No. 2021-2121

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

MYLAN PHARMACEUTICALS INC.,

Appellant,

v.

MERCK SHARP & DOHME CORP.,

Appellee.

On Appeal from the Patent Trial and Appeal Board
No. IPR2020-00040

CORRECTED RESPONSE TO COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC BY MERCK SHARP & DOHME CORP.

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2021-2121

Short Case Caption Mylan Pharmaceuticals Inc. v. Merck Sharp & Dohme Corp.

Filing Party/Entity Merck Sharp & Dohme Corp.

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1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	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. ☐ None/Not Applicable	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. ☐ None/Not Applicable
Merck Sharp & Dohme Corp.	None	Merck & Co., Inc.

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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. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

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Merck Sharp & Dohme LLC v. Mylan Pharmaceuticals Inc., No. 2023-1013 (Fed. Cir.)		
In re Sitagliptin Phosphate ('708 & '921) Patent Litigation, MDL No. 19-2902-RGA (D. Del.)		

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).

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INTRODUCTION

The panel unanimously and correctly held that substantial evidence supports the Patent Trial and Appeal Board's determination that Mylan failed to prove the challenged claims were anticipated. The panel's decision reflects the straight-forward application of law to case-specific facts.

This case concerns Merck's invention of a genus of compounds, called dipeptidyl peptidase-IV ("DP-IV") inhibitors, that are effective for treating type-2 diabetes. In international patent application WO'498, Merck disclosed an enormous genus of DP-IV inhibitors. Merck's later '708 patent disclosed and claimed one especially effective DP-IV inhibitor, in a particularly effective form for administration to humans—a sitagliptin dihydrogen-phosphate salt with a 1:1 stoichiometry (*i.e.*, a 1-to-1 ratio of sitagliptin to phosphoric acid) ("1:1 sitagliptin DHP").

Mylan urged that WO'498 anticipated the '708 patent's claims. But Mylan could not prove its case under the normal anticipation standard, as WO'498 did not expressly "disclose all elements of the claim . . . 'arranged as in the claim.'" *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). Nowhere did WO'498 expressly disclose 1:1 sitagliptin DHP.

Mylan thus invoked a narrow exception to the express-disclosure requirement. Under that exception, disclosing a "genus may anticipate a claimed species" if "the genus is ***so small*** that" skilled artisans "would '***at once envisage each member*** of

this limited class.'" *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1285 (Fed. Cir. 2017) (emphasis added). WO'498's claim 15 listed 33 DP-IV inhibitor compounds, one of which was sitagliptin. Dozens of pages earlier, WO'498 disclosed numerous acids that ***might*** form a pharmaceutically acceptable sitagliptin salt. Mylan argued that, by piecing those disclosures together, skilled artisans could envisage a genus that would include 1:1 sitagliptin DHP.

The Board rejected Mylan's "at once envisage" argument. This Court affirmed, holding the Board did "not err in finding that a class of ***957*** predicted salts that ***may*** result from the 33 disclosed compounds and eight preferred acids, some of which may not even form under experimental conditions, is insufficient to meet the 'at once envisage' standard set forth in" this Court's precedents. Op. 10 (emphasis added). Mylan's rehearing petition ***does not dispute*** that factual finding that skilled artisans would not "at once envisage" those 957 theoretical salts.

Mylan instead complains that, in applying the "at once envisage" test, the panel should have considered a genus limited to ***salts made from sitagliptin and phosphoric acid***, in their various stoichiometries. Pet. 5-6. That effort to narrow the genus through hindsight is waived: Mylan never presented that argument to the Board. Mylan's argument fails regardless because, as the panel held, WO'498 provides "no direction to select sitagliptin" from among the many listed DP-IV inhibitor

compounds. Op. 9. Nor does it "single[] out" phosphoric acid from the larger list of preferred acids. *Id*. Mylan does not dispute those factual findings, either.

Seeking to manufacture an issue that sounds worthy of rehearing, Mylan urges that the panel's decision conflicts with *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368 (Fed. Cir. 2005). It does not. According to Mylan, *Perricone* "reject[ed] the notion that a reference cannot anticipate merely because the relevant teachings 'appear[] without special emphasis in a longer list.'" Pet. 1 (quoting 432 F.3d at 1376). But *Perricone* neither involved nor addressed the "at once envisage" standard Mylan invokes here. In *Perricone*, the reference provided "***specific disclosure***" of the anticipating species. 432 F.3d at 1377 (emphasis added). The Court observed that, where a reference includes an anticipatory disclosure, it does not fail to anticipate simply because that disclosure appears in a list. *Id.* *Perricone* itself noted that "specific disclosure" is what "ma[de] th[at] case different from cases"—like this one—"involving disclosure of a broad genus without reference to the potentially anticipating species." *Id.* *Perricone* says nothing about how courts should analyze an "at once envisage" theory. The panel's decision thus could not contradict *Perricone* for the reasons *Perricone* itself gives. Mylan identifies no error requiring correction, much less an "intracircuit split" warranting rehearing en banc. Pet. 3.

BACKGROUND

I. MERCK'S BREAKTHROUGHS IN TREATING TYPE-2 DIABETES

A. Merck Discloses a Class of DP-IV Inhibitors in WO'498 and the '871 Patent

In the early 2000s, Merck invented a class of compounds, "DP-IV inhibitors," that treat type-2 diabetes. Appx368-370. In July 2002, Merck filed application WO 03/004498, which published on January 16, 2003.[1] Appx367. WO'498's claim 1 recites a generic formula, Appx417, covering "millions of compounds," Appx2630. Claim 15 identifies 33 DP-IV inhibitors, including sitagliptin, the compound at issue. Appx421-427.

WO'498's claims 1 and 15 generically encompass "pharmaceutically acceptable salts" of the DP-IV inhibitors. Appx418; Appx427. WO'498 identifies as "[p]articularly preferred" eight acids (including phosphoric) that theoretically may be used to prepare such salts. Appx377. The only salts WO'498 exemplifies, however, are hydrochloride salts. Appx27-28.

B. Merck Develops and Patents 1:1 Sitagliptin DHP

By the time WO'498 published, Merck had made advances ***not*** disclosed in that reference. From the millions of DP-IV inhibitors, Merck had identified sita-

[1] Merck simultaneously filed an application with the USPTO, and was granted U.S. Patent No. 6,699,871 on March 2, 2004. Appx504. The "'498 disclosure and the '871 patent are identical in relevant part." Op. 3 n.1; Appx42. Merck here refers to WO'498 to encompass both.

gliptin as particularly promising. And it had reduced to practice a salt for administration to humans—1:1 sitagliptin DHP (a dihydrogenphospate salt with a 1:1 "stoichiometry" of sitagliptin and phosphoric acid).

Although Merck had selected sitagliptin for clinical development by 2001, Appx3530; Appx4063-4064, it spent years attempting to formulate a pharmaceutical salt of sitagliptin with favorable characteristics for a commercial drug, Appx1094; *see* Appx1069. However, "'[n]o predictive procedure to determine whether a particular acidic or basic drug would form a salt with a particular counter-ion has been reported in the literature.'" Appx2603-2604 (quoting Appx2038). After numerous experiments, Merck ultimately produced 1:1 sitagliptin DHP, Appx1072; Appx2606, for which it was awarded U.S. Patent No. 7,326,708, Appx78-93.

II. PROCEDURAL HISTORY

A. The Board Rejects Mylan's Challenges

After Merck sued Mylan for infringement, Mylan petitioned for *inter partes* review, arguing that WO'498 anticipated claims 1-3 of the '708 patent and rendered claims 1-4 obvious. Appx177-261. To anticipate, prior-art references ordinarily must "disclose all elements of the claim . . . 'arranged as in the claim.'" *Net MoneyIN*, 545 F.3d at 1369. Mylan did not contend that WO'498 expressly disclosed 1:1 sitagliptin DHP. Instead, Mylan urged inherency. Mylan's expert, Dr.

Chorghade, asserted that a 1:1 salt forms "every time" sitagliptin and phosphoric acid react. Appx207-209 & n.8.

But Merck's expert, Dr. Matzger, showed that sitagliptin phosphate salts exist in other stoichiometries, such as 3:2 and 2:1. *See* Appx2649-2658; Appx2666-2719. He showed that "the reaction of phosphoric acid with sitagliptin" does not "necessarily or inherently result[] in a 1:1" sitagliptin DHP salt. Appx2664. Mylan's expert conceded he had done no experiments, and consulted no literature, before erroneously opining that a 1:1 stoichiometry is inherent. Appx2369(169:9-14, 172:1-7).

Mylan pivoted to a different theory of anticipation, asserting that skilled artisans would "at once envisage" 1:1 sitagliptin DHP by piecing together disclosures in WO'498. Appx210. Mylan argued that WO'498 disclosed sitagliptin among 33 compounds in claim 15; that it generically claimed "pharmaceutically acceptable salts"; and that, 44 pages earlier, it listed phosphoric acid as one of eight "particularly preferred" acids that might be considered for salt formation. Appx206-207. Those lists of potential constituents, it argued, "collapse to form a single comprehensive list, which provides the complete list of compounds and their accompanying 'pharmaceutically acceptable salts'—one of which is sitagliptin phosphate." Appx212. Mylan did not identify a disclosure of the 1:1 stoichiometry for sitagliptin DHP. *See* Appx1052-1054.

The Board rejected Mylan's challenges. Appx1-76. It was "undisputed" that 1:1 sitagliptin DHP "is not ***expressly*** disclosed in WO'498." Appx27. WO'498 did not disclose ***any phosphate salt*** of ***any*** exemplary DP-IV inhibitor; it exclusively disclosed hydrochloride salts. Appx17. And Merck had disproved Mylan's inherency argument. Appx35; Appx41.

The Board then turned to Mylan's at-once-envisaging theory. Under this Court's precedent, "disclosure of a limited number of combination possibilities" may in some circumstances effectively disclose each of the individual "combinations" themselves. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 851 F.3d 1270, 1274 (Fed. Cir. 2017). But "[e]ven accepting" Mylan's position that WO'498 could be reduced to a "'list' of 33 example active compounds" and another "'list' of eight preferred acids . . . to form potential salts, . . . there is no 'list' that identifies ***expressly*** all the phosphate salts [of those compounds] in any, much less all, the potential stoichiometric ratios." Appx29. That distinguished cases (like *Perricone*) "where the relevant subject matter was listed expressly." *Id.*

Under this Court's "envisaging" precedent, moreover, Mylan was required to prove skilled artisans "would 'at once envisage'" not just the claimed species, but "'***each member*** of th[e] limited class'"—the genus—allegedly disclosed in the prior-art reference. Appx33 (quoting *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1376 (Fed. Cir. 2006)) (emphasis added). It was "uncontested"

that, after accounting for stoichiometry, the two lists Mylan identified theoretically could yield "'957 salts.'" Appx29. Mylan's assertion that skilled artisans would "at once" envisage that broad class was "undermined" by "its own expert's testimony" on inherency, which failed to envisage the possible stoichiometries of sitagliptin phosphate salts. Appx33.[2]

B. The Panel's Decision

This Court found that the "Board did not err in determining that [WO'498] does not expressly disclose," or "inherently disclose," a "1:1 sitagliptin DHP salt." Op. 9. The panel acknowledged that, where a reference does not disclose a species, disclosure of a sufficiently small genus may anticipate if skilled artisans would "'at once envisage each member of [the] ***limited*** class'" constituting the genus. *Id.* (quoting *In re Petering*, 301 F.2d 676, 681 (C.C.P.A. 1962)). But the "key term," the panel explained, "is 'limited.'" *Id.* "[A]s the Board considered, the list of 33 compounds, with no direction to select sitagliptin from among them, plus the eight 'pharmaceutically preferred' acids and various stoichiometric possibilities, results in 957 salts, some of which may not exist." *Id.* That is a "far cry" from what prior

[2] The Board also rejected Mylan's obviousness arguments. WO'498 could not be prior art for most claims because Merck reduced the subject matter—1:1 sitagliptin DHP—to practice before WO'498's publication. Appx43-45. The Board rejected Mylan's obviousness challenges to the remaining claims on the merits. Appx55; Appx58.

decisions held could be at once envisaged. *Id.* The panel found that the Board's decision was "supported by substantial evidence." *Id.* The Court rejected Mylan's obviousness challenges, agreeing with the Board that they lacked merit. Op. 10-12.

REASONS FOR DENYING THE PETITION

I. THERE IS NO INTRACIRCUIT CONFLICT

The panel properly found that the Board's decision on anticipation was supported by substantial evidence. Further review is unwarranted.

A. The Panel Properly Applied This Court's "At Once Envisage" Precedent

To anticipate, a reference ordinarily must disclose every element of the claimed invention, arranged as in the claim. There is, however, a narrow exception: Sometimes the disclosure of a "genus may anticipate a claimed species" if "the genus is ***so small*** that" skilled artisans "would '***at once*** envisage ***each member of this limited class***.'" *Wasica*, 853 F.3d at 1285 (emphasis added). The theory is that, where there is a "small recognizable class" defined by "common properties," *In re Ruschig*, 343 F.2d 965, 974 (C.C.P.A. 1965), disclosing the genus may be equivalent to disclosing "each member," *Petering*, 301 F.2d at 681-82.

Mylan argues that, in applying that "at once envisage" standard, the panel defined the genus that must be envisaged too broadly. According to Mylan, the panel erred by using WO'498's list of 33 compounds as the "starting point for the anticipation analysis," rather than just sitagliptin. Pet. 7-8. Any supposed error is

waived. ***Mylan*** told the Board to start with the 33 compounds. Mylan urged that WO'498 disclosed two "lists"—one depicting 33 DP-IV inhibitors in claim 15, Appx421-427, and another naming eight "preferred" acids, Appx377. According to Mylan, the two lists "'collapse to form a single comprehensive list'"—*i.e.*, genus—"of all the compounds and salts." Appx20. Mylan's argument that the relevant genus is limited to sitagliptin phosphate salts was first raised on appeal. *See* Merck. Br. 36. Because it was "not raised before the Board," the argument is waived. *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1075 (Fed. Cir. 2017). Rehearing is inappropriate for that reason alone.

On the merits, the panel correctly found substantial evidence supported the Board's decision. While Mylan tries to pluck one of 33 disclosed compounds from WO'498's claim 15, it cannot deny that "WO'498 contains 'no direction to select sitagliptin from among' the 33 listed compounds." Pet. 8 (quoting Op. 9). Mylan's expert conceded the point. *See* Appx2342 (61:7-62:9), Appx2373-2374 (188:6-189:8). Nor does Mylan dispute the panel's conclusion that "nothing in [WO'498] singles out ***phosphoric*** acid or any ***phosphate*** salt of any DP-IV inhibitor." Op. 9 (emphasis added).

Mylan instead contends that "anticipation through a list disclosure does not have a selection requirement." Pet. 8. That may be correct when the anticipating species is ***expressly disclosed*** in a list. But Mylan concedes that 1:1 sitagliptin DHP

"is not ***expressly*** disclosed in WO'498." Appx27. That is why Mylan resorted to an "at once envisage" theory. And the "at once envisage" theory simply does not allow challengers to arbitrarily narrow the genus that must be "at once envisaged," as Mylan proposes. The panel's decision is consistent with circuit precedent rejecting efforts to pick-and-choose among undifferentiated lists of elements from different parts of a reference. The at-once-envisage theory does not countenance "dissection and recombination of the components of the specific illustrative compounds . . . to create hindsight anticipations." *Ruschig*, 343 F.2d at 974. Absent specific preferences suggesting a narrower genus, at-once-envisage analysis must consider the full "class of compounds" the "reference discloses." *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1383 (Fed. Cir. 2006).

Petering, which first recognized the "at once envisage" theory, makes that clear. The Court found that the patent's "broad generic disclosure" of compounds did not "itself describe[ ]" the claimed invention. 301 F.2d at 681. Only because the patent disclosed "***specific preferences***" for certain substituents did the Court find that it described a "much more limited class" that skilled artisans could "at once envisage." *Id.* (emphasis added).

Mylan errs in urging (Pet. 10) that *William Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356 (Fed. Cir. 2012), is to the contrary. *Wrigley* confirms that "at once envisage" analysis requires "each member" of a "defined and limited class"

to be "immediately apparent" to skilled artisans. *Id.* at 1361. The prior-art reference there disclosed combinations of chewing-gum cooling and flavoring agents. Disproving Mylan's argument that "special emphasis" is not needed to narrow the genus when combining lists of substituents, Pet. 1, *Wrigley* limited the class because the reference described 23 flavoring agents as "'most suitable'" and three cooling agents as "'particularly preferred,'" 683 F.3d at 1360-61. This Court's precedent, moreover, requires that skilled artisans be able to "at once envisage ***each member***" of the genus—not just the specifically anticipating species. *Eli Lilly*, 471 F.3d at 1376 (emphasis added). The sixty-nine combinations that could result from the lists in *Wrigley* were, as the panel noted, a "far cry" from the 957 potential salts here. Op. 9.

The panel committed no error in refusing to limit the relevant genus to sitagliptin phosphate salts absent disclosures singling out such salts from the 957 salts that theoretically could be formed—but might or might not exist—by combining the two lists Mylan itself proposed to the Board.[3]

[3] Mylan complains about the Board's antedation analysis, which "disqualified WO'498 as prior art" for Mylan's ***obviousness*** challenge for all but two claims. Pet. 6-7, 11. But Mylan asserts no separate grounds for rehearing, arguing only that the Board's at-once-envisage analysis "infected" its antedation decision. Pet. 6. Mylan's complaints about antedation therefore fall with its erroneous at-once-envisage arguments.

B. The Panel's Decision Does Not Conflict with *Perricone*

Mylan contends that the panel's decision "creates an intracircuit split" with *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368 (Fed. Cir. 2005). Pet. 3. That contention lacks merit. *Perricone* holds that ***expressly disclosed*** compounds can anticipate even if part of a longer list. It has no bearing on cases where express disclosure is absent and the challenger urges that skilled artisans would supposedly "at once envisage" an entire genus.

In *Perricone*, the patent claimed methods of treating sunburn through "application of [an] ascorbyl fatty acid ester," such as "ascorbyl palmitate." 432 F.3d at 1371. The accused infringer urged the patent was anticipated by the prior-art reference "Pereira," which taught "a total of fourteen skin benefit ingredients," one of which was "ascorbyl palmitate." *Id.* at 1376. This Court "reject[ed]" the patentee's argument "that one of these ingredients cannot anticipate because it appears without special emphasis in a longer list." *Id.* The Court acknowledged "other opinions stat[ing] that disclosure of a broad genus does not necessarily specifically disclose a species within that genus." *Id.* at 1377. But it found those cases distinguishable because "Pereira specifically discloses ascorbyl palmitate." *Id.* "That ***specific disclosure***, even in a list, ***makes this case different*** from cases involving disclosure of a broad genus without reference to the potentially anticipating species." *Id.* (emphasis added).

Perricone's observation makes sense. Where a reference satisfies the standard for anticipation by "disclos[ing] all elements of the claim . . . 'arranged as in the claim,'" *Net MoneyIN*, 545 F.3d at 1369, it should not ***cease*** to anticipate merely because it ***also*** discloses ***other*** items "in a longer list," *Perricone*, 432 F.3d at 1376.

In re Gleave, 560 F.3d 1331 (Fed. Cir. 2009), *see* Pet. vi, 9, is to the same effect. *Gleave* rejected the argument "that a description of a compound cannot be anticipatory where it appears in a long list of other compounds." 560 F.3d at 1337. In *Gleave*, as in *Perricone*, the prior art "***expressly*** list[ed]" the claimed species in a list of "every possible fifteen-base-long oligodeoxynucleotide sequence." *Id.* at 1338 (emphasis added).

The panel's decision cannot conflict with *Perricone* or *Gleave* because WO'498 does ***not*** "specifically disclose" the claimed 1:1 sitagliptin DHP salt, in a "list" or otherwise. Indeed, WO'498's lack of "***express***[ ] disclos[ure]" was "undisputed." Appx27 (emphasis added); *see* Appx5, Appx7. Mylan resorted to a theory that, by combining two lists in WO'498, skilled artisans would "at once envisage" a genus (of 957 potential salts) that would encompass 1:1 sitagliptin DHP. Op. 8-9.

Mylan's petition admits "that reaching sitagliptin-phosphoric acid salts requires combining two lists in the prior art." Pet. 9. But the distinction between that and express disclosure is hardly "of no moment." *Id.* Under the "at once

envisage" theory Mylan invokes, a "genus may anticipate a claimed species" only if "the genus is ***so small*** that" skilled artisans "would '***at once*** envisage ***each member*** of this limited class.'" *Wasica*, 853 F.3d at 1285 (emphasis added). Only then is disclosing the genus potentially equivalent to disclosing "each member." *Petering*, 301 F.2d at 681-82. The Board and panel correctly found that Mylan's proposed combination failed to result in a class "so small" that each member would be "at once" envisaged. Nothing in *Perricone* or *Gleave* remotely supports Mylan's argument on rehearing that, in conducting the at-once-envisage analysis, the genus should have been narrowed from the 957 hypothetical salts suggested by the two lists Mylan itself proffered below, down to a purely hindsight-based class consisting of the stoichiometries of sitagliptin phosphate salts.

While Mylan urges there is "no way to reconcile the panel opinion" with *Perricone*, Pet. 12, doing so is simple. Where the reference expressly discloses an anticipating species, as in *Perricone*, no "special emphasis" is required. 432 F.3d at 1376. But where the patentee resorts to an "at once envisage" theory, the Court assesses the breadth of the genus that must be "envisaged" by examining whether the reference discloses "specific preferences" for the relevant class. *Petering*, 301

F.2d at 681. There is no reason for "future litigants and panels of this Court to argue over which line of cases controls." Pet. 12.[4]

II. THE PANEL'S DECISION DOES NOT "JEOPARDIZE THE ONGOING UTILITY" OF ANTICIPATION

Mylan's suggestion that the panel's decision "constrains . . . the anticipation doctrine, to the point of jeopardizing its ongoing utility," Pet.13, is unsound. The "at once envisage" doctrine at issue here is a relatively obscure, narrow, and rarely invoked exception to the typical anticipation standard, as the paucity of cases invoking it makes clear. For that reason alone, the panel's decision has little importance for anticipation law generally—and certainly not such importance as to warrant the extraordinary measure of en banc review.

While Mylan asks "why would anyone turn to anticipation at all" after the panel's decision, Pet.14, parties will do so as they always have. They may do so where a reference "disclose[s] all elements of the claim . . . 'arranged as in the claim,'" *Net MoneyIN*, 545 F.3d at 1369, including when that disclosure appears in a list, *see Perricone*, 432 F.3d at 1376. And they may even do so under an at-once-

[4] Mylan's argument that the panel's decision "vitiates a critical distinction between list disclosures and genus disclosures," Pet. 12-13, is unpersuasive. WO'498 does not include a "list disclosure" of 1:1 sitagliptin DHP as contemplated by *Perricone*. It fails to "specifically disclose" that species, in a list or otherwise. 432 F.3d at 1377. While Mylan's "at once envisage" argument is based on combining different "lists" in WO'498 (as opposed to combining chemical variables in a Markush group), the combination nevertheless discloses a "genus" of DP-IV inhibitor salts.

envisage theory if the genus the reference discloses is so narrow that it is functionally equivalent to an express disclosure of each member. What parties cannot do is arbitrarily narrow the size of the genus without record basis, as Mylan proposes here.

Mylan's complaint about the panel decision "blur[ring] the lines between anticipation and obviousness," Pet. 3, 13, is backwards. ***Mylan*** seeks to utilize the "at once envisage" theory to evade the rigors of both doctrines. Mylan seeks to evade anticipation's requirement that the reference "disclose all elements of the claim . . . 'arranged as in the claim.'" *Net MoneyIN*, 545 F.3d at 1369. It instead tries to "combin[e]" disparate teachings to satisfy the claim's "elements," Pet. 1-2, but without obviousness's requirement of proof that skilled artisans "would have been motivated to combine or modify" prior art to produce the claimed invention, and would "have had a reasonable expectation of success in doing so." *Endo Pharms. Inc. v. Actavis LLC*, 922 F.3d 1365, 1373 (Fed. Cir. 2019).

III. THIS CASE IS A POOR VEHICLE

Finally, this case does not properly present the issue Mylan raises—even apart from Mylan's waiver of the issue presented. *See* pp. 9-10, *supra*. Mylan cannot prevail ***even if*** the relevant genus were limited to "sitagliptin-phosphoric acid salt[s]," as it now demands. Pet. 7-8. Under this Court's precedent, Mylan must show skilled artisans would "at once envisage ***each member***" of the genus. *Eli Lilly*, 471 F.3d at 1376. Here, the Board specifically found that Mylan's ***own expert*** "did

not even 'at once envisage' each member of the sub-class of different ***sitagliptin phosphate salts***." Appx33 (emphasis added). He initially opined that the combination would form a 1:1 stoichiometry "every time," and failed to envisage the other sitagliptin phosphate salts that have different stoichiometries. *Id.* Mylan's "envisaging theory" thus was fatally "undermined by . . . its own expert's testimony." *Id.* This case presents no issue warranting further review and none that could change the outcome here regardless.

CONCLUSION

The rehearing petition should be denied.

January 19, 2023

Respectfully submitted,

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FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2021-2121

Short Case Caption: Mylan Pharmaceuticals Inc. v. Merck Sharp & Dohme Corp.

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Signature: /s/ Jeffrey A. Lamken

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