURIAE

Founded in 1972, amicus curiae IPO is a trade association representing companies and individuals in all industries and fields of technology who own intellectual property.[1] IPO's members include more than 200 companies and over 12,000 individuals involved through their companies or individually. IPO regularly represents the interests of its members before Congress and the United States Patent and Trademark Office (USPTO) and has filed amicus curiae briefs in this Court and other courts on issues of intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the Appendix.[2]

SUMMARY OF ARGUMENT

Considering whether an issued patent should be held invalid for obviousness, the panel decision in this appeal raises two broadly applicable legal questions,

[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae* or its counsel made a monetary contribution to its preparation or submission. This brief is being filed with a motion for leave to file it.

[2] IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

deviating from this Court's precedents, and calling out for clarity from the en banc court. IPO supports BMS's petition to the extent that it raises these questions.

First, how should courts and the USPTO treat objective evidence probative of non-obviousness when that evidence becomes known *after* the time of invention or patenting? A line of cases holds that differences between a claimed compound and the prior art may be relevant evidence of non-obviousness *even if* those differences are discovered after the patent application is filed or granted. The panel here apparently took a contrary position. It ruled that evidence of the prior art's toxicity as compared to the (non-toxic) inventive compound was not a relevant difference and the non-toxicity of the inventive compound did not constitute a relevant "unexpected result" because the prior art's toxicity was not known at the time of invention.

Second, is it appropriate to use presumptions arising from patent *prosecution* when judging validity, on the ground of obviousness or non-obviousness, of issued patents in *litigation*? This Court recently explained why such "burden-shifting" presumptions applicable in prosecution should not apply in litigation. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1080 n.7 (Fed. Cir. 2012) (*Cyclobenzaprine*). Yet this Court has often applied such presumptions in ruling on the validity of issued patents. At best, this causes confusion; at worst, it undermines the statutory presumption of validity.

En banc resolution of these questions would improve clarity and predictability across the board; thereby strengthening patent protection in its role of driving the U.S. economy.

ARGUMENT

I. THE EN BANC COURT SHOULD CLARIFY THE STANDARD FOR CONSIDERING EVIDENCE OF NON-OBVIOUSNESS FIRST DISCOVERED POST-FILING, PARTICULARLY AS TO UNEXPECTED RESULTS OF CHEMICAL COMPOUNDS.

As the Supreme Court framed the obviousness inquiry:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. [*Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)].
>
> While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls. If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103.

KSR Int'l. Co. v. Teleflex, Inc., 550 U.S. 398, 406-407 (2007). As this Court recently restated the matter:

> Obviousness is a question of law based on underlying factual findings: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective considerations of nonobviousness.

Cyclobenzaprine at 1968 (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)).

With respect to the determination of probative underlying facts regarding patents to chemical compounds, this Court and its predecessor have long recognized that "[f]rom the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing." *In re Papesch*, 315 F.2d 381, 391 (C.C.P.A. 1963) (Rich, J.). *Papesch* reversed the USPTO's rejection of an application claiming a compound. The USPTO based its rejection on the compound's structural similarity to prior art, ignoring unexpected properties of the new compound. The Court reversed: "the thing that is patented is not the formula but the compound identified by it. And the patentability of the thing does not depend on the similarity of its formula to that of another compound but of the similarity of the former compound to the latter. There is no basis in law for ignoring any property in making such a comparison." *Id.*

This Court has held repeatedly that evidence establishing the differences between inventive compounds and the prior art are relevant facts underlying the four factor inquiry of *Graham*, even if these properties or benefits are later-discovered. "There is no requirement that an invention's properties and advantages were fully known before the patent application was filed…." *Knoll Pharm. Co., Inc. v. Teva Pharms. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004). Thus, "evidence of unexpected results may be used to rebut a case of prima facie obviousness even if

that evidence was obtained after the patent's filing or issue date." *Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc.*, 655 F.3d 1291, 1307 (Fed. Cir. 2011). Earlier this year, the Court again confirmed that an invention's "later-discovered benefits" could be probative of non-obviousness. *Sanofi-Aventis Deutschland GmbH v. Glenmark Phams. Inc., USA*, 748 F.3d 1354, 1360 (Fed. Cir. 2014) ("patentability may consider all of the characteristics possessed by the claimed invention, whenever those characteristics become manifest"). Hence, it appeared settled that the facts evidencing unexpected results of the claimed compound in comparison to the prior art, bearing on the obviousness or non-obviousness of the inventive matter, need not be known or fully understood at the time of the invention. Moreover, this appeared consistent with the admonition that "the overall obviousness inquiry must be expansive and flexible." *Cyclobenzaprine* at 1069 (citing *KSR*, 550 U.S. at 415, 419).

The panel decision here apparently pronounced and applied a different standard that threatens settled expectations regarding obviousness. The panel's discussion of unexpected results begins by stating: "To be particularly probative, evidence of unexpected results must establish that there is a difference between the results obtained and those of the closest prior art, and that the difference would not have been expected by one of ordinary skill in the art *at the time of the invention*." (emphasis added). In support, the panel opinion cites *Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963, 970 (Fed. Cir. 2006) and *Pfizer Inc. v. Apotex, Inc.*, 480 F.3d

1348, 1371 (Fed. Cir. 2007). *Kao* and *Pfizer* did not, however, concern later-discovered differences between the claimed invention and the prior art, and did not expressly state that the Court should only consider what facts were known "at the time" of the invention. *See id.* To the contrary, the Court more recently explained that "[a]lthough the Section 103 analysis remains properly focused 'at the time the invention was made,' it would be error to prohibit a patent applicant or patentee from presenting relevant indicia of nonobviousness, whether or not this evidence was available or expressly contemplated at the filing of the patent application." *Genetics Institute*, 655 F.3d at 1307.[3] Yet here the panel (like the district court) did not credit the apparently undisputed, surprising, and unexpected evidence of the difference in toxicity between the claimed invention and the prior art, solely because that difference was not known at the time the application was filed. Op. 17; J.A. 30-33, 36-37, 150.

This decision introduces substantial uncertainty into what appeared to be a clear legal standard; allowing this uncertainty to fester would affect countless pending and future cases. Obviousness is an issue in most patent examinations, litigations, and administrative proceedings. Particularly in unpredictable chemical

[3] This Court has regularly looked at post filing events to assess obviousness. *See, e.g., Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1352 (Fed. Cir. 2010) (affirming the district court's denial of a motion for judgment as a matter of law on the question of patent invalidity for obviousness and noting evidence of copying and praise by competitors); *see also Apple Inc. v. ITC*, 725 F.3d 1356, 1367 (Fed. Cir. 2013) (highlighting evidence of commercial success, copying by competitors, and media and industry praise of the invention).

and pharmaceutical fields, unexpected results evidencing differences and objective considerations can tip the balance between obviousness and non-obviousness. Patent owners would benefit from the certainty of an en banc ruling on when and how later-discovered differences between an invention and prior art may be considered in the obviousness analysis.

II. THE EN BANC COURT SHOULD CLARIFY WHETHER COURTS JUDGING THE VALIDITY OF ISSUED PATENTS SHOULD USE PRESUMPTIONS ARISING FROM A PATENT PROSECUTION CONTEXT.

Under 35 U.S.C. § 282, an issued patent is presumed valid and a challenger must overcome that presumption by clear and convincing evidence to prevail on an invalidity defense. *See Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2245 (2011); *accord Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2130 (2014). The challenger of an issued patent retains the burden of overcoming the presumption of validity (by clear and convincing evidence) even where the challenger's invalidity claims present new evidence that was not brought before the USPTO. *Microsoft*, 131 S. Ct. at 2250. Patent applications enjoy no such presumption. Rather, before a patent issues, the USPTO must determine by a preponderance of the evidence that the application claims are, *inter alia*, neither anticipated nor obvious over the prior art.

Nonetheless, decisions judging the validity of issued patents often reference or apply burden-shifting presumptions derived from patent prosecution appeals. For

example, in reviewing an obviousness determination made by the USPTO *during patent prosecution*, this Court held that "structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness, *and that the burden (and opportunity) then falls on an applicant to rebut that prima facie case*." (Emphasis added.) *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc). Yet "prima facie" obviousness based on structural similarity also appears in decisions involving *issued* patents, including the panel decision here. Op. 14. ("[T]he presumption is that similar compositions have similar properties") (quoting *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995), an appeal from a patent prosecution). The panel cites in support two appeals involving issued patents – however these cases ultimately draw this principle from *In re Dillon*. *See Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356 (Fed. Cir. 2007) (citing on this point *In re Dillon* and two other appeals from Board of Patent Appeals and Interferences decisions involving patent applications); *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1007 (Fed. Cir. 2009) (citing *In re Dillon*). What is *not* clear is whether this "prima facie" case shifts the burden of rebuttal to the patent owner, as it does to a patent applicant per *In re Dillon*.

The idea of burden-shifting also appears in many Federal Circuit opinions concerning objective considerations of non-obviousness. *See Cyclobenzaprine*, 676

F.3d at 1076 n.3 (collecting cases). *Cyclobenzaprine* acknowledged an inconsistency in prior obviousness decisions:

> While many panels of this court have [considered all objective evidence *before* reaching an obviousness conclusion], some instead have spoken of the obviousness analysis in terms of a "prima facie" case which *must then* be "rebutted" by the patentee. Under that framework, a court inquires whether the party challenging validity has proven a "prima facie" case of obviousness, based only on reference to the patent and the proffered prior art, and only then considers objective evidence, asking whether such evidence is sufficient to overcome the prima facie case.

Id. at 1076 (emphasis added). *Cyclobenzaprine* traced this notion of "rebutting" a "prima facie" case of obviousness back to "the test employed in appeals from the Board of Patent Appeals and Interferences." *Id.* at 1080 n.7. Notwithstanding, *Cyclobenzaprine* looked to prior Court decisions and rejected the use of burden shifting presumptions in determining obviousness:

> In *Stratoflex, Inc. v. Aeroquip Corp.* [713 F.2d 1530, 1538-39 (Fed. Cir. 1983)], we held that a fact finder in district court litigation may not defer examination of the objective considerations until after the fact finder makes an obviousness finding.
>
> > It is jurisprudentially inappropriate to disregard any relevant evidence on any issue in any case, patent cases included. Thus evidence rising out of the so-called "secondary considerations" must always when present be considered en route to a determination of obviousness…. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.

Cyclobenzaprine, 676 F.3d at 1075-76.

Citing to burden-shifting principles originating in patent prosecution when judging the validity of issued patents creates confusion and undermines the presumption of validity. The en banc court should address this issue and clarify that, as the burden of proving invalidity always remains with the challenger, no "presumption" or "prima facie case" drawn from the prior art ever shifts the burden of proof to the patentee to come forward with objective considerations "rebutting" the presumption and proving validity. As explained in *Cyclobenzaprine*, "courts should not apply the burden-shifting framework for patentability appeals to invalidity determinations appealed from a district court, however, because the prosecution and litigation contests are distinct," both given the presumption of validity and the procedural differences between prosecution and litigation. *Id.* at 1080 n.7.

CONCLUSION

For all of the foregoing reasons, IPO respectfully requests that this Court grant BMS's petition and rehear this matter en banc.

RESPECTFULLY SUBMITTED,

/s/ Robert M. Isackson

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APPENDIX

APPENDIX[1]

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CERTIFICATE OF SERVICE

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by INTELLECTUAL PROPERTY OWNERS ASSOCIATION, Amicus Curiae to print this document. I am an employee of Counsel Press.

On **July 28, 2014** counsel for Amicus Curiae has authorized me to electronically file the foregoing **Brief for Amicus Curiae** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to all counsel registered as CM/ECF users, including any of the following:

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Paper copies will also be mailed to the above principal counsel on this date.

Unless otherwise noted, sixteen copies will be sent to the Court, via overnight delivery, within the time provided in the Court's rules.

July 28, 2014

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