Santa Clara University School of Law

Santa Clara High Technology Law Journal

Volume 39 | Issue 2 Article 3

5-20-2023

THE OLD AND NEW DIVIDES OF PATENT LAW: FROM THE THEORY OF ANTEDATION TO DEFINING IMMEDIATELY ENVISAGEABLE LIMITED CLASSES

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Mylan Pharms. Inc. v. Merck Sharp & Dohme Corp., 50 F.4th 147 (Fed. Cir. 2022)[*]

Recently, the United States Court of Appeals for the Federal Circuit ("Federal Circuit") ruled on a patent case involving the application of pre-America Invents Act ("AIA") antedation and the issue of when a genus of compounds is narrowly limited enough to anticipate an individual compound found within the genus.[1] On appeal, this case generally discussed why the claimant's anticipation and obviousness claims failed.[2] While the entire Federal Circuit decision will be discussed, this Comment will discuss in greater depth the reasons why antedation is no longer applicable under the AIA, and the implications of the Federal Circuit's decision to not set a standard for what defines a "limited class" under *In re Petering*.

I. FACTS AND PROCEDURAL BACKGROUND

Merck Sharp & Dohme Corp. ("Merck"), a pharmaceutical company, owns U.S. Patent No. 7,326,708 ("the '708 patent"),[3] which describes a 1:1 salt form of sitagliptin dihydrogenphosphate ("sitagliptin DHP"), a compound used for treating non-insulin-dependent diabetes, i.e., Type 2 diabetes.[4] The '708 patent recites a sitagliptin DHP salt with a 1:1 stoichiometry in independent claim 1, containing an (R)-configuration and (S)-configuration of sitagliptin DHP in dependent claims 2 and 3, respectively.[5] Dependent claim 4 recites a crystalline monohydrate form of the (R)-configuration, which is the marketed product.[6]

Mylan Pharmaceuticals Inc. ("Mylan")—a competitor of Merck's—petitioned for *inter partes* review of the '708 patent, arguing

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[1] *See Mylan Pharms. Inc. v. Merck Sharp & Dohme Corp.*, 50 F.4th 147, 152 (Fed. Cir. 2022); *see also In re Clarke,* 356 F.2d 987, 991 (C.C.P.A. 1966); *In re Petering*, 301 F.2d 676, 681 (C.C.P.A. 1962). Additionally, all citations to the Patent Act will refer to pre-AIA statutes as the patents are governed by the pre-AIA regime.

[2] *See Mylan*, 50 F.4th at 151; *see also In re Petering*, 301 F.2d at 681.

[3] *See generally* U.S. Patent No. 7,326,708 (filed June 24, 2003) (issued Feb. 5, 2008) [hereinafter "'708 patent"].

[4] *Mylan*, 50 F.4th at 150.

[5] *Id.*

[6] *Id.*

that claims 1–3, 17, 19, and 21–23 were anticipated and that claims 1–4, 17, 19, and 21–23 were obvious.[7] Mylan asserted three prior art references in support of its petition: (1) the Merck-owned International Patent Publication WO 2003/004498 ("the '498 publication") and its equivalent U.S. Patent 6,699,871 ("the '871 patent"), collectively known as "Edmondson";[8] (2) "Structural Aspects of Hydrates and Solvates" ("Brittain")[9]; and (3) "Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities" ("Bastin").[10]

Edmondson discloses three critical facts. Firstly, it discloses a genus of 33 compounds which inhibit the dipeptidyl peptidase-IV enzyme ("DP-IV inhibitors"), one of which is sitagliptin.[11] Secondly, it discloses eight "particularly preferred" acids for forming pharmaceutically acceptable salts.[12] Finally, it discloses that salts "may exist in crystalline forms, including as hydrates."[13]

Brittain describes crystalline monohydrate forms of pharmaceutical compounds[14] and exemplifies the challenges involved with the manufacturing and development of hydrates.[15] Bastin further discusses the development of pharmaceutical compounds, teaching that a variety of salts must be prepared to analyze the properties of newly synthesized compounds.[16] In these teachings, Bastin also discloses how certain salts are poor for formulating pharmaceuticals.[17]

In deciding on anticipation and obviousness, the Patent Trial and Appeal Board ("the Board") focused on: (1) whether Edmondson expressly or inherently disclosed the sitagliptin DHP salt; (2) whether Merck could antedate Edmondson by proving that it had reduced the

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[7] *See id.* (citing *Mylan Pharms. Inc. v. Merck Sharp & Dohme Corp.*, No. IPR2020-00040, 2021 WL 1833325 (P.T.A.B. May 7, 2021) [hereinafter "*Decision*"]).

[8] *Id.* (citing International Patent Publication WO 2003/004498 col. 54 l. 16–col. 60 l. 5 [hereinafter "'498 publication"]; U.S. Patent No. 6,699,871 (filed July 5, 2002) (issued Mar. 2, 2004) [hereinafter "'871 patent"]).

[9] *Id.* (citing KENNETH R. MORRIS, STRUCTURAL ASPECTS OF HYDRATES AND SOLVATES, IN POLYMORPHISM IN PHARMACEUTICAL SOLIDS 125–181 (Harry G. Brittain ed., 1999)).

[10] *Mylan*, 50 F.4th at 150–51 (citing Richard J. Bastin, Michael J. Bowker & Brian J. Slater, *Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities*, 4 ORGANIC PROCESS RSCH. & DEV. 427 (2000)).

[11] *Id.* at 150 (citing '498 publication).

[12] *Id.* (citing '498 publication col. 10 ll. 14–15).

[13] *Id.* (citing '498 publication col. 9 ll. 32–34).

[14] *Id.* at 151.

[15] *Id.*

[16] *Mylan*, 50 F.4th at 151

[17] *Id.*

'708 patented invention to practice before the former was published; and (3) whether a person of ordinary skill would have found it obvious to create a crystalline monohydrate form of the sitagliptin DHP salt.[18]

On the first issue, the Board determined that Edmondson did not expressly disclose sitagliptin DHP, as the list of 33 compounds and 8 salts did not clearly represent a phosphate salt of sitagliptin.[19] It held that skilled artisans could not read the broad genus and "at once envisage" a 1:1 sitagliptin DHP salt from all potential compounds therein.[20] Furthermore, there was no inherent disclosure as evidence showed that a 1:1 sitagliptin DHP would not form with every reaction of sitagliptin and phosphoric acid, as Mylan had argued.[21] In fact, the record had shown that a 1:1 ratio of sitagliptin DHP was not the only possible outcome of such reactions.[22] Subsequently, the Board concluded that Edmondson neither expressly nor inherently anticipated claims 1–3, 17, 19, and 21–23.[23]

On the second issue, the Board held that Merck had successfully reduced to practice much more than was required to antedate Edmondson.[24] As a result, the invention fell under 35 U.S.C. § 102(e), rather than Section 102(a).[25] Additionally, since it was uncontested that Edmondson and the '708 patent were commonly owned by Merck, the Section 103(c)(1) exception applied, and as a result, the Board held that claims 1, 2, 17, 19, and 21–23 would not be precluded from patentability by Edmondson.[26]

The Board next considered whether the remaining claims—claims 3 and 4—were obvious in light of Edmondson, Brittain, and Bastin. Claim 3 was quickly dismissed for non-obviousness, as neither Edmondson nor Bastin disclosed an (S)-configuration of sitagliptin or anything related.[27] Moreover, the Board found no reason that a person of reasonable skill would have been motivated to create the crystalline monohydrate form of the (R)-sitagliptin recited in claim 4, nor would have even reasonably thought they would succeed in doing so.[28] Thus, the Board found that the prior art neither anticipated nor made obvious

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[18] *Id.* at 151–152.
[19] *Id.* at 151 (citing *Decision*, at *10, *12).
[20] *Id.*
[21] *Id.* (citing *Decision*, at *15–16).
[22] *Mylan*, 50 F.4th at 151 (citing *Decision*, at *10, *12).
[23] *Id.* (citing *Decision*, at *16).
[24] *Id.* (citing *Decision*, at *20).
[25] *Id.*
[26] *Id.*
[27] *Id.* at 152 (citing *Decision,* at *21).
[28] *Mylan*, 50 F.4th at 152 (citing *Decision,* at *24, *26).

the claims at issue.[29]

Following the Board's decision, Mylan appealed to the Federal Circuit on these issues of anticipation and obviousness.[30]

A. *Federal Circuit Decision*

On appeal, Mylan raised three challenges, claiming that the Board erred in determining: (1) that Edmondson did not expressly or inherently anticipate a 1:1 sitagliptin DHP; (2) that "the '708 patent antedates Edmondson"; and (3) that claims 3 and 4 were not obvious in light of Edmondson, Brittain, and Bastin.[31] The Federal Circuit reviewed the Board's legal determinations *de novo*,[32] with the underlying factual findings being reviewed for substantial evidence.[33]

1. Anticipation under *In re Petering*

In support of its first challenge, Mylan contended that Edmondson disclosed a list of 33 compounds, including sitagliptin, and phosphoric acid as one of 8 acids that form pharmaceutically acceptable salts.[34] Mylan's argument was that given these disclosures and experimental data provided by Mylan's expert, Dr. Chorghade, a skilled artisan would "at once envisage" sitagliptin DHP.[35] It reasoned that combining the 33 compounds with the 8 preferred salts, while following the synthetization of a similar compound disclosed in Edmondson, could potentially form a 1:1 sitagliptin DHP.[36] However, Merck argued that a skilled artisan would not "at once envisage" sitagliptin DHP because combining the 33 compounds with the 8 preferred salts would result in 957 possible salts, some of which were not even guaranteed to form.[37] Additionally, Merck pointed to Dr. Chorghade's testimony, which conceded that Edmondson did not directly lead a skilled artisan to sitagliptin DHP from the thirty three compounds, nor even disclose a single phosphate salt of any kind among the group.[38]

The Federal Circuit first looked at whether Edmondson expressly anticipated the claims. It quickly agreed with the Board's

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[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *See id.* (citing *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004)).
[33] *See id.* (citing *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000)).
[34] *Mylan*, 50 F.4th at 153.
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] *Id.*

decision, citing to Dr. Chorghade's testimony that Edmondson did not expressly disclose a 1:1 sitagliptin DHP salt.[39] It then turned to whether Edmondson inherently disclosed the compound. The publication would inherently disclose the compound if a skilled artisan would "at once envisage each member of [a] limited class, even though the skilled person might not at once define in his mind the formal boundaries of the class."[40] The Federal Circuit focused on the term "limited," citing back to the 957 possible salts that could possibly be created from the data disclosed in Edmondson.[41] When compared to the genus envisaged in *In re Petering* with only 20 compounds, the Federal Circuit held that 957 was far too broad and uncertain to be considered a "limited class," as all 957 salts could not be immediately envisaged individually.[42] Thus, the Federal Circuit held that the claims 1–3, 17, 19, and 21–23 were not anticipated by Edmondson.[43]

2. Antedation of Edmondson

The Federal Circuit then turned to obviousness and started by analyzing the issue of antedation.[44] Under Section 102(a), disclosures will preclude patentability of an invention if the prior art is used or known within the United States, or patented or described in a printed publication in the United States or a foreign country before the invention is reduced to practice.[45] However, Section 102(a) does not apply if a party can antedate the disclosures by showing that the party "reduced to practice at least as much as 'the reference shows of the claimed invention' before the reference's publication date."[46] In such cases of antedation, Section 102(e) might apply, which states that disclosures might be a reference under certain circumstances.[47] If

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[39] *See id.*

[40] *In re Petering*, 301 F.2d at 681.

[41] *See Mylan*, 50 F.4th at 153–54.

[42] *See id.* at 154.

[43] *See id.*

[44] *See id.*

[45] *See* 35 U.S.C. § 102(a) ("A person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the patent.").

[46] *Mylan*, 50 F.4th at 154 (citing *In re Clarke*, 356 F.2d at 991).

[47] *See* 35 U.S.C. § 102(e) ("A person shall be entitled to a patent unless . . . the invention was described in — (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined

disclosures count as a reference under Section 102(e), the Section 103(c)(1) exception might apply, which holds that subject matter that falls under Section 102(e), among other sections, will not preclude patentability on obviousness grounds where the disclosures' subject matter and claimed invention were owned by or assigned to the same party at the moment the invention was made.[48]

Mylan argued that the Board erred in finding that the 1:1 (R)-sitagliptin DHP antedated Edmondson because Merck had not reduced to practice hydrates of sitagliptin until two months after Edmondson's publication in 2003, which Mylan claims disclosed hydrates of sitagliptin phosphate.[49] Merck, however, claimed that it had developed a hydrate of sitagliptin, 1:1 sitagliptin DHP, in 2002, and that Mylan failed to argue that Edmondson also disclosed a crystalline monohydrate form of that 1:1 sitagliptin DHP salt.[50] It claimed—had Mylan truly believed that Edmondson disclosed hydrates of sitagliptin––Mylan should have also argued that Edmondson disclosed the crystalline monohydrate form of sitagliptin, another hydrate of sitagliptin.[51]

The Federal Circuit agreed with Merck, finding that the Board was supported by substantial evidence in their finding that Edmondson did not disclose a hydrate of sitagliptin.[52] It then reasoned that Merck had reduced to practice "more . . . than what is shown in [Edmondson] for the claimed subject matter" before Edmondson was published in 2003, as Edmondson only disclosed sitagliptin and Merck had created the more complex hydrate of sitagliptin, 1:1 sitagliptin DHP, by then.[53] Since Edmondson had not disclosed a 1:1 sitagliptin DHP, it follows that it could not have disclosed hydrates of that same compound.[54] As such, the '708 patent antedated Edmondson under the *In re Clarke* standard, and the Federal Circuit established Edmondson as a Section 102(e) reference, rather than as prior art under Section 102(a).[55] Since it was "undisputed that the claimed invention in the '708 patent and the subject matter of Edmondson were commonly owned by Merck at the

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in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.").

[48] *See id.* at § 103(c)(1).

[49] *Mylan*, 50 F.4th at 155.

[50] *Id.*

[51] *Id.*

[52] *See id.*

[53] *See id.* at 150, 155 (citing *Decision*, at *18).

[54] *Id.* at 155.

[55] *Mylan*, 50 F.4th at 155 (citing 35 U.S.C. § 102(e)).

time of the invention," the Federal Circuit applied the exception in Section 103(c)(1), meaning Edmondson could not be used as an obviousness reference for claims 1, 2, 17, 19, and 21–23.[56]

3. Obviousness for Claims 3 & 4

The Federal Circuit lastly analyzed whether claims 3 and 4 would have been obvious at the time the invention was made. Regarding claim 3, Mylan argued that together with Edmondson, Bastin would have made it obvious to create an (S)-configuration of 1:1 sitagliptin DHP.[57] This is because Bastin discussed the flaws of using hydrochloric acids in pharmaceuticals, which would have encouraged a skilled artisan to replace the hydrochloric acids discussed in Edmondson and reasonably expect success in formulating both (R)-sitagliptin and (S)-sitagliptin, as sitagliptin has one asymmetric carbon.[58] However, Merck argued that Bastin provided nothing to motivate a skilled artisan to consider combining it's teachings with Edmondson and attempt to create a 1:1 sitagliptin DHP, regardless of whether it was the (S)-configuration or any other racemic mixture.[59]

The Federal Circuit agreed with Merck, holding that the two references provided no motivation for, and no indication of success in making (S)-sitagliptin.[60] It reasoned that Dr. Chorghade's testimony, which stated that (S)-sitagliptin was not disclosed in Edmondson,[61] the lack of theoretical benefits of the compound, and the fact that there was no motivation to specifically make (S)-sitagliptin out of the millions of potential, unpredictable salt compounds, warranted substantial evidence that claim 3 was not obvious.[62]

Regarding claim 4, Mylan argued that a skilled artisan would have had a reasonable expectation of success in creating a crystalline monohydrate form of (R)-sitagliptin because Edmondson disclosed that salts exist in different crystalline forms and as hydrate, and because Brittain discusses hydrates in way that would motivate the research and development of such a hydrate.[63] On the other hand, Merck argued that there was no persuasive motivation, as skilled artisans would avoid attempts to make hydrates as they are notoriously challenging to

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[56] *See id.* at 154.
[57] *See id.*
[58] *Id.*
[59] *Id.*
[60] *See id.* at 156.
[61] *See Mylan*, 50 F.4th at 156 (citing *Decision*, at *21).
[62] *See id.*
[63] *Id.* at 155.

produce.[64] Additionally, it argued that the monohydrate's properties were unexpectedly favorable, and that positive unexpected results are indicative of nonobviousness.[65]

The Federal Circuit found no motivation within Edmondson, Bastin, nor Brittain, that would indicate to a person of ordinary skill that there would be a reasonable expectation of success, exemplified by Dr. Chorghade's testimony in which he said that skilled artisans "couldn't predict [hydrate formation] with any degree of certainty."[66] Furthermore, the Federal Circuit explained that literary sources dissuading skilled artisans from producing hydrates was substantial enough evidence to support the finding that claim 4 was not obvious, further shown by a statement from Merck's expert, Dr. Myerson, who claimed that forming hydrates and crystalline salts is highly unpredictable.[67]

In total, the Federal Circuit agreed with the Board on every issue and found that its decision was supported by substantial evidence,[68] thus affirming the Board's decision.[69]

II. DISCUSSION

This decision exemplifies the antiquated antedation is post-AIA and raises the question of what constitutes a "limited class" that can be "at once envisaged," under *In re Petering.* To illustrate the outdatedness of antedation, unless stated otherwise, the following section will assume all patents and disclosures were made after 2013 such that post-AIA law would apply.

A. *AIA Effects on Antedation*

Merck relied on the theory of antedation, pre-AIA Section 102(e), and pre-AIA Section 103(c)(1) to remove Edmondson as an obviousness reference, and in doing so, was able to circumvent pre-AIA Section 102(a).[70] However, had post-AIA laws applied, this would not have been possible, as the AIA changed patent law from a first-to-

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[64] *Id.* at 156.

[65] *Id.*

[66] *See id.* (citing *Decision*, at *21; Chorghade Dep. 238:8–18 (Aug. 6, 2020)).

[67] *See Mylan*, 50 F.4th at 156. Although the Board did not discuss the unexpected positive properties, it did state that such properties could further undermine Mylan's claims. *See Hamilton Beach Brands, Inc. v. F'real Foods, LLC*, 908 F.3d 1328, 1343 (Fed. Cir. 2018).

[68] *Mylan*, 50 F.4th at 156–157.

[69] *See id.* at 157.

[70] *Id.* at 154–155.

invent system to a first-to-file system.[71] The antedation principle allowed an inventor to defeat Section 102(a) by showing that they had conceived of and reduced to practice at least as much as the reference showed before the reference was published.[72] But by moving to a first-to-file system, this is rendered obsolete, as it no longer matters when something is invented, conceived of, or reduced to practice, but rather when it is filed in the Patent and Trademark Office.[73] Under post-AIA laws, Section 102(a)(1) can only be defeated through Section 102(b)(1)(A) or Section 102(b)(1)(B).[74] Under Section 102(b)(1)(A), a disclosure made one year or less before the effective filing date of the claimed invention can defeat Section 102(a)(1) if said disclosure was made by the inventor(s) or someone else who obtained the subject matter directly or indirectly from the inventor.[75] This established a more burdensome standard as opposed to the pre-AIA "common ownership" standard.[76] Furthermore, under Section 102(b)(1)(B), the same disclosure will not count as prior art if the related subject matter had already been disclosed by the inventor(s) or someone else who obtained the subject matter directly or indirectly from the inventor.[77]

Applying post-AIA law, Edmondson would have fallen under Section 102(a)(1) as it was published in January of 2003, five months before the '708 patent's priority date.[78] As such, Mylan would have only been able to remove Edmondson as prior art under one of the two exceptions. Under Section 102(b)(1)(A), Merck would have to show not just ownership of Edmondson, but that it was the inventor, or obtained the disclosure directly or indirectly from the inventor.[79] While it is possible that Merck could satisfy this standard, it would be more arduous than simply showing that it owned both the '708 patent and Edmondson, as it could have done pre-AIA. However, Merck would not likely be able to satisfy Section 102(b)(1)(B). Nothing in the record shows that Merck publicly disclosed the subject matter of Edmondson before it was published. Without these facts, Merck would have to rely

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[71] *See generally* U.S. PAT. & TRADEMARK OFF., *Detailed Discussion of AIA 35 U.S.C. 102(a) and (b), in* MANUAL OF PATENT EXAMINING PROCEDURE § 2152 (9th ed., rev. 11.2013, 2020) [hereinafter "MPEP"].

[72] *In re Clarke*, 356 F.2d at 991.

[73] *See* MPEP, *supra* note 71.

[74] *Id.*

[75] *See* 35 U.S.C. § 102(b)(1)(A).

[76] *Compare id. with id.* at § 103(c)(1).

[77] *Id.* at § 102(b)(1)(B).

[78] *See id.* at § 102(a); *see also* '708 patent, *supra* note 3; '498 publication, *supra* note 8.

[79] *See* 35 U.S.C. § 102(b)(1)(A).

solely on Section 102(b)(1)(A), making it more difficult for Merck to avoid having Edmondson being used as a reference for obviousness.

B. *The Uncertainty of the "Limited Class"*

What has yet to be determined is the point at which each member of a "limited class" can no longer be "at once envisaged."[80] While *Mylan* makes clear that a genus of 957 compounds is not narrow enough for each compound to individually be "at once envisaged," it does not set a clear ceiling on how large a genus can be until it is no longer narrowly limited.[81] So, while 20 compounds in *In re Petering* sets the floor for what constitutes a narrowly limited genus, that "limited class" remains undefined.[82]

This anticipatory analysis will continue to be dependent upon the facts of the case, which in hindsight, might have been a procedural oversight on the part of the Federal Circuit. Depending on how often the *In re Petering* analysis is asserted, it might have been efficient for the Federal Circuit to have set a clear line rather than leaving it ambiguous, so as to make explicit to litigants whether their argument for a "limited class" would comply or not. Establishing this standard could potentially even have the effect of reducing the number of arguments made on petition, or prevent them altogether. Although, a clear standard might also encourage parties to bring claims forward, knowing that they satisfy the standard, whereas before they might have avoided litigation due to uncertainty.

Yet, while having clear rules is beneficial, developing such rules would lack foundation if they were created without strong analysis. Here, the Federal Circuit was given a genus of 957 compounds, which they found to be far too broad to constitute a "limited class."[83] There was little discourse about whether this number was comparable to the 20 compounds from *In re Petering*,[84] meaning if it had decided to embark on establishing a standard, there would have been a lack of concrete, present data and analysis of such to support a decision on where a hard line would be. Had the genus in *Mylan* potentially been smaller, there could have been more analysis about where that line should be, providing a foundation for the standard backed by facts, examples, and analysis, rather than arbitrarily decided upon simply to effectuate a potentially more efficient legal system.

Comparatively, the Federal Circuit also struggled when

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[80] *In re Petering*, 301 F.2d at 681.
[81] *Mylan*, 50 F.4th at 153–54.
[82] *In re Petering*, 301 F.2d at 681.
[83] *See Mylan*, 50 F.4th at 155.
[84] *In re Petering*, 301 F.2d at 681.

attempting to expressly define the doctrine of equivalents, a doctrine which to this day remains malleable and flexible in its application.[85] Commentators have suggested many possible reasons for this doctrine's continued ambiguity, including in part the goal of promoting innovation.[86] For example, inventions that achieve "pioneer status" are granted a broader range of equivalents by some judges, essentially rewarding innovation with a wider scope of protection.[87] By expressly defining what is "equivalent" to patent claims, markets for inventions with "pioneer status" could become quickly saturated, as would-be equivalent inventions would have no consequence for existing. This saturation would only discourage innovation, as the incentive to innovate and have a quasi-monopoly over the market and a broad range of its equivalents would be null. Allowing the doctrine to remain ambiguous allows the courts to have discretion in deciding when to expand the range of equivalents, such as in times of promoting innovation.

As applied to the "limited class" standard, creating a clear, hard-line standard might similarly discourage innovation. Innovators would want less opportunity for prior art to inherently disclose their claimed inventions, and thus would benefit from a "limited class" that is more flexible and allows for situational applicability. A broader hard-line standard, for example, would not allow for any flexibility and might discourage inventors from creating compounds found within broad genus as there would be more chances for claimants to show that each compound could be at once envisaged. Of course, this analysis is uncertain in its practical application, as seen through the multiple court decisions on the doctrine of equivalents and years of discourse and confusion as to its application.[88] Yet, it is reasonable to assume that allowing courts the discretion to expand or restrict the definition of a "limited class" for instances of novel inventions would better promote innovation than a strict standard would.

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[85] *See Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 609 (1950) (The doctrine of equivalents extends patent protection beyond the claims to infringements that "perform substantially the same function in substantially the same way to obtain the same result."); *see generally* Daryl Lim, *Judging Equivalents*, 36 SANTA CLARA HIGH TECH. L.J. 223 (2020).

[86] *See, e.g.,* Lim, *supra* note 85, at 266–69.

[87] *Id.* at 266 ("'Pioneer status' depends on whether the invention makes a significant technological advance in the field."); *see Westinghouse v. Boyden Power Brake Co.*, 170 U.S. 537, 561–62 (1898).

[88] *See generally* Lim, *supra* note 85.

III. CONCLUSION

In the end, *Mylan Pharms. Inc. v. Merck Sharp & Dohme Corp.* does little in terms of establishing groundbreaking law. What it does do, however, is stand as an example of how patent law has changed following the AIA and raise a genuine question for the future of patent law that may never be expressly answered. In a sense, the entire case can be seen as a timepiece, reflecting both laws that have undergone changes, and ones that are still uncertain and developing.