Nos. 2025-1210, -1211

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

MERCK SERONO S.A.,

Appellant,

v.

HOPEWELL PHARMA VENTURES, INC.,

Appellee.

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2023-00480 and IPR2023-00481.

APPELLANT MERCK SERONO S.A.'S CORRECTED COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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December 1, 2025

CERTIFICATE OF INTEREST

Counsel for Appellant Merck Serono S.A. certifies the following:

1. Represented Entities. Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case.

Merck Serono S.A.

2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

Merck KGaA, Ares Trading S.A.

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

Merck KGaA

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

[X] Yes (file separate notice; see below) [ ] No [ ] N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). Please do not duplicate information. This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

Already filed.

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None.

Dated: December 1, 2025

/s/ David B. Bassett

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STATEMENT OF COUNSEL UNDER CIRCUIT RULE 40(C)(1)

Based on my professional judgment, I believe the panel decision is contrary to the following precedents of this Court or this Court's predecessor:

Applied Materials, Inc. v. Gemini Research Corp., 835 F.2d 279 (Fed. Cir. 1987);

Allergan, Inc. v. Apotex Inc., 754 F.3d 952 (Fed. Cir. 2014); and,

In re Kaghan, 387 F.2d 398 (C.C.P.A. 1967).

Based on my professional judgment, I believe that this appeal requires answers to the following precedent-setting questions of exceptional importance:

(i) Whether a disclosure of an invention may be treated as a disclosure "by others" or "by another" under 35 U.S.C. § 102(a), (e)[1] and thus as prior art to a patent filed within one year of the disclosure when nobody "other" than the patent's co-inventors contributed to the disclosure.

(ii) Whether the Administrative Procedure Act ("APA") entitles a party to notice and a fair opportunity to respond to an agency's decision to deviate from its longstanding administrative interpretation of law.

/s/ David B. Bassett
DAVID B. BASSETT

[1] Statutory references are to the pre-America Invents Act ("AIA") statute, which governs all patent applications with at least one claim with an effective filing date before March 16, 2013.

STATEMENT UNDER CIRCUIT RULE 40(B)(1)(E)

The panel overlooked or misapprehended Merck Serono's demonstration that the APA entitles Merck Serono to notice and an opportunity to respond to the Patent Office's deviation from its longstanding interpretation of law.

INTRODUCTION

An earlier reference is prior art to a patent when the disclosure is "by others" or "by another." 35 U.S.C. § 102(a), (e). The panel, seeking to "clarify … precedent" interpreting this language, ruled that a disclosure is "by another" even if nobody ***other*** than the patent's co-inventors conceived of the earlier disclosure. Op.2. The panel held that "[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." Op.21-22.[2] Under the panel's decision, inventors' own work disclosed to the public can be used against them as prior art merely because they collaborated with an additional co-inventor on an ultimate patent application within the one-year statutory grace period. Neither the statute nor precedent compels this unjust bright-line rule.

The statute provides that a reference is prior art only if its disclosure was the work of another ***not*** on the later-filed patent. In addition to contradicting the statutory language, the panel's interpretation conflicts with precedent stating that an earlier disclosure by ***one or more*** of the co-inventors is not necessarily prior art "by another," and is inconsistent with how other circuits and the Patent Office interpreted the law. Nor is there any sound policy reason to punish inventors who collaborate

[2] Emphases added unless otherwise noted.

with later inventors to promote the progress of science. The pre-AIA statute will continue to govern cases through at least 2039, and this issue may have significance beyond then if the panel's rule is similarly applied to the AIA. The full Court should clarify the law to secure uniformity of the Court's decisions and answer this precedent-setting question of exceptional importance.

In the alternative, rehearing is warranted because the panel overlooked or misapprehended Merck Serono's additional argument under the APA. The panel appears to have believed, at Appellee's urging, that Merck Serono sought to treat the Patent Office's interpretation of Section 102 in the Manual of Patent Examining Procedure as binding on this Court. *E.g.*, Op.24. That was not Merck Serono's argument. Rather, Merck Serono invoked the MPEP's statements—which the panel did not deny support Merck Serono's legal position—as the reason why Merck Serono developed the evidentiary record it did and sought to carry its burden of production under the MPEP's interpretation. While the Patent Office was permitted to announce a new interpretation differing from the MPEP's (assuming consistency with Section 102), the APA requires notice of that change and an opportunity to build a record to meet it. Even if the rule applied here were correct, it was

inconsistent with longstanding agency practice on which Merck Serono relied. Merck Serono is entitled to a remand to develop a record satisfying that rule.[3]

BACKGROUND

Four scientists from Serono (Merck Serono's predecessor) are co-inventors on two patents claiming dosing regimens treating multiple sclerosis. Op.6. Earlier work by Serono's own scientists was described (but not claimed) in a patent application ("Bodor") published less than one year before Serono's co-inventors applied for the patents-at-issue. Op.5.

There is no dispute that the disclosure was attributable to ***at least one*** of Serono's co-inventors, Dr. Munafo. Specifically, Dr. Munafo submitted a declaration explaining that the pertinent disclosure was invented by the Serono team, not the others named on the Bodor application, Drs. Bodor and Dandiker, who claimed a different invention. Op.4. Drs. Bodor and Dandiker worked for a different company (IVAX) and learned of the dosing method under a confidential joint development agreement. They testified that they did ***not*** invent the relevant subject matter; the Serono scientists did.

[3] The panel issued a companion decision in *Merck Serono S.A. v. TWi Pharmaceuticals, Inc.*, 2025 WL 3034165 (Fed. Cir. Oct. 30, 2025). Merck Serono separately petitions for rehearing in *TWi* for the panel to apply the same disposition warranted here.

The record did not develop the specific contribution of one Serono co-inventor, Dr. De Luca, to the disclosure, as this was unnecessary under the statute's language, precedent, and the agency's longstanding interpretation, which focus on whether "one or more" co-inventors conceived of the disclosure. *E.g.*, *Applied Materials, Inc. v. Gemini Rsch. Corp.*, 835 F.2d 279, 281 (Fed. Cir. 1987) ("Even though an application and a patent have been conceived by different inventive entities, if they share ***one or more*** persons as joint inventors, the 35 U.S.C. § 102(e) exclusion for a patent granted to 'another' is not necessarily satisfied."); MPEP § 2132.01 ("An inventor's or ***at least one joint inventor's*** disclosure of his or her own work within the year before the application filing date cannot be used against the application as prior art."); MPEP §§ 715.01, 716.10, 2136.05(b).

At Appellee's urging, however, the Patent Trial and Appeal Board held that Bodor qualifies as prior art unless the inventors of the relevant disclosure were ***exactly the same*** as the patents' co-inventors. Appx30; Appx37. The Board first adopted this rule in its Final Written Decisions, such that Merck Serono had no opportunity to build a record to satisfy the rule by providing evidence of each Serono co-inventor's contributions to the disclosure.

Merck Serono appealed, arguing that the Board's rule was inconsistent with the statute and precedent. Merck Serono did not argue that the MPEP trumped this Court's decisions. Rather, Merck Serono argued in the alternative that, even if the

Board's deviation from the MPEP were legally correct, the APA permitted Merck Serono to rely on the MPEP in agency proceedings. If the agency changed its mind, Merck Serono was entitled to notice and an opportunity to present evidence under the new rule.

A panel of this Court affirmed, recognizing the need to "clarify … precedent" regarding the meaning of "'by another' … when a reference and the patent-at-issue identify overlapping inventors." Op.2-3.

The panel concluded that *In re Land*, 368 F.2d 866 (C.C.P.A. 1966)—a case involving a fundamentally different patent scheme—obligated it to hold that "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." Op.21. The panel did not reconcile this bright-line rule with the statutory language, nor did it offer any policy justification. Indeed, the panel stated no disagreement with Merck Serono's position that "*adding* an inventor (like adding [Dr.] De Luca here) merely indicates that all the inventors of the prior disclosure collaborated with additional inventors within the grace period afforded by §§ 102(a) and 102(e), an activity that should be encouraged." *Id*. (emphasis in original). The panel's only explanation for rejecting that approach was that *Land* "precludes … adoption" of it. *Id*.

Separately, although the panel acknowledged that "some arguably contrary language in the MPEP" supported Merck Serono's interpretation (Op.1-2, 24), the

panel ruled that the MPEP does not "restrict[] our interpretation (or the Board's interpretation) of substantive law." Op.24-25. But Merck Serono never argued otherwise. Rather, Merck Serono's position was that it was entitled to rely on the MPEP when litigating before the agency, and that although the agency could deviate from the MPEP (consistent with Section 102), the APA required notice of that deviation and an opportunity to adduce evidence satisfying it.

REASONS FOR GRANTING REHEARING

I. THE PANEL'S BRIGHT-LINE HOLDING IS CONTRARY TO STATUTE, PRECEDENT, AND POLICY

The panel's decision conflicts with statute and precedent and lacks any policy justification. To the extent any decisions suggest otherwise, they should be confined to their facts or overruled *pro tanto*.

A. Under The Statute's Plain Language, Disclosure Of The Invention Of A Subset Of Co-Inventors Is Not Disclosure "By Another"

Section 102 provides that disclosures of inventions by "others" (or "another") who are ***not*** the co-inventors of the patents-at-issue are prior art. Section 102(e) recites: "A person shall be entitled to a patent unless … the invention was described in" an earlier reference "***by another***." Section 102(a) provides that an inventor is entitled to a patent unless the invention is known or used "***by others***." And Section 102(b) provides a one-year grace period wherein an inventor may apply for a patent on their own disclosed work.

Thus, if inventor A learns of and describes B's invention, the disclosure of B's invention is not prior art to B's patent application filed within one year, because the disclosure is not an invention "by another." *E.g.*, *In re Mathews*, 408 F.2d 1393, 1394-1395 (C.C.P.A. 1969) (Dewey's patent disclosing (but not claiming) Mathews's invention was not prior art to Mathews's later patent). However, if the earlier reference discloses the work of someone ***not*** reflected on the later patent, that disclosure is prior art. *E.g.*, *In re Katz*, 687 F.2d 450, 455 (C.C.P.A. 1982) ("[t]he specific question" is whether "the subject disclosure was [a patent applicant's] original work, and his alone" and not by others ***not*** named on the application).

The statute does not provide what the panel here held—that earlier disclosure of work by a ***subset*** of co-inventors is necessarily prior art to a patent by the ***full set*** of co-inventors. On the contrary, the statement that a "person shall be entitled to a patent unless" the invention was previously disclosed "by another" indicates that a group of co-inventors is entitled to a patent unless it was the invention of someone ***other*** than the co-inventors.

The panel did not reconcile the statutory language with its holding that an earlier disclosure is prior art unless there is "complete identity" between the inventors of the earlier disclosure and the patents-at-issue. Op.20. Nor could it; when a subset of co-inventors discloses their own work, they disclose their own

invention, not that of any "other." That does not change because they add a co-inventor on their patent application.

B. The Panel's Bright-Line Rule Conflicts With Precedent And Policy

This Court was clear in *Applied Materials*, where an earlier McNeilly-Benzing patent was not prior art to a later continuation-in-part patent that "included the addition of Locke as an inventor": "Even though an application and a patent have been ***conceived by different inventive entities***, if they ***share one or more persons*** as joint inventors, the [Section] 102(e) exclusion for a patent granted to 'another' is not necessarily satisfied." 835 F.2d at 280-281.

The panel construed that statement as "implying" that the McNeilly-Benzing patent "was merely McNeilly and Benzing describing the invention eventually claimed by McNeilly, Benzing, and Locke." Op.17. But *Applied Materials* did not say that and could not have. As Merck Serono explained, but the panel did not address, the earlier McNeilly-Benzing patent did not disclose the key claim elements of the later McNeilly-Benzing-Locke patent—a "crystal" with "substantially no crystallographic slip." Reply Br.6-8. Rather, the McNeilly-Benzing-Locke patent described those elements in two new figures, five new paragraphs, and multiple new sentences.

Indeed, as the panel acknowledged, the McNeilly-Benzing-Locke patent "resulted from a ***continuation-in-part***" (Op.18), which allowed new matter not

disclosed in the parent application, 37 C.F.R. § 1.53(b) (pre-AIA). The panel suggested this "weaken[ed]" *Applied Materials*' reasoning (Op.18), but in fact it only weakens the panel's effort to read into *Applied Materials* an unstated "impl[ication]" contradicting the case's facts and statements of law.

The panel's bright-line rule further conflicts with *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952 (Fed. Cir. 2014), where earlier "Brandt" references by patentee VanDenburgh listed others (Brandt, Chen, and Whitcup) ***not*** on the later VanDenburgh-Woodward patent. The Court was not concerned with the addition of a contributor (Woodward), because the "relevant inquiry must be whether the Brandt references … were solely Dr. VanDenburgh's work and hers alone." *Id.* at 969. As the panel acknowledged, *Allergan* turned not on the lack of complete identity of inventorship, but on the specific finding that "several authors of the Brandt references were ***excluded*** as named inventors." Op.19. The record is the opposite here—the patents-at-issue do not exclude ***any*** inventor of the pertinent disclosure.[4]

Nor does it matter that *Allergan* did not decide "whether Brandt would be prior art to the VanDenburgh-Brandt[5] patent if the Brandt reference *was* solely the

[4] Although the Board alternatively found that Drs. Bodor and Dandiker contributed to the relevant disclosure, Merck Serono demonstrated legal error in that analysis (*see* Opening Br.43-48; Reply Br.20-22), which the panel did not address (Op.27).

[5] The panel may have misapprehended *Allergan*'s facts, as the patent was to VanDenburgh-Woodward, not VanDenburgh-Brandt. There was no argument that Woodward conceived of the earlier disclosures.

work of Dr. VanDenburgh." Op.19 (emphasis in original). The point is that, under the panel's complete-identity rule, the "relevant inquiry" would not have been whether "the Brandt references … were solely Dr. VanDenburgh's work and hers alone." 754 F.3d at 969. That would have been ***irrelevant***, because the lack of complete identity between VanDenburgh alone and VanDenburgh-Woodward would have been dispositive. *Allergan* delved into the evidence of VanDenburgh's inventorship precisely because the panel's rule is ***not*** the law.

Moreover, the law should not be as the panel decreed it. Joint innovation "promote[s] the Progress of Science and useful Arts." U.S. Const. art. I, § 8. Section 102(b)'s one-year grace period allows an inventor "to perfect, develop and apply for a patent on his invention and publish descriptions of it." *Katz*, 687 F.2d at 454. And "an inventor may use the services, ideas, and aid ***of others*** in the process of perfecting his invention ***without losing his right to a patent***." *Hobbs v. U.S. Atomic Energy Comm'n*, 451 F.2d 849, 864 (5th Cir. 1971). Collaboration is undoubtedly "an activity that should be encouraged." Op.21.

Neither the panel nor Appellee advanced any contrary policy supporting the panel's bright-line rule, which needlessly punishes inventors for collaborating and sharing credit with other inventors. The panel believed its hands were tied by precedent. Op.21. That is incorrect and demonstrates the need for rehearing.

C. Precedent Does Not And Should Not Compel The Panel's Bright-Line Rule

The panel believed *Land* compelled its bright-line rule, but *Land* arose under a very different patent regime and did not involve a disclosure within Section 102's one-year grace period. Inventors Land and Rogers had individually filed patent applications on earlier inventions, and together filed a joint application on later inventions, which were "all copending." 368 F.2d at 874. Because the joint application was filed five years before either individual application was granted, neither was published under then-applicable law. Had the joint application issued, it risked extending the patent monopoly over the inventions for years. Reply Br.5.

Land only considered whether the record showed "knowledge by another prior to the time appellants made their [joint] invention." 368 F.2d at 878. Because "Land and Rogers brought their knowledge of their individual work, and of each other's work, with them 'when they made the invention jointly claimed,'" the unpublished solo applications demonstrated knowledge of those inventions before any joint invention, making the unpublished solo applications prior art. *Id.* at 881. Thus, *Land* at most considered whether a co-inventor's prior knowledge of an invention, as evidenced by his unpublished application, constituted knowledge "by another;" it did not address, and had no need to address, disclosure followed by collaboration within the grace period, as Section 102(b) allows. There is no reason to infer any broader rule from *Land* than its reasoning required.

Riverwood International Corp. v. R.A. Jones & Co., 324 F.3d 1346 (Fed. Cir. 2003), does not support the panel's rule either. In *Riverwood*, the earlier Ziegler-Olson-Lovold patent was asserted as prior art to a Ziegler patent and a Ziegler-Lashyro-Vulgamore patent. The Court first explained that "[i]f Ziegler was the sole inventor of the portions of the [Ziegler-Olson-Lovold] patent … then the [Ziegler-Olson-Lovold] patent is not prior art to the [Ziegler] patent" (*id.* at 1357)—a statement fully consistent with Merck Serono's position, as the conclusion would turn on whether the earlier reference disclosed an invention by Ziegler alone or by "others" not named on the Ziegler patent (Olson and Lovold). *Riverwood* went on to state that "if [patentee] Riverwood sustains its burden of proof that Ziegler is the sole inventor of the [Ziegler-Lashyro-Vulgamore] patent, then the [Ziegler-Olson-Lovold] patent would not be prior art." *Id*. But that was not a requirement of "complete identity of inventive entity" (Op.20). Rather, it simply reflected the fact that the patentee had sought to correct inventorship of the later Ziegler-Lashyro-Vulgamore patent under 35 U.S.C. § 256 to remove Lashyro and Vulgamore. Op.20 n.11; *Riverwood*, 324 F.3d at 1356. If that effort succeeded, then an earlier disclosure by Ziegler alone would not be prior art to a later patent by Ziegler alone, which is all the Court said. The Court did not say what would have happened if Ziegler were found to be the sole inventor of the Ziegler-Olson-Lovold disclosure, but the later patent remained the joint invention of Ziegler, Lashyro, and Vulgamore.

The panel cited other cases where the earlier disclosure included inventors "other" than the later patent's named co-inventors. None applied, much less justified, the panel's bright-line rule. *Google LLC v. IPA Techs. Inc.*, 34 F.4th 1081, 1088 (Fed. Cir. 2022) (Moran-Cheyer-Martin disclosure was potentially prior art to Martin-Cheyer patent); *EmeraChem Holdings, LLC v. Volkswagen Grp. of America, Inc.*, 859 F.3d 1341, 1345-1348 (Fed. Cir. 2017) (Campbell-Guth-Danziger-Padron patent was prior art to Campbell-Guth patent); *Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, 914 F.3d 1347, 1357 (Fed. Cir. 2019) (if Schwarz, an author ***not*** on the patent-at-issue, were "a joint inventor of the anticipating disclosure, then it is 'by another'"); *see* Op.21 (acknowledging that, in these cases, the patents-at-issue "named *some* but *not all* the inventors of the disclosure in the references" (emphases in original)). Accordingly, the Court may—and should—adopt Merck Serono's view of the law without overruling any precedent.

In the alternative, however, *Land* should be confined or overruled. *Land* arose in a very different time, when patent applications published only after patents issued, *see* 35 U.S.C. § 122 (1952). After the American Inventors Protection Act of 1999, applications now generally publish automatically after 18 months, which starts the one-year grace period, 35 U.S.C. § 122(b). Since disclosures published over one year earlier (even by the same inventor) are always prior art, any concern that inventors could improperly extend their monopolies is minimized. Additionally,

there is no reason for "a 'hard and fast' rule that the inventive entity for both patents must be identical" after the "liberalization of the requirements for filing a U.S. application as joint inventors." *Abbott GmbH & Co. v. Centocor Ortho Biotech, Inc.*, 870 F. Supp. 2d 206, 242 (D. Mass. 2012), *aff'd*, 759 F.3d 1285 (Fed. Cir. 2014).

Other circuits and the Patent Office thus interpreted *Land* based on its idiosyncratic facts and legal setting. *E.g.*, *General Motors Corp. v. Toyota Motor Co.*, 667 F.2d 504, 506-507 (6th Cir. 1981) (holding *Land* does not apply to situations where the prior invention was "the product of concerted effort within a business entity. … Where numerous 'inventors' all worked under the aegis of one employer toward a common goal, it is appropriate to define the concept of joint invention broadly."); *Shields v. Halliburton Co.*, 667 F.2d 1232, 1236 (5th Cir. 1982) (holding *Land* applies where "the initial individual inventor ***seeks a patent for his own work*** and then subsequently applies for a second patent with a collaborator"; by contrast, "where Bassett does some work, ***seeks no patent***, collaborates with Olsen, and subsequently they together seek a patent, the joint application declares that their work submitted as a whole is a single invention—the first of its kind"); MPEP § 2136.05(b) (an "inventor's or ***at least one*** joint inventor's own work may not be used against the application … unless there is a time bar" (citing *Land*)). Even the law firm representing Appellee here recognized that "*Land* suggests the earlier

patent or published application may *not* be prior art, even though it lacks one-to-one overlap in the named inventors." Wright, *Availability of Prior Art Under Pre-AIA Section 102(e) Based on Changing Inventorship* (Aug. 3, 2021), https://www.sternekessler.com/news-insights/publications/availability-prior-art-under-pre-aia-section-102e-based-changing/ (emphasis in original).

To the extent *Land* is inconsistent with the statutory language and contrary to patent policy, the *en banc* Court should confine it to its facts or overrule it in relevant part.

II. ALTERNATIVELY, THE PANEL OVERLOOKED OR MISAPPREHENDED MERCK SERONO'S DEMONSTRATION THAT THE APA REQUIRED NOTICE AND AN OPPORTUNITY TO MAKE A RECORD UNDER THE AGENCY'S DEVIATION FROM THE MPEP

The panel overlooked or misapprehended Merck Serono's alternative argument that the Board's complete-identity rule deviated from the MPEP, such that the APA required giving Merck Serono an opportunity to supplement the record with evidence of each co-inventor's contribution to the disclosure.

The agency, through the MPEP, espoused the legal interpretation Merck Serono advanced throughout the proceedings. MPEP § 2132.01 ("An inventor's ***or at least one joint inventor's*** disclosure of his or her own work within the year before the application filing date cannot be used against the application as prior art."); *see* MPEP §§ 715.01, 716.10, 2136.05(b). The Patent Office applied this interpretation for decades. Opening Br.34-35 & n.11 (identifying examples). The panel

acknowledged "some arguably contrary language in the MPEP" supporting Merck Serono. Op.24. Merck Serono therefore argued that if the Court upheld the agency's deviation from the MPEP, then Merck Serono was entitled to develop the record under the agency's new position. Opening Br.36-37; Reply Br.13; Oral Arg.6:08-28.

Nonetheless, at Appellee's urging, the panel appears to have misunderstood Merck Serono to argue that the MPEP ***controlled*** this Court's statutory interpretation. Op.25 (rejecting "the proposition that an interpretation of this court's caselaw in the MPEP restricts our interpretation (or the Board's interpretation) of substantive law"); Response Br.38-39. But Merck Serono's "position is ***not*** that the MPEP 'bind[s]' this Court." Reply Br.13; *see also* Oral Arg. 6:08-28. Rather, Merck Serono was "'entitled to rely in good faith'" on the "'express provisions of [the] MPEP'" and, at a minimum, a remand is required "so that Merck may develop a record responsive to the Board's new rule." Opening Br.36-37 (quoting *Kaghan*, 387 F.2d at 401). The panel did not address this APA violation.

A party to an agency proceeding is entitled to notice of "the matters of fact and law asserted" and "to submit rebuttal evidence." 5 U.S.C. §§ 554(b)(3), 556(d); *see Gates & Fox Co. v. Occupational Safety & Health Review Comm'n*, 790 F.2d 154, 156 (D.C. Cir. 1986) (Scalia, J.) (agencies must provide parties "fair warning of the conduct [the regulation] prohibits or requires"). The agency "'may not change

theories in midstream without giving respondents reasonable notice' and 'the opportunity to present argument under the new theory.'" *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1080 (Fed. Cir. 2015) (quoting *Rodale Press, Inc. v. FTC*, 407 F.2d 1252, 1256-1257 (D.C. Cir. 1968)). The unfair surprise is particularly pronounced given the agency's longstanding practice. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 158 (2012) ("potential for unfair surprise is acute" when "preceded by a very lengthy period" of inaction); Opening Br.34-35 & n.11 (identifying numerous examples between 2004-2023 where the Patent Office followed the MPEP, not the bright-line rule applied here).

Rehearing is thus warranted to consider Merck Serono's overlooked APA arguments and to allow Merck Serono to develop a record under the agency's bright-line rule.

CONCLUSION

The petition should be granted.

Respectfully submitted,

/s/ David B. Bassett

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December 1, 2025

ADDENDUM

United States Court of Appeals for the Federal Circuit

MERCK SERONO S.A.,
Appellant

v.

HOPEWELL PHARMA VENTURES, INC.,
Appellee

2025-1210, 2025-1211

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2023-00480, IPR2023-00481.

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.

JOHN CHRISTOPHER ROZENDAAL, Sterne Kessler Goldstein & Fox PLLC, Washington, DC, argued for appellee. Also represented by CHRISTINA ELIZABETH DASHE, ELDORA ELLISON, TYLER LIU, OLGA PARTINGTON, CHANDRIKA VIRA.

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

LINN, *Circuit Judge*.

Merck Serono S.A. ("Merck") appeals the determinations by the Patent Trial and Appeal Board ("Board") in two consolidated inter partes reviews ("IPR"). This case is a companion case to *Merck Serono S.A. v. TWi Pharms., Inc.*, 2025-1463, -1464, argued on the same day, and decided contemporaneously herewith. In this case, the Board held claims 36, 38, 39, and 41–46 of Merck's U.S. Patent No. 7,713,947 ("'947 patent") and claims 17, 19, 20, and 22–27 of Merck's U.S. Patent No. 8,377,903 ("'903 patent") unpatentable as obvious over a combination of Bodor[1] and Stelmasiak.[2] *Hopewell Pharma Ventures, Inc. v. Merck Serono S.A.*, IPR2023-00480 (P.T.A.B. Sept. 18, 2024) (U.S. Pat. No. 7,713,947) (hereinafter, "FWD"); *Hopewell Pharma Ventures, Inc. v. Merck Serono S.A.*, IPR2023-00481 (P.T.A.B. Sept. 18, 2024) (U.S. Pat. No. 8,377,903). The parties argue all claims of both patents together.

Because we see no legal or factual errors in the Board's analysis, we affirm the Board's unpatentability determination and clarify our precedent on the interpretation of the phrase "by others" or "by another" under pre-AIA

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[1] Bodor, et al., "Oral Formulations of Cladribine," Int'l Pub. No. WO 2004/087101, published Oct. 14, 2004 ("Bodor").

[2] Zbigniew Stelmasiak, et al., *A pilot trial of cladribine (2-chlorodeoxyadenosine) in remitting-relapsing multiple sclerosis*, 4 Med. Sci. Monit. 1, 4 (Mar. 1, 1998) ("Stelmasiak").

35 U.S.C. §§ 102(a), (e)[3] when a reference and the patent-at-issue identify overlapping inventors.

BACKGROUND

I

Multiple sclerosis ("MS") is a chronic, often progressive, demyelinating disease of the central nervous system that may lead to neurological disabilities and physical symptoms. '947 patent, col. 1, ll. 25–42. Prior to the earliest priority date of the patents-in-suit, cladribine was a known treatment of MS. *Id.*, col. 2, l. 14–col. 3, l. 21. At that time, because of the "narrow margin of safety between the efficacy dose and the dose of occurrence of [adverse effects]," cladribine was primarily administered either intravenously or subcutaneously. *Id.*, col. 2, ll. 63–66.

In 2002, Serono[4] partnered with manufacturer and formulator IVAX Corporation ("Ivax") to develop oral cladribine to treat MS. 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 7581 (Manufo Decl. ¶¶ 24–25). Serono and Ivax exchanged confidential information during the partnership period, as reflected, for example, in the minutes of an August 2003 meeting in Amsterdam ("Amsterdam Minutes") where the parties

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[3] Because the priority date for the patents here is before March 16, 2013, we apply the pre-AIA Patent Act. *See Leahy-Smith America Invents Act*, Pub. L. No. 112-29, 125 Stat. 284, 293 (2011) ("AIA"); 35 U.S.C. § 100 (note). The views expressed in this opinion are therefore limited to the text and context of the pre-AIA statute.

[4] "Serono" refers to Serono S.A. and its affiliates. Merck acquired Serono in 2006. J.App'x 7577 ¶ 15.

discussed the formulation progress, patent filings, regulatory and clinical study strategy, and marketing. J.App'x 7197–204 (subject to protective order). The minutes note participation by three of the four named inventors on the patents-in-suit, Drs. Lopez-Bresnahan, Ythier, and Munafo; several other Serono participants; and Ivax participants including Dr. Dandiker, one of the authors of the Bodor reference. The Amsterdam Minutes obliquely reference de Luca. J.App'x 7200; J.App'x 32 n.17 (quoting J.App'x 7200).[5]

In December 2003, Serono emailed Ivax a "Briefing Document" with a draft of a dosing regimen, with the following parameters: (1) administering oral cladribine tablets for 5 consecutive days in each of 2 months; (2) administering a placebo for 4 months; and (3) not administering any pills for 6 months." J.App'x 7589–92 (¶¶ 42–46) (Munafo Decl. discussing briefing document); J.App'x 7185, 7192–94 (briefing document).

On March 26, 2004, Ivax employees Drs. Bodor and Dandiker filed the Bodor[6] international patent application. The application was published on October 14, 2004, less than one year before the effective filing date of the patents-in-suit. Bodor notes "[t]herapeutically effective dosages described in the literature for . . . multiple sclerosis (from about 0.04 to about 1.0 mg/kg/day (see U.S. Patent No. 5,506,214))." J.App'x 1938, col. 22, ll. 19–22. Bodor describes administering an oral cladribine-cyclodextrin

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[5] The parties have marked the note in the Amsterdam Minutes allegedly referencing De Luca as confidential, but Merck Serono's non-confidential opening brief to this court states that "The Amsterdam Minutes mention Dr. De Luca," citing the Board's redacted footnote. Appellant's Opening Br. at 17 (citing J.App'x 32 n.17).

[6] This opinion refers to the reference as "Bodor" and one of its authors as Dr. Bodor.

complex for the treatment of MS according to a particular dosing regimen that the parties refer to as the "six-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.

J.App'x 1939, col. 23, ll. 15–20.[7] Bodor also discloses an alternative dosing regimen, where a patient "would be treated with 10 mg of cladribine in the instant complex cladribine-cyclodextrin complex in the instant dosage form once per day for a period of five to seven days per month for a total of six months, followed by eighteen months of no treatment." *Id.*, col. 23, ll. 20–24.

In 1998, the Stelmasiak reference was published. Stelmasiak describes administering cladribine to patients either orally (at 10 mg per day) or subcutaneously (5 mg per day), with six courses of monthly treatment (each course comprising five consecutive days of treatment), and two additional courses at 9 and 12 or 15 months. J.App'x 1849. Stelmasiak teaches "[i]n patients with remitting relapsing [MS,] treatment with cladribine decreases lymphocyte counts in peripheral blood, to 1/3 of the initial value on

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[7] In the companion 2025-1463, -1464 case, the parties refer to the same disclosure as the "seven-line disclosure" or, sometimes, the "one-line disclosure." All of these characterizations refer to the same quoted language in Bodor.

average," J.App'x 1851, which shows "a tendency towards normalization" "at the end of the 2-year observation period." J.App'x 1849–50. Stelmasiak also teaches that "[t]he therapy appeared to be effective in seven patients who reported a very marked (almost five-fold on average) reduction in the relapse rate during the 2 years after the initiation of the treatment." J.App'x 1851.

II

On December 22, 2004, within a year of Bodor's filing, the parent applications to which the patents-in-suit claim priority were filed. Both patents-in-suit are titled "Cladribine Regimen for Treating Multiple Sclerosis," and are generally directed to methods of treating MS by orally administering the pharmaceutical cladribine according to a particular dosing regimen. The patents-in-suit note that oral administration of cladribine was previously known but that "the therapeutic efficacy of the oral regimen [described in a prior study] versus the [intravenous] infusion therapy was questioned." '947 patent, col. 3, ll. 17–18. Both patents list as inventors: Drs. De Luca, Ythier, Munafo, and Lopez-Bresnahan (collectively, "named inventors"). All four 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:
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> > (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;
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> (ii) a cladribine-free period lasting from about 8 months to about 10 months, wherein no cladribine is administered;
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> (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;
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> (iv) a cladribine-free period wherein no cladribine is administered.

Claim 17 of the '903 patent is substantively identical for purposes of this appeal. Dependent claims further limit the total induction period dose to 1.7mg/kg. The parties argue all claims of both patents together, and we likewise treat them all together.

III

Hopewell Pharma Ventures, Inc. ("Hopewell") filed two IPRs, respectively challenging claims 36, 38, 39, and 41–46 of the '947 patent (IPR 2023-00480) and claims 17, 19–20, and 22–27 of the '903 patent (IPR 2023-00481) as obvious over Bodor and Stelmasiak.

In its FWD,[8] the Board held that all challenged claims were unpatentable as obvious over Bodor in view of Stelmasiak. First, the Board determined that Bodor was prior art. The Board held that Petitioner met its initial burden to show that Bodor was prior art because it was filed and

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[8] Unless otherwise stated, this opinion exclusively references the Board's FWD in IPR2023-00480 and the '947 patent specification.

published prior to the patents' priority date, and "there is no facial overlap in the named inventors or assignees of Bodor and the '947 patent." J.App'x 30. The Board then shifted the burden of production to patentee "to come forward with evidence sufficient to support the proposition that Bodor is not prior art," *id.* at 31 (citing, inter alia, *Google LLC v. IPA Techs. Inc.*, 34 F.4th 1081, 1085–86 (Fed. Cir. 2022)), noting that "the ultimate burden of persuasion in an IPR remains with Petitioner," *id.* The Board ultimately held that Merck did not satisfy the burden of production because Merck failed to "produce[] documents and testimony [showing] credible and corroborated evidence that inventor De Luca, named on the '947 patent, provided an inventive contribution to the 6-line regimen that appears in Bodor." *Id.* In doing so, the Board rejected patentee's legal argument that "a reference's disclosure of the invention of a *subset* of inventors is disqualified as prior art against the invention of *all* the inventors." *Id.* at 36 (emphasis in original). The Board also rejected patentee's factual argument that the evidence of De Luca's contribution was sufficiently corroborated to provide compelling evidence that De Luca did in fact contribute to the six-line disclosure in Bodor. *Id.* at 36–37.

The Board also held, in the alternative, that even if Merck had proven an inventive contribution to the six-line disclosure by all the named inventors, "Drs. Bodor and Dandiker are at least co-inventors of all applied portions" of Bodor because they provided sufficiently significant contributions to the disclosure under the test set forth in *Duncan Parking*, and therefore Bodor would still be "by another" and available as prior art. J.App'x 40. *See Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, 914 F.3d 1347, 1357–58 (Fed. Cir. 2019).

Having thus concluded that Bodor's six-line disclosure is prior art, the Board next held that the instituted claims were unpatentable as obvious over Bodor and Stelmasiak. The Board held that the six-line disclosure in Bodor taught

the induction period and the subsequent cladribine-free period as recited in claim 36, and that "it would have been obvious to follow Bodor's 2-month induction period and 10-month cladribine-free period with a retreatment or maintenance phase," *id.* at 53, given Stelmasiak's teaching of the retreatment period and subsequent cladribine-free period and MS's chronic nature.

The Board found a reason to combine the references and a likelihood of success, by "following Bodor's express guidance" for its regimen and its advantages for the induction and cladribine-free periods, and credited Dr. Aaron Miller's testimony of the motivation to re-treat patients who relapse by repeating Bodor's initial regimen and optimizing dosing for the retreatment period. *Id.* at 64. The Board also explained that the cladribine dose/duration were result-effective variables that could be quantified and optimized by reference to lymphocyte suppression, and that an ordinary artisan would have used Bodor's dosing as a starting point for dosing in the retreatment period. *Id.* at 64–65, 79.

The Board also rejected Merck Serono's argument that the claims were limited to weight-based dosing, noting that "the claims include no active steps of determining a patient's weight or performing *a priori* calculations to arrive at any alleged 'weight-based' dosing before cladribine is taken or administered," *id.* at 47–48, and held that "[i]n any event, the evidence points to the obviousness of converting so-called flat and weight-based expressions of the dose," *id.* at 48. Thus, the Board found all claims obvious over Bodor and Stelmasiak.

Merck timely appealed. We have jurisdiction to review the Board's final written decisions under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. §§ 141(c), 319.

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*, 34 F.4th at 1085; *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 969 (Fed. Cir. 2014). We review whether the Board applied the correct legal standard, 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). "Claim construction is an issue of law that we review de novo." *Allergan*, 754 F.3d at 957.

II

Merck argues that the Board legally and factually erred by treating the six-line disclosure in Bodor as prior art. It raises three legal and one factual argument in support. We address each in turn.

A

Under pre-AIA § 102(e), a patent is anticipated if "the invention was described in . . . a patent granted on an application for patent *by another* filed in the United States before the invention by the applicant for patent." 35 U.S.C. 102(e) (emphasis added). Conversely, absent a statutory bar, "[o]ne's own work is not prior art under § 102(a) even though it has been disclosed to the public in a manner or form which would otherwise fall under § 102(a)." *Allergan*, 754 F.3d at 968 (quoting *In re Katz*, 687 F.2d 450, 454 (CCPA 1982)); *see also EmeraChem Holdings, LLC v. Volkswagen Grp. of Am., Inc.*, 859 F.3d 1341, 1345 (Fed. Cir. 2017) ("The statute's reference to 'by another' means that an application issued to the *same*

inventive entity cannot qualify as § 102(e) prior art." (emphasis added)).[9] Moreover, the parties here do not dispute that art available under § 102 is also available under § 103. *See In re Land*, 368 F.2d 866, 877 (CCPA 1966) (noting that "the prior art outlined in [§] 102 [] supplies the evidence of obviousness").

While the meaning of the statutory phrase "by another" is apparent when only a single inventor is involved, its meaning becomes less clear when the invention of joint inventors is at issue. The question presented to us in this appeal is whether and to what extent a disclosure invented by fewer than all the named inventors of a patent may be deemed a disclosure "by another" and thus included in the prior art, or whether the disclosure should properly be treated as "one's own work" and therefore excluded from the prior art. Merck argues for the latter and asserts that the Board erroneously adopted a bright line rule it contends has been rejected by this court requiring complete identity of inventive entities to exclude a reference as not "by another." Appellant's Opening Br. 27. Merck focuses on the following two sentences in *Applied Materials, Inc. v. Gemini Res. Corp.*, 835 F.2d 279 (Fed. Cir. 1987):

> However, the fact that an application has named a different inventive entity than a patent does not necessarily make that patent prior art.

Id. at 281 (citing *In re Kaplan*, 789 F.2d 1574, 1576 (Fed. Cir. 1986)); Appellant's Opening Br. 30–31. And:

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[9] Neither the parties nor the Board distinguish between § 102(a) and § 102(e) prior art. *See, e.g.*, J.App'x 21 n.10. For purposes of this appeal, the issue-in-dispute does not require us to differentiate between § 102(a) and § 102(e) prior art.

> Even though an application and a patent have been conceived by different inventive entities, *if they share one or more persons as joint inventors*, the 35 U.S.C. § 102(e) exclusion for a patent granted to 'another' is not necessarily satisfied.

Applied *Materials*, 835 F.2d at 281 (emphasis added); Appellant's Opening Br. 29.

Hopewell responds that Merck misreads these cases and ignores the rule set out in *Land*, 368 F.2d 866—consistently applied for the last 60 years and applied by the Board here—that a prior disclosure is only excluded from the prior art as the work of the patentee when there is complete identity of inventive entity between the inventors of the disclosure being relied upon and the challenged patent. Appellee's Br. 26 ("In other words, *if the disclosure in the prior art reveals the work of the same inventive entity as the challenged patent*, then the work is not 'by another,' no matter who is listed as the author or inventor on the earlier reference." (emphasis in original)).

We largely agree with Hopewell. In *Land*, joint inventors Land and Rogers—assignors to Polaroid Corporation—filed a patent application ("'135 Application") on February 13, 1956, for a photographic color process. 368 F.2d at 867–68. The application was rejected as obvious over a combination of references including a patent issued to Land individually ("Land," with a priority date of August 9, 1954) and a patent issued to Rogers individually ("Rogers," with one of two priority dates of March 9, 1954, and June 29, 1955). *Id.* at 868, 876 n.5. Patentee argued that those references were unavailable as prior art because they were not "by another," but rather disclosed the named inventors "own knowledge and disclosures, just as much as if the earlier filed sole applications had been joint applications." *Id.* at 880.

Our predecessor court framed the issue in *Land* broadly:

> There appears to be no dispute as to the law that A is not 'another' as to A, B is not 'another' as to B, or even that A & B are not 'another' as to A & B. But that is not this case, which involves, as did Blout, the question whether either A or B is 'another' as to A & B as joint inventors under section 102(e).

Id. at 877. The court answered that "[o]f course they are different 'entities in the sense that an invention made jointly by A & B cannot be the sole invention of A or B and vice versa." *Id.* at 879. But this was not enough to determine whether the specific disclosures relied on in the individual references should be considered prior art because those portions of the reference may also disclose the joint invention:

> When the joint and sole inventions are related, as they are here, inventor A commonly discloses the invention of A & B in the course of describing his sole invention and when he so describes the invention of A & B he is not disclosing 'prior art' to the A & B invention, even if he has legal status as 'another.'

Id. In such a situation, the disclosure of the joint invention in the individual references would not "evidence . . . knowledge by another prior to the time appellants made their invention," *id.* at 878; it would only evidence knowledge by the individual inventor of the joint inventors' necessarily prior invention.

Turning to the facts of the case and having found "no indication that the portions of the references relied on disclose anything they did jointly" or "any showing that what they did jointly was done before the filing of the reference

patent applications," the court concluded that the individual Land and Rogers references were "by another" and therefore were prior art with respect to the jointly filed patent. *Id.* at 881. The court stated, "[t]he real issue is whether all the evidence, including the references, truly shows knowledge by another prior to the time appellants made their invention or whether it shows the contrary. It is a question of fact." *Id.* at 878.

When the court noted that "[i]t is a question of fact," it was referring to the key question of "who invented the subject matter disclosed," *id.,* and whether it was the same inventive entity as the named authors of the patent. It was *not* opining on who qualifies as the same or "another." *Id.* at 881 ("[T]he weight of authority [] regard[s] Land and Rogers individually as separate legal entities from Land and Rogers as joint inventors, as they would be regarded relative to each other if a Land application were rejected on a Rogers copending patent.").

Merck next attempts to cabin *Land* based on the unusual facts of that case, which involved ***"two*** individual patents," Appellants Reply Br. 4 (emphasis in original), that claimed priority to earlier applications and would "expire ***over 6 years*** before the joint application," *id.* at 5 (emphasis in original), and where the individual references *claimed* their individual inventions and were attempting "to remove each other's earlier inventions from the prior art simply by filing another application naming them jointly (which, if granted would have extended the patent monopoly over those earlier inventions for years)." *Id.* at 5–7. But the *Land* opinion did not rest on those idiosyncrasies of the case.

Merck finds no further support for its position in *Applied Materials*. In *Applied Materials*, patentee filed a single application naming McNeilly and Benzing as inventors. 835 F.2d at 280. This application was subject to a restriction requirement by the Patent Office, and Patentee

elected to pursue its claims for a radiantly heated chemical vapor deposition reactor, which issued as U.S. Patent No. 3,623,712 ("'712 reference patent"). *Id.* Patentee also filed a divisional application for a chemical vapor deposition coating process and apparatus. *Id.* Patentee then filed a continuation-in-part for the coating process and apparatus in which, importantly for our purposes here, patentee added Locke as an inventor. *Id.* After the Patent Office issued another restriction requirement, patentee again divided the application into coating method claims (which included Locke as an inventor) that eventually issued as U.S. Patent No. 4,081,313 ("'313 patent"), and coating apparatus claims (which eventually excluded Locke). *Id.*

Patentee asserted infringement of the '313 patent (listing McNeilly, Benzing, and Locke as inventors), among other patents, against Gemini Research Corporation. *Id.* The district court held the '313 patent was invalid as anticipated by the '712 reference patent, because the addition of Locke as an author resulted in a different "inventive entity" from McNeilly and Benzing alone. *Id.*

This court vacated the district court's judgment, holding that the '712 reference patent was *not* prior art against the '313 patent, despite the distinct authorship of the '313 patent (McNeilly, Benzing, and Locke) and the '712 reference patent (McNeilly and Benzing). *Id.* at 281. We explained that the district court erred by placing too much reliance on the inventive entity "*named*" in the '712 reference patent: "[T]he fact that an application has *named* a different inventive entity than a patent does not necessarily make that patent prior art." *Id.* (emphasis added). Instead, like in *Land*, the key question was whether the disclosure in the earlier reference, here the '712 reference patent, evidenced knowledge by "another" before the patented invention. *Id.* We explained that, because the '712 reference patent and the '313 patent "all grew from the same original application," "if the invention claimed in the '313 patent is fully disclosed in the '712 patent, this invention had to be invented before the filing

date of the '712 patent and the latter cannot be 102(e) prior art to the '313 patent." *Id.*

Merck argues that *Applied Materials* held that the '712 reference patent was not prior art "because McNeilly and Benzing were common to both applications," Appellant's Opening Br. 31, and that it therefore rejected a bright-line rule requiring an identical inventive entity to exclude a reference as not "by another." *See* 835 F.2d at 281 ("Even though an application and a patent have been conceived by different inventive entities, *if they share one or more persons as joint inventors*, the 35 U.S.C. § 102(e) exclusion for a patent granted to 'another' is not necessarily satisfied." (emphasis added)).

Merck overreads *Applied Materials*. That decision, as modified,[10] did not rely on the fact that two of the three named inventors in the '313 patent were named in the '712 reference patent. Instead, the decision rested on the fact that the '313 patent and the '712 reference patent were descendants of the same application, thus undermining the logical link between the disclosure in the '712 reference patent

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[10] The original opinion in *Applied Materials did* rely on that basis when it expressly held that a reference disclosure authored by a subset of inventors was *not* prior art to a patent with additional authors. *Compare Applied Materials Inc. v. Gemini Res. Corp.*, 1988 WL 252444, at *4 (Fed. Cir. Dec. 16, 1987) ("In this case, since the applications which matured into the '712 and '313 patents all grew from the same original application, and since the work of McNeilly and Benzing continued with the addition of Locke, the district court was in error in holding that the '712 patent was prior art against the '313 patent."), *with* 835 F.2d at 281 (replacing the aforementioned paragraph with the text discussed in the main body herein). *See* 1A Chisum on Patents § 3.08[2][a] (relaying history of the modification).

as evidence of prior knowledge/invention by *anyone* else. *Id.* ("[I]f the invention claimed in the '313 patent is fully disclosed in the '712 patent, this invention had to be invented before the filing date of the '712 patent and the latter cannot be 102(e) prior art to the '313 patent."). Even if the '712 reference patent were to disclose the subject matter of the '313 patent (as found by the *Applied Materials* district court in the opinion under review), it would not evidence knowledge "by another"—it would only evidence knowledge by the *same inventors* as the '313 patent, 835 F.2d at 281—and so, could not be used as prior art.

Indeed, *Applied Materials* qualifies the general rule requiring complete identity of inventive entity when a reference's authors describe an invention made by others in the course of describing their own inventions. *Applied Materials*, 835 F.2d at 281 ("When the joint and sole inventions are related, as they are here, inventor A commonly discloses the invention of A & B in the course of describing his sole invention and when he so describes the *invention* of A & B he is not disclosing 'prior art' to the A & B invention, even if he has legal status as 'another . . . .'") (emphasis in original) (quoting *In re Kaplan*, 789 F.2d at 1576 (in turn quoting *Land*, 368 F.2d at 879)); *see also id.* ("Even though an application and a patent have been conceived by different inventive entities, if they share one or more persons as joint inventors, the 35 U.S.C. § 102(e) exclusion for a patent granted to 'another' is not necessarily satisfied."). And when applying that qualification, the court cited *Land* in support, implying that the '712 reference patent was merely McNeilly and Benzing describing the invention eventually claimed by McNeilly, Benzing, and Locke in the '313 patent: "When the 102(e) reference patentee ['712] . . . had knowledge of the joint applicants' invention ['313] by being one of them, and *thereafter* describes it, he necessarily files the application ['712] *after* the ['313] applicant's invention date." *Id.* at 281 (quoting *Land*, 368 F.2d at 879) (all alterations in *Applied Materials*).

Granted, the '313 patent resulted from a continuation-in-part, thus weakening the syllogism relied on by the court. But this weakness in the reasoning does not justify extracting a wholly different theory, particularly one that was rejected by the court on rehearing.

Later opinions of this court have consistently required identity of inventive entity to exclude a reference from the prior art as not "by another." In *Allergan*, this Court considered whether the Brandt references, listing as authors VanDenbergh, Brandt, Chen, and Whitcup, were prior art to U.S. Patent No. 7,351,404 ("'404 patent") (listing as authors Woodward and VanDenbergh). 754 F.3d at 967. Patentee argued that the Brandt references were not prior art with respect to the '404 patent because VanDenbergh was the sole true author of the disclosures in the Brandt references and the other listed authors were merely her "hands," *id.* at 968 (quoting *Mattor v. Coolegem*, 530 F.2d 1391, 1395 (CCPA 1976)). This court analyzed whether "the evidence appellees presented at trial could [] support the legal conclusion that the Brandt references represented Dr. VanDenburgh's own work." *Id.* at 969. Because it found that the evidence could not support that conclusion, it determined that VanDenbergh was *not* the sole author of the Brandt reference and, thus, concluded that the Brandt references were prior art (and thereafter held the '404 patent claims obvious). *Id.* at 970.

Merck argues that *Allergan* stands for the proposition for determining whether a reference is by another is whether the earlier reference "was solely the work of at least ***one*** of the inventors named on the later patent, and not the work of others from the earlier reference who were not included on the later patent." Appellant's Opening Br. 32 (emphasis in original). In its Reply Brief, Merck doubles-down, arguing that "[t]he Court explained that, had the earlier disclosure been of VanDenburgh's work alone, it would ***not*** have been prior art against the VanDenburgh-Woodward patent" and

that this "squarely refutes the Board's bright-line rule." Appellant's Reply Br. 8–9.

We fail to see anything in *Allergan* that supports Merck's characterization of that case. At most, the *Allergan* court framed the issue as whether "the Brandt references . . . were solely Dr. VanDenburgh's work and hers alone." *Allergan*, 754 F.3d at 969 (citing *Katz*, 687 F.2d at 455). Because the court held that the "evidence appellees presented at trial could not support the legal conclusion that the Brandt references represented Dr. VanDenburgh's own work," and thus several authors of the Brandt references were excluded as named inventors, it held that the Brandt references were prior art to the '404 patent. *Id.* at 969–70. But the court did not address the question of whether Brandt would be prior art to the VanDenburgh-Brandt patent if the Brandt reference *was* solely the work of Dr. VanDenburgh.

In *Riverwood Int'l Corp. v. R.A. Jones & Co.*, this court considered the prior art status of U.S. Patent No. 5,241,806 ("'806 reference patent"), issued to inventors Ziegler, Olson, and Lovold, with respect to two patents-at-issue: U.S. Patent No. 5,666,789 ("'789 patent") issued to Ziegler alone, and U.S. Patent No. 5,692,361 ("'361 patent") issued to Ziegler, Lashyro, and Vulgamore. 324 F.3d 1346, 1349 (Fed. Cir. 2003). Determining whether the '806 reference patent was prior art required the court to "look beyond the superficial fact that the references were issued to different inventive entities" to determine "whether the portions of the reference relied on as prior art, and the subject matter of the claims in question represent the work of a common inventive entity." *Id.* at 1356. "If Ziegler was the sole inventor of the portions of the '806 [reference] patent relied upon by [the accused infringer] in its obviousness arguments, then the '806 [reference] patent is not prior art to the '789 patent [issued to Ziegler alone]," and if patentee "sustains its burden of proof that Ziegler is the sole inventor of the '361 patent, then the

'806 patent would not be prior art to the '361 patent."[11] *Id.* at 1357. Because the district court had not made these determinations, we vacated and remanded to the district court to decide the inventorship of the portion of the '806 reference patent and the '361 patent. *Id.*

Riverwood supports our analysis of *Land* and *Applied Materials* above because it required complete identity of inventive entity between the earlier reference and the patents-at-issue. That is, we required the district court on remand to determine whether the patentee satisfied its burden to show that Ziegler was the "sole inventor of the '361 patent" even if it determined that Ziegler was the sole inventor of the disclosure in the '806 reference patent. This was a required showing to exclude the contributions of additional named inventors Lashyro and Vulgamore.

In *EmeraChem Holdings*, this court considered whether a reference patent, U.S. Patent No. 5,451,558 ("Campbell '558 reference patent") was prior art to the patent-at-issue, U.S. Patent No. 5,599,758 ("'758 patent"). 859 F.3d at 1343. The '558 patent listed as inventors Campbell, Guth, Danziger, and Padron, and the '758 patent listed just Campbell and Guth. *Id.* at 1344. Because there was not enough corroborated evidence that the portions of the Campbell '558 reference patent relied on for unpatentability were authored solely by Campbell and Guth, the reference and the patent-at-issue did not share a "common inventive entity," and therefore remained prior art. *Id.* at 1345 (quoting *Riverwood*, 324 F.3d at 1356)); *id.* at 1348.

More recent cases have likewise required complete identity of inventive entities to exclude a reference disclosure as not by "another." *See Google*, 34 F.4th at 1088 (Fed. Cir.

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[11] Ziegler also sought correction of inventorship of the '361 patent to remove Lashyro and Vulgamore. 324 F.3d at 1357.

2022) (requiring the Board to analyze the significance of Moran's contribution to a reference disclosure naming Moran, Cheyer, and Martin as authors, to determine whether the reference was prior art as to a patent naming only Martin and Cheyer); *Duncan Parking*, 914 F.3d at 1359 (holding that a reference disclosure invented by King and Schwarz was prior art as to a patent listing King, Hunter, Hall, and Jones because Schwarz's contribution to the prior reference "was significant").

Merck argues that each of these cases is distinguishable because the patents-at-issue in each named *some* but *not all* the inventors of the disclosure in the references, rather than including all of the inventors and *adding additional inventors*. Merck suggests that in the former circumstances, treating the reference as "by another" makes sense because it protects the inventive contributions of the excluded inventor from being coopted by the other inventors. In contrast, Merck argues, *adding* an inventor (like adding De Luca here) merely indicates that all the inventors of the prior disclosure collaborated with additional inventors within the grace period afforded by §§ 102(a) and 102(e), an activity that should be encouraged.

Our case law—in particular, *Land*—precludes our adoption of the policy argument presented by Merck. As those cases make clear, for a reference not to be "by another," and thus unavailable as prior art under pre-AIA § 102(e), the disclosure in the reference must reflect the work of the inventor of the patent in question. That is clear enough when a single inventor is involved. What should also be clear is that 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. That showing may be made by fewer than all the inventors but nonetheless must evince the joint work of them all to avoid being considered a work "by another" under the statute. Any 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 from or added to the patent. *See Land*, 368 F.2d at 879.

B

Merck next argues that it was surprised by the Board's application of the above-discussed rule requiring complete identity of inventive entity because the rule is contrary to several provisions of the Manual of Patent Examining Procedure ("MPEP"), and that the Board erred by not giving Merck an opportunity to submit arguments and rebuttal evidence, as required by the Administrative Procedure Act ("APA"). Appellant's Opening Br. 33–37. Merck therefore demands a vacatur and remand for it to present additional evidence (to at least show De Luca's contributions to the six-line disclosure) and additional argument in light of this allegedly new rule. *Id.*; *see* 5 U.S.C. § 554(b) ("Persons entitled to notice of an agency hearing shall be timely informed of . . . [inter alia,] the matters of fact and law asserted"), *id.* § 554(c) (requiring the agency to provide an opportunity to submit facts and arguments), § 556(d) (requiring the agency to provide an opportunity to "submit rebuttal evidence . . . as may be required for a full and true disclosure of the facts").

Merck relies on the following MPEP sections. Appellant's Opening Br. 34. MPEP § 2132.01 (emphasis added):

> An inventor's *or at least one joint inventor's disclosure of his or her own work* within the year before the application filing date cannot be used against the application as prior art.

And MPEP § 2136.05(b) (emphasis added):

> [E]ven if an inventor's *or at least one joint inventor's work* was publicly disclosed prior to the patent application, the inventor's *or at least one joint inventor's own work* may not be

> used against the application subject to pre-AIA 35 U.S.C. 102 unless there is a time bar.

See also MPEP § 715.01 (37 C.F.R. § 1.131 affidavits may prove "invention of the claimed subject matter by the inventor or *at least one joint inventor*" (emphasis added)); MPEP § 716.10 (similar). Merck argues that it was "entitled to rely in good faith [on the MPEP] in the orderly conduct of their business in the Patent Office." Appellant's Opening Br. 36 (quoting *In re Kaghan*, 387 F.2d 398, 401 (CCPA 1967)).

Hopewell responds that Merck did not lack notice of the rule because the MPEP expressly adopts the rule of *Land* in § 2136.04 (titled "Different Inventive Entity; Meaning of 'By Another'"):

> "Another" means other than applicants, in other words a different inventive entity. The inventive entity is different if not all inventors are the same. The fact that the application and reference have one or more inventors in common is immaterial.

(citing *Land*, 368 F.2d at 866). And the MPEP qualified the statement Merck cites from MPEP § 2136.05(b) to address the situation in *Land* and here, as follows:

> In the situation where one application is first filed naming sole inventor X and then a later application is filed naming joint inventors X & Y, it must be proven that the joint invention was made first, was thereafter described in the sole inventor's patent, or was thereafter described in the sole inventor's U.S. patent application publication or international application publication, and then the joint application was filed.

(citing *Land*, 367 F.2d at 866). Hopewell also argues that the MPEP interpretation of our case law "does not control,"

EmeraChem Holdings, 859 F.3d at 1348 n.2; *see also Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995) (stating that the MPEP "does not have the force of law"), and that the rule was announced in *Land* and consistently applied for 60 years.

We agree with Hopewell that Merck had sufficient notice that a disclosure of an invention made by a subset of named inventors was a disclosure "by another." First, as discussed in detail above, *Land* controls the legal definition of "by others" or "by another" in §§ 102(a), (e). Merck thus cannot claim a lack of knowledge of the rule of law based on some arguably contrary language in the MPEP. "To the extent the MPEP describes our case law differently, that interpretation does not control." *EmeraChem Holdings*, 859 F.3d at 1348 n.2 (cleaned up). Second, the MPEP explains the application of this rule to the specific circumstances of this case by reference to *Land* in the description in § 2136.05(b) and in § 2136.04, helpfully titled "Different Inventive Entity; Meaning of 'By Another,'" both of which describe a disclosure by a subset of inventors as a disclosure "by another." Merck's disagreement with the rule of law or misinterpretation of the law does not justify a remand.

This is not a case like *In re Kaghan*, where we required the Board to honor the procedural mandates it included in the MPEP. 387 F.2d 398, 400–01 (CCPA 1967). There, the MPEP prohibited rejections based on res judicata where a prior decision was not final and still appealable to the Board or the Court of Customs and Patent Appeals, and guaranteed a right to a substantive examination after an applicant filed a continuation. *Id.* Applicants filed a continuation-in-part after a substantive rejection of a parent application but were rejected without substantive adjudication of the merits based only on res judicata over the nonfinal adjudication of the parent application. *Id.* at 399–401. Our predecessor court held that the Patent Office was prohibited from making such a rejection in light of the MPEP

provisions, "on which applicants for patents are entitled to rely in good faith in the orderly conduct of their business in the Patent Office." *Id.* at 401.

Kaghan does not stand for the proposition that an interpretation of this court's caselaw in the MPEP restricts our interpretation (or the Board's interpretation) of substantive law. Rather, *Kaghan* required the Patent Office to honor the *procedural* mechanisms that it had set forth for the "orderly conduct" of examinations *in the Patent Office*. In *Kaghan*, there was no conflict with this Court's case law. Here, by contrast, honoring Merck's interpretation of those provisions of the MPEP would conflict with our case law on a substantive interpretation of the law and inconsistent with other provisions and comments in the MPEP. As we said in a related context: "To the extent the MPEP describes our case law differently, however, that interpretation does not control." *EmeraChem Holdings*, 859 F.3d at 1348 n.2.

C

Next, Merck argues that the Board erred in finding that Merck had not established that De Luca was a contributing inventor of the six-line disclosure. Appellant's Opening Br. 37–43.

First, Merck argues that the Board legally erred by requiring Merck to show a "specific contribution made by De Luca." *Id.* at 37 (quoting J.App'x 32). Merck argues that, instead, the Board should have applied the "rule of reason" and considered all the evidence to determine whether the inventors' testimony about De Luca's contribution was corroborated. *See Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1461 (Fed. Cir. 1998) ("Whether the inventor's testimony has been sufficiently corroborated is evaluated under a 'rule of reason' analysis."). The rule of reason requires "an evaluation of *all* pertinent evidence so that a sound determination of the credibility of the alleged

inventor's story may be reached." *Id.* (quoting *Price v. Symsek*, 988 F.2d 1187, 1195 (Fed. Cir. 1993) (cleaned up)).

The Board here did not fail to apply the "rule of reason" by seeking corroboration of De Luca's "specific contribution," J.App'x 32, to the Bodor disclosure. For De Luca to be considered a joint inventor of the disclosure—as would be required to exclude the disclosure from the prior art, *see supra*—his "contribution [had to be] significant enough, when measured against the full anticipating disclosure, to render him a joint inventor of the applied portions of the reference," *Duncan Parking*, 914 F.3d at 1358, and not merely some unspecified involvement in the development of the dosing regimen disclosed in Bodor.

There is no doubt that the Board here considered all the evidence in making that evaluation. The Board considered the testimony of Dr. Munafo, on which Merck primarily relies, but focused on Dr. Munafo's statement that he was "not aware of [De Luca's] . . . personal intellectual contribution," and could not "give details" of his contribution, "besides the fact that [De Luca's] department was also represented [o]n the project team." J.App'x 4885 (Munafo Testimony at 95). The Board also considered the testimony of Drs. Bodor and Dandiker, noting that they too could not "say anything" about De Luca's contribution to the dosing regimen." J.App'x 31. The Board also noted De Luca's cursory mention in the Amsterdam Minutes and explained why it found that unconvincing to support De Luca's inventive contribution to the Bodor dosing regimen. J.App'x 32 n.17 (redacted).

Even if there is undisputed evidence that De Luca contributed *something* to the Bodor disclosure, the Board did not fail to apply the rule of reason by asking whether that contribution was "significant," as required by *Duncan Parking*. *See* J.App'x 31 (finding that Merck failed to produce evidence "that named inventor De Luca provided *an inventive* contribution to the 6-line regimen that appears in

Bodor" (emphasis added)). We see no legal error, and Merck does not challenge the purely factual sufficiency of the Board's determination that De Luca did not provide an inventive contribution to the Bodor disclosure.

Second, Merck argues that the Board legally erred when it "effectively place[d] the burden of persuasion" on Merck, Appellant's Opening Br. 43, by requiring Merck "to show that De Luca must necessarily be a co-inventor of Bodor's 6-line disclosure," *Id.* (quoting J.App'x 34).

The Board did not shift the burden of persuasion to Merck. Rather, the Board expressly shifted *only* the burden of production to Merck. J.App'x 31 ("We agree with Patent Owner that the ultimate burden of persuasion in an IPR remains with Petitioner."); J.App'x 30–31 ("Petitioner met its initial burden to show that Bodor is 102(a) and (e) art . . . . The burden thus shifted to Patent Owner to come forward with evidence sufficient to support the proposition that Bodor is not prior art."). The only basis for Merck's assertion that the Board shifted the burden of persuasion is its disagreement with the Board's finding that De Luca did not significantly contribute to the Bodor disclosure based on the evidence Merck proffered. This is not legal error.

D

Finally, Merck factually argues that the Board lacked substantial evidence to support its alternative finding that Drs. Bodor and Dandiker *did* contribute to the dosing regimen in Bodor and were thus joint inventors of the six-line disclosure. We need not and do not address the correctness of the Board's alternative determination because, for the reasons discussed above, we hold that the Board did not legally or factually err in holding that the six-line disclosure was prior art as to the patents-in-suit.

We turn next to the Board's determination of obviousness.

III

The independent claims-at-issue here all include a series of sequential steps: an "induction period" of oral cladribine administration "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," followed by "a cladribine-free period lasting from about 8 months to about 10 months," and, key in this appeal, "a maintenance period lasting from about 2 months to about 4 months" of oral cladribine administration, "wherein the total dose of cladribine reached at the end of the maintenance period is about 1.7 mg/kg."

The Board found that Bodor suggested a retreatment period, crediting the testimony of Hopewell's expert, Dr. Miller, that "Bodor's recitation of specific durations for the drug-free periods logically suggests a retreatment period," J.App'x 53, given cladribine's quantifiable effect on suppressing lymphocytes and given MS's chronic nature, particularly where prior art like Stelmasiak taught retreatment specifically using cladribine. J.App'x 57 (noting that prior art "*specific to cladribine* expressly teaches MS-treatment regimens that include cladribine-free periods and suggests retreating patients with cladribine as needed"). The Board explained that a skilled artisan would have logically used Bodor's two-month treatment period and dose as a "starting point" for optimization of the maintenance phase, J.App'x 54, and optimal dosing would be "easily determined," as stated by Bodor, *id.* (quoting Bodor, col. 24, ll. 6-9, J.App'x 1940).

Merck first argues that substantial evidence does not support the Board's finding that Bodor "teaches or suggests" retreatment merely by stating a timeframe for a cladribine-free period. Merck argues that the end of the cladribine-free period does not imply retreatment, any more than a warning not to administer a second x-ray within two weeks implies the administration of a second x-

ray thereafter. Appellant's Opening Br. at 51. Merck argues that even if the nature of MS and Bodor's limited cladribine-free period does suggest retreatment of some kind, it does not suggest retreatment using cladribine (selected from among all the available MS drugs), administered orally, at the particular claimed dose for the particular claimed dosing period, and with the particular subsequent no-treatment period, as required by the claims. *Id.* Finally, Merck argues that Stelmasiak does not cure this lack in Bodor because its teaching of retreatment with cladribine used a wholly different dosing regimen. *Id.* at 53.

Hopewell essentially argues that it won the battle of the experts, and its expert, Dr. Miller, provided substantial evidence of the disclosure and reason to re-treat. Appellee's Br. 50 (citing J.App'x 1061 (¶ 87), J.App'x 1059–61 (¶¶ 84–86), J.App'x 1033–39 (¶¶ 39–49), J.App'x 5491 (¶ 70)). It argues that because MS is a chronic disease, Bodor's identification of a 10-month cladribine-free period, J.App'x 1939, col. 23, l. 20, implies retreatment because the MS will inevitably become worse and require retreatment "if cladribine is to become a practical long-term therapy for MS." J.App'x 58; *see also* J.App'x 2310 (Romine et al., incorporated by reference by Bodor: "The lengthy but impermanent duration of effect of cladribine means that retreatment will be necessary if cladribine is to become a practical long-term therapy for MS."). Hopewell also argues that the Board reasonably found that an ordinary artisan would use the Bodor initial dosing regimen as the starting point for retreatment based on Hopewell's expert testimony. Appellee's Br. 51 (citing J.App'x 1074–76 (¶¶ 102–104)).

Substantial evidence supports the Board's determination that Bodor and Stelmasiak disclose retreatment. At the most basic level, there is no dispute that Stelmasiak teaches retreatment with cladribine after initial treatment

and a cladribine-free period. J.App'x 58; J.App'x 1061–62 (¶ 88) (Miller Decl. asserting that Stelmasiak teaches cyclically administering cladribine for a six month induction period, a three month cladribine-free period, then a maintenance period, and another cladribine-free period); J.App'x 1849 (Stelmasiak describing regimen with six cladribine monthly courses and additional courses at 9 and 12 or 15 months); Appellant's Opening Br. 53 (recognizing Stelmasiak's two or five month "no-treatment periods"). Bodor's disclosure of a discrete cladribine-free period also supports Stelmasiak's teaching given that MS is a chronic disease that often requires continuous treatment. J.App'x 44; J.App'x 58; J.App'x 1061 (¶ 87) (Miller Decl. stating that "there is no known cure for MS," and "MS patients typically receive more than one course of drug therapy to treat active relapses, prevent relapses, and/or prevent or slow further progression of the disease"); J.App'x 1060–61 (¶86) (Miller Decl. opining that a "POSA would have understood that Bodor teaches a cyclical cladribine regimen, in that cladribine is re-administered at the end of the specified cladribine-free period—otherwise, the specified length of time of the cladribine-free period is meaningless.").

Merck responds that the prior art did not teach retreating a patient after a cladribine-free period "unless and until a need arises (such as disease progression) **and** it is safe," rather than retreating regardless of progression or safety as Merck alleges the claims require. Appellant's Opening Br. 50 (emphasis in original). We agree with the Board that, even if true, this does not undermine the disclosure of the limitation, because the claims do not require automatic retreatment with cladribine regardless of safety or disease progression. *See* '947 patent, cl. 36. Merck does not contest that the prior art (in Stelmasiak and other references of record, like Rice) teaches retreatment of MS with cladribine. *Cf.* Appellant's Opening Br. 54 (arguing error in the Board's motivation to combine because, inter alia, "a skilled artisan considering re-treatment would have taken

account of multiple factors . . . such as disease progression, the drug's therapeutic profile, and safety criteria"). Even if sometimes retreatment would not occur because of safety concerns or temporary disease remission, that does not undermine the disclosure of this limitation. J.App'x 59 (citing J.App'x 1072–73 (¶¶ 100–01)) ("[A]t least some patients would be expected to exhibit signs of disease relapse during or after Bodor's initial treatment, motivating retreatment for the relapsing patient after the 10-month cladribine-free period[.]"); J.App'x 53–54 (citing J.App'x 5491 (¶ 70) ("[S]uch re-treatments were consistent with prior clinical studies where patients relapsed during or after cladribine therapy, such as Stelmasiak.")).

This approach is not improper "[t]heorizing [of] hypothetical results" of Bodor. Appellant's Opening Br. 54. Merck is simply incorrect that the claims require "re-treatment in ***every*** case." *Id.* at 55 (emphasis in original). The claims merely require retreatment, and a disclosure that retreatment will occur sometimes is enough to show anticipation. *Cf. Allergan*, 754 F.3d at 959 ("[W]here a disclosure was written to provide an optional ingredient, structure, or step, we have held that the optional component still anticipates.").

Substantial evidence also supports the Board's finding that an ordinary artisan would look to Bodor's initiation dosing regimen as a safe and effective starting point for the dosing for the retreatment period. As Bodor expressly states, the optimal dosing regimen is "easily determined," and there is no reason for this to be less true of the retreatment than the initial treatment. J.App'x 1940, col. 24, ll. 1–9 ("[O]ne of skill will appreciate that the therapeutically effective amount of cladribine administered herein may be lowered or increased by fine tuning and/or by administering cladribine according to the invention with another active ingredient . . . . Therapeutically effective amounts 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 54 (quoting same).

Substantial evidence also supports the Board's finding that Bodor and Stelmasiak suggest a cladribine-free period after the retreatment, largely for the same reasons that Bodor teaches a cladribine-free period after the initial treatment: "to manage possible adverse effects" such as toxicity and increased infection, that were well-known from prolonged treatment with cladribine, J.App'x 63; J.App'x 1075–77(¶¶ 103–05) (Miller Decl.), and consistent with Stelmasiak's teaching of cyclical cladribine and cladribine-free periods.

Finally, substantial evidence supports the Board's finding of a reason to combine Bodor and Stelmasiak with a reasonable expectation of success. Dr. Miller's testimony, quoted above, that an ordinary artisan would have retreated with cladribine patients who show signs of relapse supports the Board's finding, as does the Board's determination that "it would have been logical to use Bodor's initial treatment dose/duration as a starting point for optimization." J.App'x 64. Substantial evidence also supports the Board's determination that lymphocyte suppression was a result-effective variable. *Id.* The Board also held that the combination would have a reasonable expectation of success because the claims "are not limited to any efficacy degree," J.App'x 65 (citation omitted), and that Bodor, prior art incorporated by reference into Bodor, and Stelmasiak, all show efficacy of MS treatment with Cladribine. J.App'x 66–68.

Merck argues that "there were significant concerns about cladribine's safety and efficacy for MS treatment," Appellant's Opening Br. 56, but Bodor and Stelmasiak indisputably disclose efficacy of cladribine as an MS treatment. The Board credited Dr. Miller's testimony and these references over the doubts Merck identifies, and Merck identifies nothing to undermine the substantial evidence

accepted by the Board. J.App'x 56 (citing multiple sources including Stelmasiak and several others).

Merck argues that Dr. Miller questioned the efficacy of cladribine prior to this litigation before flipping in his current testimony, but this too does not undermine substantial evidence of the motivation to combine because the Board is entitled to credit Miller's testimony presented at trial.

Moreover, we identify no error in the Board's determination that dosing optimization was a result-effective variable based on optimizing a patient's lymphocyte count. J.App'x 65–66; J.App'x 1074–75 (¶ 102). Merck argues that dosing cannot be a result-effective variable because reducing lymphocyte count is not the goal of cladribine treatment. *See* Appellant's Opening Br. 58. This is inapposite because substantial evidence supports the Board's determination that lymphocyte count may be used to optimize a dose. Cladribine's efficacy was indisputably well-documented in the prior art—the limiting variable was safety, which can be evaluated by lymphocyte count. J.App'x 76; J.App'x 1065 (Miller Decl. ¶ 91); J.App'x 4475 at p. 72 ll. 8–13 (Merck's expert Dr. Lublin confirming that "yes," "one [can] confirm the pharmacological effect of cladribine by measuring lymphocyte count before and after cladribine administration").

We conclude that substantial evidence supports the Board's determination that Bodor and Stelmasiak taught all the limitations in the claims here and that the prior art motivated the combination of Bodor and Stelmasiak with a reasonable expectation of success.

IV

Finally, Merck argues that the Board erred in construing the claims to cover flat dosing rather than weight-based dosing. Appellant's Opening Br. 59–63. Merck argues that because the claims indicate the dosage at the end of the

induction period in terms of dose per kilogram, i.e. "from about 1.7 mg/kg to about 3.5 mg/kg," the claims require determining the dose based on the patients weight.

We disagree. As Hopewell correctly argues, the claims cover a particular "*total dose of cladribine reached*" at the end of the induction and maintenance periods—not a technique for determining the dose. As Hopewell argues and as the Board noted, there is no step in the claims requiring acquiring or knowing a patient's weight, a step that would be required to prove infringement (and disclosure in the prior art). J.App'x 47. Thus, a disclosure administering a particular dose to a particular patient that fits within the claimed range would be a disclosure of the limitation—regardless of how that dose was determined.

Moreover, Merck's argument is belied by its attempts to show inventorship of Bodor's six-line disclosure (a flat-dosing disclosure) by reference to weight-based research, Appellant's Opening Br. 12–13 (citing J.App'x 7200 (Amsterdam minutes showing mg/kg dosing) and citing J.App'x 7184–85 (Briefing Document showing mg/kg dosing) ("[The six-line disclosure in Bodor] is very similar to the regimen described by Serono in the Amsterdam Minutes and Briefing Document"), and the multiple references in the patent and its incorporated references translating without comment between flat and weight-based dosing, as noted by the Board. J.App'x 42–43.

CONCLUSION

For the foregoing reasons, we affirm the Board's determination that the Bodor six-line disclosure is prior art to the patents-in-suit here, and the Board's determination that the combination of Bodor and Stelmasiak renders obvious all the claims-at-issue.

AFFIRMED

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

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