NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

MERCK SERONO S.A.,
Appellant

v.

TWI PHARMACEUTICALS, INC.,
Appellee

2025-1463, 2025-1464

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2023-00049, IPR2023-00050.

Decided: October 30, 2025

MARK CHRISTOPHER FLEMING, Wilmer Cutler Pickering Hale and Dorr LLP, Boston, MA, argued for appellant. Also represented by JAMES M. LYONS, EMILY R. WHELAN; DAVID B. BASSETT, GARY M. FOX, JENNIFER L. GRABER, New York, NY; HELENA RACHAEL MILLION-PEREZ, Denver, CO; NORA N. XU, Washington, DC.

PHILIP D. SEGREST, JR., Husch Blackwell LLP, Chicago, IL, argued for appellee. Also represented by DONALD J. MIZERK; STEPHEN REID HOWE, Milwaukee, WI.

Before HUGHES, LINN, and CUNNINGHAM, *Circuit Judges*.

LINN, *Circuit Judge*.

This case is a companion case to *Merck Serono S.A. v. Hopewell Pharma Ventures, Inc.*, No. 2025-1210, -1211, (Fed. Cir. argued July 11, 2025; decided Oct. 30, 2025) (hereinafter *Hopewell*), argued on the same day and decided contemporaneously herewith.

Merck Serono S.A. ("Merck") appeals the determinations by the Patent Trial and Appeal Board ("Board") in two inter partes reviews ("IPR") that claims 36, 38, 39, and 41–48 of Merck's U.S. Patent No. 7,713,947 ("'947 patent") and claims 17, 19–20, and 22–29 of Merck's U.S. Patent No. 8,377,903 ("'903 patent") are unpatentable as obvious (collectively "patents-in-suit"). *TWi Pharms., Inc. v. Merck Serono SA*, IPR2023-00049 (P.T.A.B. Dec. 18, 2024) (addressing U.S. Pat. No. 7,713,947) (hereinafter "FWD"); *TWi Pharms., Inc. v. Merck Serono SA*, IPR2023-00050 (P.T.A.B. Dec. 18, 2024) (addressing U.S. Pat. No. 8,377,903). The parties argue all claims of both patents together, and, unless otherwise stated, we reference the Board's FWD in IPR2023-00049 exclusively in this opinion.

Because Bodor is prior art based on our analysis in *Hopewell*, and because we see no legal or factual errors in the Board's analysis in this case, we *affirm*.

BACKGROUND

I

The background of the development of the patents-in-suit is largely the same as laid out in *Hopewell* and we refer the parties thereto for a more comprehensive statement of facts. In brief, Merck partnered with generic manufacturer and formulator IVAX to develop oral cladribine to treat

multiple sclerosis ("MS"), a chronic disease of the central nervous system. Under their joint research agreement, Merck would "'conduct clinical trials' to determine 'the dose, safety, and/or efficacy'" of cladribine oral tablets, and IVAX would "develop an oral dosage formulation of [cladribine] in tablet or capsule form suitable for use in clinical trials and commercial sale." J.App'x 6076 (Munafo Decl. at ¶¶ 24–25).

On October 14, 2004, IVAX employees Drs. Bodor and Dandiker filed PCT application PCT/US2004/009387,[1] which later became U.S. Patent No. 7,888,328 ("Bodor"), titled "Oral Formulations of Cladribine." Bodor[2] includes the following key passage that the parties refer to as the "seven-line disclosure":

> At the present time, it is envisioned that, for the treatment of multiple sclerosis, 10 mg of cladribine in the instant complex cladribine-cyclodextrin complex in the instant solid dosage form would be administered once per day for a period of five to seven days in the first month, repeated for another period of five to seven days in the second month, followed by ten months of no treatment.

Bodor, col. 13, ll. 19–25.[3]

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[1] The PCT application is the primary reference in the companion *Hopewell* case. For purposes of this appeal, the PCT Application and the U.S. Patent to Bodor are substantively identical.

[2] This opinion refers to the U.S. Patent as "Bodor," and refers to its author Dr. Bodor as "Dr. Bodor."

[3] In the companion 2025-1210 case, the parties refer to the same disclosure as the "six-line disclosure" or,

II

Within a year of Bodor's filing, on December 22, 2004, Merck filed the applications to which the patents-in-suit claim priority. Both patents list as inventors: Drs. De Luca, Ythier, Munafo, and Lopez-Bresnahan (collectively, "named inventors"), all of whom were employees of Serono and, in at least some way, were a part of the development team that developed the claimed oral cladribine regimen. The '947 patent issued in 2010, and the '903 patent issued in 2013.

In representative claim 36 of the '947 patent, Merck claimed the dosing regimen as follows:

> 36. A method of treating multiple sclerosis comprising the oral administration of a formulation comprising cladribine following the sequential steps below:
>
> (i) an induction period lasting from about 2 months to about 4 months wherein said formulation is orally administered and wherein the total dose of cladribine reached at the end of the induction period is from about 1.7 mg/kg to about 3.5 mg/kg;
>
> (ii) a cladribine-free period lasting from about 8 months to about 10 months, wherein no cladribine is administered;
>
> (iii) a maintenance period lasting from about 2 months to about 4 months, wherein said formulation is orally administered and wherein the total dose of cladribine reached at the end of the maintenance period is about 1.7 mg/kg;
>
> (iv) a cladribine-free period wherein no cladribine is administered.

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sometimes, the "one-line disclosure." All of these characterizations refer to the same quoted language in Bodor.

Claim 17 of the '903 patent is substantively identical for purposes of this appeal. Dependent claims in both patents further limit "the total dose of cladribine reached at the end of the induction period" to "about 1.7mg/kg." '947 patent, Cl. 39; '903 patent, Cl. 20.

Claim 47 in the '947 patent depends from claim 36, and adds the limitation: "wherein the steps (iii) to (iv) are repeated at least one or two times." Claim 48 in the '947 patent also depends from claim 36, adds the limitation "wherein the formulation is administered in combination with interferon-beta." The limitations are identically echoed in claims 28 and 29 (both depending from claim 17) of the '903 patent.

The parties argue all claims of both patents together.

III

TWi Pharmaceuticals, Inc. ("TWi") filed IPRs challenging claims 36, 38, 39, and 41–48 of the '947 patent in IPR2023-00049, and challenging claims 17, 19–20, and 22–29 of the '903 patent in IPR2023-00050 on three grounds: anticipation over Bodor; obviousness over Bodor and the knowledge of persons of ordinary skill; and obviousness over Bodor and Rice.[4] The challenged claims here largely overlap with those held unpatentable in the companion *Hopewell* appeal, except for claims 47 and 48 of the '947 patent and claims 28 and 29 of the '903 patent, which were not challenged in *Hopewell*.

Rice, incorporated by reference into Bodor, col. 13, ll. 5–8, is a publication discussing a double-blind clinical study on subcutaneous administration of cladribine on

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[4] Rice et al., "Cladribine and progressive MS: clinical and MRI outcomes of a multicenter controlled trial." *Neurology*, 54(5): 1145-55 (2000). J.App'x 2254–64.

patients with the progressive form of MS. Rice disclosed treatment cycles of administering placebo or cladribine at 0.07mg/kg per day for five consecutive days every four weeks for either two or six cycles, followed by placebo for a total of eight cycles. J.App'x 2254–56. Rice included an open label follow-up retreatment phase for patients who showed "evidence of disease progression" and "fulfilled the hematologic dosing criteria" with further doses administered "at least 12 months" after the last dose of cladribine. J.App'x 2255.

In its FWD, the Board held that all challenged claims were unpatentable as obvious over Bodor in view of Rice and *not* unpatentable as anticipated. The Board did not reach the alternative ground that the claims were unpatentable as obvious over Bodor in light of the knowledge of persons of ordinary skill in the art. J.App'x 65 n.19. The Board also noted that "Patent Owner raises no separate argument for any of the dependent claims." J.App'x 64.

The Board first considered whether Bodor was prior art. Because Bodor names entirely different authors than the named inventors, the Board shifted the burden of production to patentee "to come forward with evidence sufficient to support the proposition that Bodor is not prior art." J.App'x 23 (citing, inter alia, *Google LLC v. IPA Techs. Inc.*, 34 F.4th 1081, 1085–86 (Fed. Cir. 2022)).

To show that Bodor was not prior art, the Board sought evidence that the seven-line disclosure in Bodor was not "by another," which the Board said required "credible and corroborated evidence that each named inventor [of the patents] Munafo, Lopez-Bresnahan, Ythier, and De Luca provided an inventive contribution to the 7-line dosing regimen." J.App'x 23; *see also* J.App'x 26 (requiring evidence "that the disclosure was invented by the *same* 'inventive entity' as the '947 patent's challenged claims"). The Board rejected patentee's testimony from named inventor Dr. Munafo that the Board said was only enough to

show that "the team at Serono" contributed to the disclosure, but not what "any one of the named inventors, individually or as a group" contributed. J.App'x 24 (cleaned up).

On the merits, the Board held that the instituted claims were unpatentable as obvious over Bodor and Rice. The Board held that the seven-line disclosure "teaches or suggests" the induction period and cladribine-free period. J.App'x 40. The Board also found persuasive the testimony of Dr. Greenberg at J.App'x 2086–87 (¶¶ 110–113) that it summarized as follows: "MS is a disease without a cure that typically needs ongoing treatment and, reading Bodor in that context, [an ordinary artisan] would have thought to re-administer cladribine after the specified cladribine-free period." J.App'x 40. Moreover, the Board found that it would have been obvious to follow the maintenance phase with another cladribine-free period, based on Rice's following each treatment phase with a cladribine-free period and on Dr. Greenberg's testimony that such a period would help control drug toxicity. J.App'x 46–47; *see* J.App'x 2132–33 (Dr. Greenberg testimony at ¶¶ 196–98); J.App'x 2093 (¶ 124); J.App'x 2087–89 (¶¶ 113–18).

The Board found a reason to combine the references to reach the claimed induction, cladribine-free, retreatment and cladribine-free periods and a likelihood of success in such combination because "the symptoms of MS were likely to relapse and repeat" and ordinary artisans would logically repeat Bodor's induction dosing in the retreatment phase, J.App'x 49, at least for those patients who showed signs of relapse, J.App'x 51.

Merck timely appealed. We have jurisdiction to review the Board's final written decision after an IPR under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. §§ 141(c).

DISCUSSION

I

Whether a reference is a work "by another" for purposes of prior art is a question of law reviewed de novo, based on underlying facts reviewed for substantial evidence. *Google LLC*, 34 F.4th at 1085; *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 969 (Fed. Cir. 2014) ("The question of whether a reference is a work of others for the purposes of § 102(a) is, like that of inventorship, a question of law based on underlying facts."). We review whether the Board applied the correct law, a legal determination, de novo. *Princeton Vanguard, LLC v. Frito-Lay N. Am., Inc.*, 786 F.3d 960, 964 (Fed. Cir. 2015). Obviousness is a question of law based on underlying facts reviewed for substantial evidence. *Voice Tech Corp. v. Unified Pats., LLC*, 110 F.4th 1331, 1342 (Fed. Cir. 2024).

II

Most of Merck's arguments here parallel those it made in the related *Hopewell* case. Merck first argues that the Board applied an incorrect legal rule requiring complete identity of inventive entity to exclude a reference as the inventor's own work, whereas *Applied Materials, Inc. v. Gemini Res. Corp.*, 835 F.2d 279 (Fed. Cir. 1987), and the Manual of Patent Examining Procedure ("MPEP") exclude a reference from the prior art if a subset of inventors named in the patent authored the reference and no authors of the reference are excluded. TWi responds that the Board correctly applied the rule in *In re Land*, 368 F.2d 866 (CCPA 1966), requiring complete identity of inventive entity to exclude a reference from the prior art.

We agree with TWi. As we explained in our *Hopewell* decision, "when the patented invention is the result of the work of joint inventors, the portions of the reference disclosure relied upon must reflect the collective work of the same inventive entity identified in the patent to be

excluded as prior art," slip op. at 21, and "[a]ny incongruity in the inventive entity between the inventors of a prior reference and the inventors of a patent claim renders the prior disclosure 'by another,' regardless of whether inventors are subtracted or added to the patent," *id.* at 21–22 (citing *Land*, 368 F.2d at 879). This is the rule applied by the Board here, *see* J.App'x 20, 26; that rule is not erroneous.

Merck argues that the Board decision here is distinguishable from the Board's decision in *Hopewell* because the Board here did not consider the *Applied Materials* decision. *See Applied Materials*, 835 F.2d at 279. As we explained in *Hopewell*, we do not read *Applied Materials* as deviating from the rule set forth in *Land* and applied by the Board here. Slip op. at 14–18. This is therefore a distinction without a difference.

Next, like in the *Hopewell* case, Merck demands a vacatur of the Board's decision because, it says, the Administrative Procedures Act ("APA") requires the Board to provide an opportunity to submit rebuttal arguments and evidence to address the Board's surprise adoption of its bright-line rule, in violation of the MPEP. We disagree for the reasons set forth in *Hopewell*. Slip op. at 22–25.

Next, like in the *Hopewell* case, Merck argues that the Board erroneously shifted the burden of persuasion to Merck to show the named inventors' contributions to the Bodor disclosure. Again, we disagree for the reasons set forth in *Hopewell*. Slip op. at 27.

Relatedly, Merck argues that the Board legally erred in its corroboration analysis, erroneously requiring corroborated evidence of particular contributions by each inventor rather than applying the rule of reason in light of all the evidence. That the board here found a lack of evidence of corroboration with respect to *all* the inventors does not distinguish this case from *Hopewell*: it is enough that there is insufficient corroborated evidence of De Luca's contribution, as we affirmed in *Hopewell*. *Id.* at 25–27. Merck does

not identify any additional evidence here that would show legal (or factual) error in the Board's analysis of De Luca's contribution. We reject this argument for the reasons discussed in *Hopewell*. *Id.*

As in the *Hopewell* case, we need not and do not address Merck's additional argument that the Board erred in concluding that Drs. Bodor and Dandiker were co-inventors of the Bodor disclosure. *Id.* at 27.

III

Merck next argues that even if Bodor is prior art, that the Board lacked substantial evidence that the combination of Bodor and Rice rendered the claimed invention obvious.

In *Hopewell*, this court affirmed the Board's determination that claims 36, 38, 39, and 41–46 of the '947 patent and claims 17, 19–20, and 22–27 of the '903 patent were unpatentable as obvious over the Bodor PTC application and the Stelmasiak reference. *Id.* at 28–33.

Merck makes several arguments that largely parallel those made in the companion *Hopewell* decision. First, Merck argues that neither reference suggested the claimed retreatment period regimen after an 8–10 months no-treatment period because: (1) the Board's finding that Bodor does not disclose the retreatment period for purposes of anticipation is internally inconsistent with its later determination that Bodor *suggests* retreatment, *compare* J.App'x 34–35 *with* J.App'x 45; (2) Bodor's time-limited cladribine-free period does not imply retreatment with cladribine; and (3) Rice does not disclose automatic retreatment except when certain safety criteria are met, and, even then, Rice does not disclose the particular dosing claimed regimen with 8–10 months of no treatment and a 1.7mg/kg total dose during retreatment.

We disagree with each of Merck's arguments. We see no internal inconsistency between the Board's finding that

Bodor does not expressly or inherently disclose retreatment and the Board's finding that Bodor suggests retreatment. J.App'x 44–45 (citing J.App'x 2086–89 (¶¶ 109, 111–16) (Greenberg Decl.) and J.App'x 3855 (¶ 39) (Greenberg Rebuttal Decl.)). Bodor says that practitioners should conduct "continuous clinical evaluations . . . to determine *subsequent therapy*," which will "aid and inform in evaluating whether to increase, reduce or continue a particular treatment dose." Bodor, col. 14, ll. 43–51 (emphasis added); *id.* at col. 13, ll. 24–30 (noting closed-ended periods of "ten months of no treatment" or "eighteen months of no treatment"). Moreover, Rice expressly teaches retreatment, as Merck admits. Appellant's Opening Br. 51 (citing Rice at J.App'x 2255) ("Rice contemplated re-treatment ***only*** when certain safety criteria were met" (emphasis in original)). That Rice discloses certain criteria prior to retreatment does not undermine Rice's disclosure of retreatment because the claims do not require that the retreatment be automatic, as we explained in *Hopewell*. Slip op. at 30-31**.**

The fact that Rice alone does not disclose the specific claimed dosing regimen is of no moment because it is the *combination* of the references that the Board held renders the claims obvious. "[O]ne cannot show non-obviousness by attacking references individually." *In re Keller*, 642 F.2d 413, 426 (CCPA 1981). Substantial evidence supports the Board's finding that the combination suggested using Bodor's initial treatment dosage "as a logical starting point in a maintenance phase" and optimizing from there, given the express statements in Bodor that "the therapeutically effective amount of cladribine administered herein may be lowered or increased by fine[-]tuning" and that "[t]herapeutically effective amounts [of cladribine] may be easily determined, for example, empirically by starting at relatively low amounts and by step-wise increments with concurrent evaluation of beneficial effect." J.App'x 45–46; Bodor, col. 13, ll. 31–40; J.App'x 2087–90 (¶¶ 111–18) (Greenberg Decl.). Substantial evidence supports the conclusion that

ordinary artisans could optimize the dosage for the retreatment phase as easily as for the initiation phase.

Merck argues that, unlike in *Hopewell*, TWi here did not argue that lymphocyte suppression was a result-effective variable, and the Board thus violated the APA by relying on that reasoning in support of its obviousness determination here. *See* Appellant's Opening Br. 57–58. The Board's optimization holding was primarily based on the text of Bodor and Dr. Greenberg's declaration, which adequately support the Board's decision. Moreover, Dr. Greenberg expressly noted that cladribine's "mechanism of action . . . was to induce death of lymphocytes," J.App'x 3845 (¶ 21), which undermines Merck's argument that TWi never raised the lymphocytes level as a basis to optimize the dosage.

Finally, Merck argues that the Board erred by discounting "somewhat" the weight of Merck's unexpected result because Merck did not compare the results to Bodor, the closest prior art. *See* J.App'x 62. Merck argues that it could not compare its product to Bodor because Bodor did not include any efficacy results. We disagree. Merck does not dispute that, if Bodor is prior art, it is the closest prior art. Therefore, as the Board correctly noted, the unexpected result analysis properly entails a comparison to Bodor. It is inapposite that Bodor did not include efficacy results—Merck carried the burden of production to show unexpected results. *See Zup, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1373 (Fed. Cir. 2018) ("[A] patentee bears the burden of production with respect to evidence of secondary considerations of nonobviousness."). Moreover, the Board considered Merck's evidence of unexpected results, assigning it "moderate weight" that was merely "somewhat" discounted. J.App'x 61–62. We see no error.

IV

The Board's decision here includes an unpatentability determination of claims 47 and 48 of the '947 patent and

claims 26 and 27 of the '903 patent, which were not challenged and thus not addressed directly in the *Hopewell* decision. Merck argues these claims together with the independent claims, and does not present any argument why we should treat these claims differently from the claims already held to be obvious.

V

Like in *Hopewell*, Merck argues that the claims here should be limited to covering weight-based dosing. We reject this argument for the reasons discussed in *Hopewell*. Slip op. at 33–34.

CONCLUSION

Because Bodor is prior art based on our analysis in *Hopewell*, and because we see no legal or factual errors in the Board's analysis in this case, we *affirm*.

AFFIRMED