

Precedential Patent Case Decisions During October 2017

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I. Introduction

This paper abstracts what I believe to be the significant new points of law from the precedential decisions in patent cases this month. Cases captions relating to the PTAB are in red text. Case captions of extraordinary importance are in blue text.

II. Abstracts of New Points of Law

Mastermine Software, Inc. v. Microsoft Corporation, 2016-2465 (Fed. Cir. 10/30/2017).

This is an opinion on appeal from the D.Minn district court case 0:13-cv-00971-PJS-TNL. The district court construed the claims adversely to Mastermine, leading to a stipulation judgment of noninfringement and invalidity in which Mastermine reserved the right to appeal. Mastermine appealed. The Federal Circuit affirmed-in-part, reversed-in-part, and remanded.

Legal issue: 35 USC 112, definiteness, claims reciting both apparatus and method limitations.

Here, the Federal Circuit concluded that the claims were not indefinite. They were apparatus claims with appropriate functional language, instead of indefinite mixed apparatus/method claims.

MasterMine also challenges the district court's determination that claims 8 and 10 of the '850 patent and claims 1, 2, and 3 of the '518 patent are invalid for indefiniteness. *** Here, the district court determined that claims 8 and 10 of the '850 patent and claims 1, 2, and 3 of the '518 patent are invalid for indefiniteness for introducing method elements into system claims. We disagree. *** Though claim 8 includes active verbs—presents, receives, and generates—these verbs represent permissible functional language used to describe capabilities of the “reporting module.” Like the claims in *MEC*, *HTC*, and *UltimatePointer*, the claims at issue here merely claim that the system “possess[es] the recited structure [which is] capable of performing the recited functions.” *MEC*, 520 F.3d at 1375. These claims are also distinguishable from those at issue in *IPXL Holdings* and *Katz*, as the claims here do not claim activities performed by the user. While these claims make reference to user selection, they do not explicitly claim the user's act of selection, but rather, claim the system's capability to receive and respond to user selection. The limitations at issue here (“receiv[ing] from the user a selection” and “generat[ing] a database query as a function of the user selected database fields”) focus on the capabilities of the system, whereas the claims in *IPXL Holdings* (“the user uses the input means”) and *Katz* (“said individual callers digitally enter data”) focus on specific actions performed by the user.

Moreover, unlike the claims in *Rembrandt*, the functional language here does not appear in isolation, but rather, is specifically tied to structure: the reporting module installed within the CRM software application. [Mastermine Software, Inc. v. Microsoft Corporation, 2016-2465 (Fed. Cir. 10/30/2017).]

Merck Sharp & Dohme Corp. v. Hospira, Inc., 2017-1115 (Fed. Cir. 10/26/2017).

This is a decision on appeal from the D. Del. district court cases 1:14-cv-00915-RGA and 1:14-cv-00916-RGA. The district court found Merck's patent claims invalid under 35 USC 103. Merck appealed. A majority consisting of Judges Lourie and Hughes affirmed. Judge Newman dissented, and would have remanded.

Legal issue: 35 USC 103, obviousness, impact of blocking patents on weight accorded commercial success evidence.

The district court found the weight of Merck's proof of commercial success lessened by the existence of other patents exclusively licensed to Merck that blocked third parties from entering the market. While the Federal Circuit majority did not find clear error in the district court's conclusion of obviousness, it did find the district court's discounting of weight accorded commercial success evidence, solely because of the existence of blocking patents, to be improper.

Thus, it was reasonable for the district court to deduce from the evidence that the order and detail of the steps, if not already known, would have been discovered by routine experimentation while implementing known principles. The court's analysis thus involved no legal error. *** We next address the district court's treatment of Merck's objective evidence. *** Merck's evidence of commercial success should not have been discounted simply because of the existence of another patent of which Merck was the exclusive licensee. We have previously held that where "market entry was precluded" by another patent and by exclusive statutory rights stemming from FDA marketing approvals, "the inference of nonobviousness . . . from evidence of commercial success[] is weak." *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005). But ... multiple patents do not necessarily detract from evidence of commercial success of a product or process, which speaks to the *merits of the invention*, not to how many patents are owned by a patentee. Commercial success is thus a fact-specific inquiry that may be relevant to an inference of nonobviousness, even given the existence of other relevant patents. Nonetheless, we do not discern clear error in the district court's determination that Merck's evidence of commercial success could not overcome the weight of the evidence that the claimed process was substantially described in the prior art and required only improvement by the use of established variations. [Merck Sharp & Dohme Corp. v. Hospira, Inc., 2017-1115 (Fed. Cir. 10/26/2017).]

And the Federal Circuit's prior holding in *Merck & Co. v. Teva Pharmaceuticals USA*, 395 F. 3d 1364 (Fed. Cir. 2005) supported the conclusion in this new decision. In that prior case, where

commercial success was discounted because of the existence of blocking patents, the Federal Circuit found that that patentee had admitted that the difference between the claimed invention and the prior art was obvious. It was in that setting that the Federal Circuit concluded that commercial success was not relevant when patents blocked third party entry into the market:

For the Lunar News articles to render claims 23 and 37 obvious, the district court need only have found a suggestion or motivation to modify the dosages from those in the articles to those in the claims. *See, e.g., SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356 (Fed. Cir. 2000). But as noted above, Merck's own inventors admit the difference in dosing amount is obvious. *** Commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art. Thus, the law deems evidence of (1) commercial success, and (2) some causal relation or "nexus" between an invention and commercial success of a product embodying that invention, probative of whether an invention was non-obvious. *** That rationale has no force in this case. *** Although commercial success might generally support a conclusion that Merck's claimed invention was non-obvious in relation to what came before in the marketplace, the question at bar is narrower. It is whether the claimed invention is non-obvious in relation to the ideas set forth in the Lunar News articles. Financial success is not significantly probative of that question in this case because others were legally barred from commercially testing the Lunar News ideas. [*Merck & Co. v. Teva Pharmaceuticals USA*, 395 F. 3d 1364 (Fed. Cir. 2005).]

In contrast to *Merck & Co. v. Teva Pharmaceuticals USA*, in this *Merck Sharp & Dohme Corp. v. Hospira, Inc.* case, (1) the patentee did not admit that the differences from what a prior art reference taught and what was claimed was obvious, and (2) the district court's conclusion of obviousness required application of both experimentation and known principles based upon proved prior art. From the foregoing, it appears that the Federal Circuit concludes that the amount of reduction in probative weight accorded to commercial success evidence, due to the existence of blocking patents, scales with how strongly the prior art suggests the claimed invention.

Legal issue: 35 USC 103, obviousness, analytical procedure for consideration of evidence and burden of proof on obviousness.

Judge Newman, dissenting, would have remanded on the basis that the district court erred by failing to assess all of the evidence specified by *Graham*, before reaching a conclusion regarding obviousness. In her view, that procedure distorts the burden of proof by requiring secondary indicia to rebut a prima facie case of obviousness.

However, some Federal Circuit decisions appear to have sought a shortcut, and converted three of the four *Graham* factors into a self-standing "prima facie" case, whereby the objective considerations must achieve rebuttal weight. *** However, as the Court established, it is incorrect to consign the objective

evidence to rebuttal against the other three Graham factors. Merck is correct that the question is not whether the evidence of copying and commercial success “could not overcome the weight of the competing evidence of obviousness of the claimed process.” Maj. Op. at 11. The question is whether the entirety of the evidence relating to the Merck process, including the evidence of copying and commercial success, establish obviousness. The analysis whereby less than the full factual record is consulted for the “prima facie case,” with one of the four *Graham* factors shifted to rebuttal, distorts the placement and the burden of proof. [Merck Sharp & Dohme Corp. v. Hospira, Inc., 2017-1115 (Fed. Cir. 10/26/2017)(Dissent by Judge Newman).]

Arista Networks, Inc. v. ITC, 2016-2563, 2016-2539 (Fed. Cir. 9/27/2017; but released to the public on 10/18/2017; and re-released 10/19/2017).

This is a decision on appeals from the ITC investigation 337-TA-944. The ITC inter alia entered a limited exclusion order against Arista Networks, Inc., finding patent infringement. Arista appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 1337(d), scope of ITC exclusion order in connection with induced infringement.

The Federal Circuit concluded that the ITC had broad discretion in crafting an exclusion order to bar "imports of articles that induce patent infringement."

The Commission’s limited exclusion order prohibits importation of “network devices, related software and components thereof” that infringe the ’537 patent, ’592 patent, and ’145 patent. J.A. 568. Arista’s main challenge is that the Commission did not make specific findings that the components of its accused products contribute to or induce infringement of the ’537 patent, and thus the Commission exceeded its authority to regulate “articles that infringe.” 19 U.S.C. § 1337(a)(1)(B)(I). We disagree. *** The Commission expressly adopted the ALJ’s final initial determination findings that were consistent with its opinion. *** We note that the Commission has “broad discretion in selecting the form, scope, and extent of [a] remedy, and judicial review of its choice of remedy necessarily is limited.” *Hyundai Elecs.*, 899 F.2d at 1209 (*quoting Viscofan, S.A. v. Int’l Trade Comm’n*, 787 F.2d 544, 548 (Fed. Cir. 1986)). Courts will not interfere in the Commission’s remedy determination except when “the remedy selected has no reasonable relation to the unlawful practices found to exist.” *Id.* (*quoting Viscofan*, 787 F.2d at 548). “[I]f the Commission has considered the relevant factors and not made a clear error of judgment, we affirm its choice of remedy.” *Id.* Blocking imports of articles that induce patent infringement has a reasonable relationship to stopping unlawful trade acts. *Suprema*, 796 F.3d at 1352–53. Accordingly, we see no error in the Commission’s limited exclusion order. [Arista Networks, Inc. v. ITC, 2016-2563, 2016-2539 (Fed. Cir. 9/27/2017).]

Smart Systems Innovations, LLC v. Chicago Transit Authority, 2016-1233 (Fed.

Cir. 10/18/2017).

This is a decision on appeal from the N.D. Ill. district court case 1:14-cv-08053. Judge Wallach rendered the opinion for the Federal Circuit. Judge Linn issued an opinion dissenting in part and concurring in part. The district court entered judgement on the pleadings that claims of the subject patent were invalid under 35 USC 101. Smart Systems Innovation (SSI) appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 101, subject matter eligibility, *Alice* step 1.

The Federal Circuit majority found the claims limited to financial transactions in a particular technological field (rail transit) failed *Alice* step 1:

SSI's arguments are unavailing. The Asserted Claims of the '003 and '617 patents involve acquiring identification data from a bankcard, using the data to verify the validity of the bankcard, and denying access to a transit system if the bankcard is invalid. *See* '003 patent col. 14 l. 58–col. 15 l. 14 (claim 1), col. 15 l. 50–col. 16 l. 6 (claim 14); '617 patent col. 11 ll. 7–29 (claim 1), col. 11 l. 62– col. 12 l. 18 (claim 13). The Asserted Claims of the '816 patent involve acquiring identification data from a bankcard and funding a transit ride from one of multiple balances associated with that bankcard. *See* '816 patent col. 25 ll. 11–38 (claim 1). Moreover, the Asserted Claims of the '390 patent involve identifying whether a presented bankcard is associated with a timepass (e.g., a monthly subway card) and, if the timepass is found, charging a different fare. *See* '390 patent col. 24 l. 41–col. 25 l. 5 (claim 1). Taken together, the Asserted Claims are directed to the formation of financial transactions in a particular field (i.e., mass transit) and data collection related to such transactions. The Asserted Claims are not directed to a new type of bankcard, turnstile, or database, nor do the claims provide a method for processing data that improves existing technological processes. Rather, the claims are directed to the collection, storage, and recognition of data. We have determined that claims directed to the collection, storage, and recognition of data are directed [sic; "are not directed" corrected to "are directed" in an errata published 10/19/2017] to an abstract idea. *See Elec. Power*, 830 F.3d at 1353 (stating that we “have treated collecting information . . . as within the realm of abstract ideas”); *Content Extraction*, 776 F.3d at 1347 (surveying previous opinions that found “claims directed to the mere formation and manipulation of economic relations” through “financial transactions” abstract); *accord Intellectual Ventures I LLC v. Capital One Fin. Corp.*, 850 F.3d 1332, 1340 (Fed. Cir. 2017) (discussing abstract idea precedent related to organizing, displaying, and manipulating data). Accordingly, the Asserted Claims are directed to an abstract idea under *Alice* step one. [*Smart Systems Innovations, LLC v. Chicago Transit Authority*, 2016-1233 (Fed. Cir. 10/18/2017).]

Legal issue: 35 USC 101, subject matter eligibility, *Alice* step 2.

The Federal Circuit majority found that, unlike in *Diehr* (which the Federal Circuit characterized the Supreme court decision as having found that claims used an "equation in a process to solve a technological problem"), the claims at issue use generic computer components

“in which to carry out the abstract idea” (of "collection, storage, and recognition of data"). The majority found that, unlike in *DDR Holdings* (which the Federal Circuit characterized its prior decision to have found that the claims "had no pre-Internet analog"), the subject claims did not “attempt to solve a challenge particular to the Internet.”

Neither *Diehr* nor *DDR Holdings* demonstrate that the Asserted Claims contain an inventive concept. In *Diehr*, the Supreme Court held that a computer implemented process for curing rubber was patent eligible because, even though it employed a well-known mathematical equation, it used the equation in a process to solve a technological problem in conventional industry practice. See 450 U.S. at 185–93. *Diehr* does not apply when, as here, the claims at issue use generic computer components “in which to carry out the abstract idea.” *LendingTree, LLC v. Zillow, Inc.*, 656 F. App’x 991, 997 (Fed. Cir. 2016) (footnote omitted). In *DDR Holdings*, we found claims patent eligible under § 101 because, inter alia, they had no pre-Internet analog. See 773 F.3d at 1257–59. *DDR Holdings* does not apply when, as here, the asserted claims do not “attempt to solve a challenge particular to the Internet.” *In re TLI Commc’ns LLC Patent Litig.*, 823 F.3d 607, 613 (Fed. Cir. 2016) (internal quotation marks and citation omitted). We agree with the District Court that the Asserted Claims recite the abstract idea of collecting financial data using generic computer components. The Asserted Claims therefore offer no inventive concept that transforms them into patent-eligible subject matter. [Smart Systems Innovations, LLC v. Chicago Transit Authority, 2016-1233 (Fed. Cir. 10/18/2017).]

Judge Linn dissented in part on the general principle that the judicially created exception to patentability should be construed narrowly.

...Because the representative claims of the ’003 and ’617 patents are not directed to abstract ideas under any reasonable application of the *Alice/Mayo* test, I respectfully dissent. Because the majority’s determination with respect to the representative claims of the ’816 and ’390 patents is consistent with past decisions finding ineligibility, I concur with that part of its decision, not because the inventions covered by the claims do not deserve patent protection but because I am bound by precedent to reach that conclusion. *** Claims directed not merely to basic building blocks of scientific or technological activity but instead to innovative solutions to real problems that result from human activity and are not capable of performance solely in the human mind should be fully eligible for patent protection and not lightly discarded. [Smart Systems Innovations, LLC v. Chicago Transit Authority, 2016-1233 (Fed. Cir. 10/18/2017) (Judge Linn, dissenting.)]

Secured Mail Solutions LLC v. Universal Wilde, Inc., 2016-1728 (Fed. Cir. 10/16/2017).

This is a decision on appeal from the C.D. Cal. district court case

2:15-cv-07562-DOCGJS. The district court granted an FRCP 12(b)(6) motion to dismiss upon finding that the claims of the subject patents failed to comply with 35 USC 101. The Federal Circuit affirmed.

Legal issue: 35 USC 101 patent eligibility, *Alice*, step 1 factual analysis.

The Federal Circuit concluded that the claims failed *Alice*, step 1, stating:

The claims of the three sets of patents are not limited by rules or steps that establish how the focus of the methods is achieved. Instead, the claims embrace the abstract idea of using a marking affixed to the outside of a mail object to communicate information about the mail object, i.e., the sender, recipient, and contents of the mail object. Because the claims are directed to an abstract idea, we turn to the second step of the *Alice* inquiry. [Secured Mail Solutions LLC v. Universal Wilde, Inc., 2016-1728 (Fed. Cir. 10/16/2017).]

In reaching the conclusion that the subject claims failed *Alice*, step 1, the Federal Circuit distinguished the claims in this case with the claims in *Enfish*, stating, that, in contrast:

...In contrast, the claims of Secured Mail’s patents are not directed to an improvement in computer functionality. For example, the claims are not directed to a new barcode format, an improved method of generating or scanning barcodes, or similar improvements in computer functionality. [Secured Mail Solutions LLC v. Universal Wilde, Inc., 2016-1728 (Fed. Cir. 10/16/2017).]

The Federal Circuit explained that the various claims were purely functional, noting that:

The claims of the Intelligent Mail Barcode patents are not directed to specific details of the barcode or the equipment for generating and processing it. The claims generically provide for the encoding of various data onto a mail object but do not set out how this is to be performed. The claims state that various identifiers are affixed to a mail object, stored in a database, scanned from the mail object, and retrieved from the database. No special rules or details of the computers, databases, printers, or scanners are recited. *Cf. McRO*, 837 F.3d at 1315 (finding patent eligibility where the “claimed process uses a combined order of specific rules that renders information into a specific format that is then used and applied to create desired results”); *Thales*, 850 F.3d at 1349 (finding patent eligibility where the “claims specify a particular configuration of inertial sensors and a particular method of using the raw data from the sensors”). There is no description of how the unique identifier is generated or how a unique identifier is different from a personal name, or return address. Rather, the claim language cited by Secured Mail merely recites that the unique identifier is generated by the sender. The fact that the sender generates a barcode, which itself is not claimed, does not render the idea any less abstract. [Secured Mail Solutions LLC v. Universal Wilde, Inc., 2016-1728 (Fed. Cir. 10/16/2017).]

Legal issue: FRCP 12(b)(6) motions to dismiss for patent ineligibility. The Federal Circuit reaffirmed the viability of district courts granting motions to dismiss for patent ineligibility under 12(b)(6) on two basis. First, noting its prior holding that a section 101 inquiry was an issue of law and could be determined from the existing record. Second, noting that a court need not need not accept as true allegations that contradict matters properly subject to judicial notice or by exhibit.

Secured Mail argues that because the district court’s conclusions address questions of fact, it was inappropriate for the district court to dismiss the case via Rule 12(b)(6). Yet, this court has determined claims to be patent ineligible at the motion to dismiss stage based on intrinsic evidence from the specification without need for “extraneous fact finding outside the record.” *See, e.g., In re TLI Commc’ns LLC Patent Litig.*, 823 F.3d 607, 613–14 (Fed. Cir. 2016); *Content Extraction*, 776 F.3d at 1349; *cf. OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1362 (Fed. Cir. 2015) (holding that a Section 101 inquiry is a question of law). [Secured Mail Solutions LLC v. Universal Wilde, Inc., 2016-1728 (Fed. Cir. 10/16/2017).]

Secured Mail also argues that the district court erroneously shifted the burden of proof on the question of whether more than just industry-standard technology is claimed. According to Secured Mail, the district court improperly required it to prove that affixing a URL or barcode to a mail object was unconventional. Secured Mail’s argument is misplaced. In ruling on a 12(b)(6) motion, a court need not “accept as true allegations that contradict matters properly subject to judicial notice or by exhibit,” such as the claims and the patent specification. *Anderson v. Kimberly-Clark Corp.*, 570 F. App’x 927, 931 (Fed. Cir. 2014) (quoting *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001)). Here, the district court did not place any special burden of proof on Secured Mail, but simply concluded from the claims that they were directed to patent-ineligible subject matter. [Secured Mail Solutions LLC v. Universal Wilde, Inc., 2016-1728 (Fed. Cir. 10/16/2017).]

Note: The court's statement "based on intrinsic evidence from the specification" was probably particular to the facts of this and prior cases in which the record did not include expert testimony submitted with the complaint. Presumably, an expert declaration filed with the complaint that supported subject matter eligibility would have to be considered by the court in ruling on a 12(b)(6) motion to dismiss for patent ineligibility. *Cf. Rocky Mountain Helium, LLC V. United States*, 2016-1278, 841 F. 3d 1320 (Fed. Cir. 2016); and FRCP 10(c).

[Owens Corning v. Fast Felt Corporation](#), 2016-2613 (Fed. Cir. 10/11/2017).

This is a decision on an appeal from PTAB case IPR2015-00650. The PTAB concluded that Owens Corning had not shown the challenged claims to be unpatentable. Owens appealed. The Federal Circuit reversed.

Legal issue: 35 USC 112, BRI claim construction of “roofing or building cover

material.”

The claim recited “roofing or building cover material” but *did not* recite that those materials “are or will be coated or saturated with asphalt or asphalt mix.” The Federal Circuit concluded that the PTAB correctly construed the claim to not require that the claimed “roofing or building cover material” were limited to materials that “are or will be coated or saturated with asphalt or asphalt mix” but incorrectly analyzed obviousness assuming the claim was so limited. The Federal Circuit stated that:

In the claim-construction portion of its opinion, the Board construed the claim term “roofing or building cover material” to mean “base substrate materials such as dry felt, fiberglass mat, and/or polyester mat, before coating or saturation with asphalt or asphalt mix, and asphalt coated or saturated substrates such as tar paper and saturated felt.” Final Decision, 2016 WL 8999740, at *4. It later noted, correctly, that this construction “does not require an asphalt-coated substrate.” *Id.* at *14. But when evaluating Owens Corning’s arguments regarding motivation to combine and reasonable expectation of success, the Board made clear its understanding of its construction, and hence of the claims, as requiring materials that would eventually be coated with asphalt even if they had not already been coated before printing. *** The Board simply did not address roofing or building cover materials that would never be coated in asphalt. [Owens Corning v. Fast Felt Corporation, 2016-2613 (Fed. Cir. 10/11/2017).]

And the Federal Circuit then reviewed the specification and extrinsic evidence and found the claims not limited to materials that are or would be coated or saturated with asphalt or asphalt mix, and concluded that under this broader interpretation the claims were not patentable over the prior art.

[Organik Kimya AS v. Rohm and Haas Company, 2015-1983, 2015-2001 \(Fed. Cir. 10/11/2017\).](#)

This is a decision on appeals from PTAB cases IPR2014-00185 and IPR2014-00350. The PTAB sustained patentability of the challenged claims. Organik appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 112, claim construction, broadest reasonable construction, specification ambiguities.

The Federal Circuit concluded that when the specification includes an ambiguous statement regarding whether the invention is limited to materials having certain properties and the “specification makes clear” elsewhere that the invention is limited to materials having those properties, the BRI of a claim to those materials is still limited to material having those properties. That is, a grammatically based ambiguity at one point in the specification does not trump the overall teachings of the specification regarding the scope of the invention, for BRI purposes.

The Federal Circuit explained that the Board was correct that the recitation “**include, are those which**” in the recitation:

Suitable swelling agents **include, are those which**, in the presence of the multistage emulsion polymer and monomer, are capable of permeating the shell and swelling the core. Swelling agents may be aqueous or gaseous, volatile or fixed bases or combinations thereof.

did not introduce an ambiguity in the meaning of the claimed "swelling agents" that would expand the meaning of "swelling agents" beyond those "capable of permeating the shell and swelling the core." The Federal Circuit explained that this was because such an expansive meaning would be divorced from the specification and record evidence. The Federal Circuit stated that:

The Board did not deem the criticized words to be ambiguous, observing that "the Specification's use of the word 'include,' in this instance, is modified by the phrase immediately following it, i.e., 'are those which,' suggesting that suitable swelling agents include only those which exhibit the functional characteristics thereafter described." '435 Pat. Op. at *5. The Board is correct, for the specification makes clear that the swelling agent is a base capable of permeating the shell and swelling the core under the reaction conditions described in the specification. *See, e.g., Microsoft*, 789 F.3d at 1298 ("Even under the broadest reasonable interpretation, the Board's construction 'cannot be divorced from the specification and the record evidence,' and 'must be consistent with the one that those skilled in the art would reach.'" (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011) and *In re Cortright*, 165 F.3d 1353, 1358 (Fed. Cir. 1999))). [Organik Kimya AS v. Rohm and Haas Company, 2015-1983, 2015-2001 (Fed. Cir. 10/11/2017).]

Amgen Inc. v. Sanofi, 2017-1480 (Fed. Cir 10/5/2017).

This is a decision on appeal from D.Del district court cases 1:14-cv-01317-SLR, 1:14-cv-01349-SLR, 1:14-cv-01393-SLR, 1:14-cv-01414-SLR. The district court held patents not invalid and granted a permanent injunction. Sanofi (et al) appealed. The Federal Circuit remanded for a new trial on validity (specifically on written description and enablement); affirmed the district court's grant of appellee's JMOL of non-obviousness; and vacated the district court's permanent injunction.

Legal issue: 35 USC 112, written description, admissibility of post priority date (or benefit date) evidence to show lack of representativeness of a claimed genus.

The Federal Circuit concluded that post priority date evidence logically was probative of lack of representativeness, and therefore admissible.

Appellees are correct that written description is judged based on the state of the art as of the priority date. *Ariad*, 598 F.3d at 1355. Accordingly, evidence illuminating the state of the art subsequent to the priority date is not relevant to written description. *Id.* Appellants, however, are also correct that a patent claiming a genus must disclose "a representative number of species falling within the scope of the genus or structural features common to the members of the genus

so that one of skill in the art can ‘visualize or recognize’ the members of the genus.” *Id.* at 1351. Evidence showing that a claimed genus does not disclose a representative number of species may include evidence of species that fall within the claimed genus but are not disclosed by the patent, and evidence of such species is likely to postdate the priority date. If such evidence predated the priority date, it might well anticipate the claimed genus. Here, Appellants sought to introduce evidence not to illuminate the state of the art on the priority date but to show that the patent purportedly did not disclose a representative number of species. Appellants’ Br. 12. As a logical matter, such evidence is relevant to the representativeness question. Simply, post-priority-date evidence of a particular species can reasonably bear on whether a patent “fails to disclose a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.” *Ariad*, 598 F.3d at 1350. [*Amgen Inc. v. Sanofi*, 2017-1480 (Fed. Cir 10/5/2017).]

Legal issue: 35 USC 112, enablement, admissibility of post priority date (or benefit date) evidence to show lack of enablement of a claimed genus.

The Federal Circuit concluded that post priority date evidence logically was probative or lack of enablement, and therefore admissible.

For many of the same reasons, the district court’s improper exclusion of post-priority-date evidence requires a new trial on enablement as well. Under the enablement requirement, “the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.” *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). Appellants purportedly sought to introduce post-priority-date evidence showing that Appellees engaged in lengthy and potentially undue experimentation to enable the full scope of the claims. Such evidence could have been relevant to determining if the claims were enabled as of the priority date and should not have been excluded simply because it post-dated the claims’ priority date. *See, e.g., White Consol. Indus., Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788, 791 (Fed. Cir. 1983) (determining, based on post-priority-date expert evidence that “1½ to 2 man years of effort” would be needed to practice an invention, that patent claims were not enabled). Accordingly, we reverse the district court’s decision excluding Appellants’ post-priority-date evidence of enablement and remand for a new trial on enablement. [*Amgen Inc. v. Sanofi*, 2017-1480 (Fed. Cir 10/5/2017).]

Legal issue: jury instructions, on written description.

The Federal Circuit concluded that the jury instruction was improper because it allowed the jury to make a finding of written description for the claimed genus based upon the jury finding enablement. The Federal Circuit stated that the district court properly “instructed the jury that in order to satisfy the written description requirement, a patentee may disclose ... structural

features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus," but improperly instructed the jury that "the correlation between structure and function may also be satisfied by the disclosure of a newly characterized antigen by its structure, formula, chemical name, or physical properties." The Federal Circuit concluded that the district court's test "contradicts the statutory 'quid pro quo' of the patent system" by "allow[ing]... patentees to claim antibodies by describing something that is not the invention, i.e., the antigen."

Additionally, however, the district court further instructed the jury that: ["]In the case of a claim to antibodies, the correlation between structure and function may also be satisfied by the disclosure of a newly characterized antigen by its structure, formula, chemical name, or physical properties if you find that the level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against such an antigen was conventional or routine.["] *** The essential problem with the jury instruction given in this case is that it effectively permitted the jury to dispense with the required finding of a "written description of the invention." 35 U.S.C. § 112. Our en banc decision in *Ariad*, reflecting earlier decisions such as *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 56–57 (1938), and *In re Ruschig*, 379 F.2d 990, 991–95 (CCPA 1967), made clear that, to satisfy the statutory requirement of a description of the invention, it is not enough for the specification to show how to make and use the invention, i.e., to enable it. *Ariad*, 598 F.3d at 1345–46, 1347–48. Yet the instruction in this case invites just that improper equation. A jury would naturally understand the instruction to permit it to deem any antibody within the claim adequately described merely because the antibody could easily be "produc[ed]" (and, implicitly, used as an antibody). J.A. 1580 (requirement "may . . . be satisfied" if antigen is newly characterized and "production of antibodies against such an antigen was conventional or routine"). Indeed, the instruction does not even require any particular antibody to be easily made; all it requires is that "production of antibodies"—some, not all—"against [a newly characterized] antigen" be conventional or routine. By permitting a finding of adequate written description merely from a finding of ability to make and use, the challenged sentence of the jury instruction in this case ran afoul of what is perhaps the core ruling of *Ariad*. [*Amgen Inc. v. Sanofi*, 2017-1480 (Fed. Cir 10/5/2017).]

The Federal Circuit continued:

Further, the "newly characterized antigen" test flouts basic legal principles of the written description requirement. Section 112 requires a "written description of the invention." But this test allows patentees to claim antibodies by describing something that is not the invention, i.e., the antigen. The test thus contradicts the statutory "quid pro quo" of the patent system where "one describes an invention, and, if the law's other requirements are met, one obtains a patent." *Ariad*, 598

F.3d at 1345. Indeed, we have generally eschewed judicial exceptions to the written description requirement based on the subject matter of the claims. *See Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 925 (Fed. Cir. 2004) (noting that “the statute applies to all types of inventions”). And Congress has not created a special written description requirement for antibodies as it has, for example, for plant patents. *See, e.g.*, 35 U.S.C. § 162 (exempting plant patents from § 112 “if the description is as complete as is reasonably possible”). [*Amgen Inc. v. Sanofi*, 2017-1480 (Fed. Cir 10/5/2017).]

Legal issue: 35 USC 102(e)(2), effect of provisional applications.

The Federal Circuit explained that the parent application analysis in *Dynamic Drinkware* applied equally to published applications in addition to issued patents.

Appellants argue that the district court erred by misapplying our decision in *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015). According to Appellants, that case only related to whether “a patent asserted as prior art under § 102(e)(2) was prior art as of the filing date of a parent application” but does not relate to whether “published patent applications asserted as prior art under § 102(e)(1)” were prior art as of the filing date of their provisional applications. Appellants’ Br. 46. Appellants are incorrect. In *Dynamic Drinkware*, we clearly explained that for a non-provisional application to claim priority to a provisional application for prior art purposes, “the specification of the provisional [application] must contain a written description of the invention . . . in such full, clear, concise, and exact terms, to enable an ordinarily skilled artisan to practice the invention claimed in the non-provisional application.” 800 F.3d at 1378. Further, we have previously stated that “for the non-provisional utility application to be afforded the priority date of the provisional application, . . . the written description of the provisional must adequately support the claims of the non-provisional application.” *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002). [*Amgen Inc. v. Sanofi*, 2017-1480 (Fed. Cir 10/5/2017).]

Legal issue: 35 USC 283, injunction, public interest factor.

In *dicta*, the Federal Circuit noted two errors in the district court's injunction analysis. The key points are that the plaintiff must show that the public interest would not be disserved by an injunction, and that reduction in choice of drugs cannot be the sole reason for a district court to deny an injunction.

First, the district court misapplied *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). *** Despite that finding, the court issued a permanent injunction. J.A. 33–34. That was in clear violation of *eBay*. If a plaintiff fails to show “that the public interest would not be disserved by a permanent injunction,” then the district court may not issue an injunction. *eBay*, 547 U.S. at 391. [*Amgen Inc. v. Sanofi*, 2017-1480 (Fed. Cir 10/5/2017).]

Second, the district court also erred in its analysis of the “public interest” factor. *** It then “conclude[d] that the public interest of having a choice of drugs should prevail.” *** But eliminating a choice of drugs is not, by itself, sufficient to disserve the public interest. Under such an approach, courts could never enjoin a drug because doing so would always reduce a choice of drugs. *** We previously rejected such reasoning in *WBIP, LLC v. Kohler Co.* *** Accordingly, a reduction in choice of drugs cannot be the sole reason for a district court to deny an injunction. [*Amgen Inc. v. Sanofi*, 2017-1480 (Fed. Cir 10/5/2017).]

[Aqua Products, Inc. v. Matal, 2015-1177 \(Fed. Cir. 10/4/2017\) \(en banc\).](#)

The Federal Circuit ordered rehearing of its panel decision on an appeal from PTAB case IPR2013-00159. The en banc court vacated and remanded.

The en banc order asked two questions.

(a) When the patent owner moves to amend its claims under 35 U.S.C. § 316(d), may the PTO require the patent owner to bear the burden of persuasion, or a burden of production, regarding patentability of the amended claims as a condition of allowing them? Which burdens are permitted under 35 U.S.C. § 316(e)?

(b) When the petitioner does not challenge the patentability of a proposed amended claim, or the Board thinks the challenge is inadequate, may the Board *sua sponte* raise patentability challenges to such a claim? If so, where would the burden of persuasion, or a burden of production, lie?

On rehearing, the en banc court, represented by eleven participating judges, fractured, providing five opinions. A majority of the court agreed to vacate and remand the case to the PTAB, but for different reasons.

Legal issue: 35 USC 316(d), burdens of production and persuasion on patentability of substitute claims, in an IPR proceeding.

Aqua Products holds that the PTAB cannot place the burden of persuasion on a motion to substitute claims in an IPR proceeding, to show patentability of substitute claims, on the patent owner (at least, not until after the PTO promulgates a rule specifying the patent owner has the burden of persuasion).

Aqua Products holds that the PTAB is authorized to impose "obligations ... on the patent owner to produce evidence pertinent to the required assessment of patentability."

Aqua Products does not expressly hold that the petitioner has burden of persuasion to show substitute claims in an IPR proceeding are not patentable.

For now, the burden of persuasion has shifted away from the patent owner. However, whether the PTO could shift that burden to the patent owner by promulgating a rule, is likely, but remains an open legal question, as explained below.

Judge O'Malley wrote a minority opinion joined by a total of five judges (including O'Malley; Newman; Lourie; Moore; and Wallach). The O'Malley minority concluded "that §

316(e) unambiguously requires the petitioner to prove all propositions of unpatentability, including for amended claims." The O'Malley minority concluded "that the Board must consider the entirety of the record before it when assessing the patentability of amended claims under § 318(a) and must justify any conclusions of unpatentability with respect to amended claims based on that record." These are minority conclusions.

However, the O'Malley minority, joined by Judges Reyna and Dyk, and therefore constituting a majority, concluded "in the alternative that there is no interpretation of the statute by the Director of the Patent and Trademark Office ("PTO") to which this court must defer under *Chevron, U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)."

Judge Reyna wrote a minority opinion having parts I, II, and III. Parts I and II of Judge Reyna's opinion were joined only by Judge Dyk.

Judge Reyna concluded in part I of his opinion that:

Accordingly, I concur with Part III of Judge Taranto's Opinion only with respect to his conclusion that § 316(e) is ambiguous and that the Patent Office has the authority within § 316(a)(9) to promulgate regulations on the burden of persuasion, and I join that limited portion of his opinion. Taranto Op. 8, 25.

Judge Reyna concluded in part II of his opinion that:

...The Patent Office has yet to proffer a fully considered interpretation of the inter partes review statute directed to the evidentiary burdens for motions to amend necessary for *Chevron* deference, and its attempt to promulgate a rule through ad hoc adjudication is too procedurally defective to receive *Chevron* deference. *Negusie*, 555 U.S. at 521; *Encino*, 136 S. Ct. at 2125; *Mead*, 533 U.S. at 227. *** I also conclude that the Patent Office does not possess the statutory authority to issue through adjudication a substantive rule that creates and allocates a burden of persuasion. If at all, it can only do so through the promulgation of a regulation consistent with the APA, 5 U.S.C. § 553. Where an agency exceeds its delegated authority by improperly issuing a substantive rule, it acts ultra vires and the resulting rule is a nullity. *City of Arlington v. FCC*, 133 S. Ct. 1863, 1869 (2013); *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979); see also *Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574, 583 (1999); *Steel Co. v. Citizens for a Better Env't.*, 523 U.S. 83, 94 (1998).

Judge Reyna also concluded in part II of his opinion that:

Where a statute is silent on the allocation of an evidentiary burden and there is no agency action that earns *Chevron* deference such as a wholesome interpretation of the question at hand, the court's review of the agency's choices typically begins with the ordinary default rules of evidence. *** Here, as discussed further below, § 316(d) and the Patent Office's regulations governing motions to amend claims override any default evidentiary rules by placing only a burden of production on a patent owner to satisfy the requirements of § 316(d)

and 37 C.F.R. § 42.121. [Footnote 7 omitted.] Under the statute, therefore, the default rule is that the patent owner does not bear the burden of persuasion on the patentability of its proposed amended claims.

Part III of Judge Reyna's opinion was joined by a total six judges (including Reyna; Dyk; Prost; Taranto; Chen; and Hughes). Part III was therefore joined by a majority of the eleven participating judges. In part III, Judge Reyna, first, forcefully asserted that this part of his opinion represented the judgment of the Court:

Contrary to Judge O'Malley's suggestion, Part III of my opinion, joined by a majority of this court, is not "dictum." See O'Malley Op. 63–64. Instead, Part III of this opinion sets forth the judgment of this court on what the Board may and may not do with respect the burden of production on remand in this case.

However, in her opinion, Judge O'Malley disagreed, stating in her opinion that:

While Judge Reyna calls this section [sic; part III of Judge Reyna's opinion] a "judgment" of the court describing what the Board may do "regarding the burden of production on remand in this case," that, respectfully, cannot be true. Only two of the six judges who join in that conclusion have concurred in the judgment vacating the Board's decision denying Aqua's motion to amend and ordering a remand; that is the only judgment this court enters today.

Judges O'Malley and Reyna therefore disagree on whose opinion(s) represent(s) the judgment of the Federal Circuit.

In Part III of Judge Reyna's opinion, the six member majority held that (*italics added for emphasis*):

There is no disagreement that the patent owner bears a burden of production in accordance 35 U.S.C. § 316(d). Indeed, the Patent Office has adopted regulations that address what a patent owner must submit in moving to amend the patent. 37 C.F.R. §§ 42.20(a), 42.22(a), 42.121(a)(2)(I). For instance, § 42.22(a) requires a movant to provide in a motion "[a] full statement of the reasons for the relief requested, including a detailed explanation of the significance of the evidence including material facts, and the governing law, rules, and precedent." *** These regulations are not called into question by today's decision. Contrary to Judge O'Malley's suggestion, Part III of my opinion, joined by a majority of this court, is not "dictum." See O'Malley Op. 63–64. Instead, Part III of this opinion sets forth the judgment of this court on what the Board may and may not do with respect the burden of production on remand in this case. To that extent, *a patent owner is not excused from assisting the Board* to perform its statutory obligation to "issue a final written decision with respect to the patentability of . . . any new claim added under section 316(d)." 35 U.S.C. § 318(a).

Judge Taranto wrote a partially dissenting opinion joined in the dissent by a total of four judges (Judges Taranto; Prost; Chen; and Hughes). Judge Taranto concluded in dissent that:

...First, in an inter partes review (IPR), 35 U.S.C. § 316(a) authorizes the Director of the Patent and Trademark Office (PTO) to address who has the burden of persuasion on the patentability of substitute claims that the patent owner proposes to add to the patent in a motion to amend the patent. Second, 35 U.S.C. § 316(e) does not unambiguously bar assigning that burden to the patent owner. *** In my view, a PTO regulation assigns the burden of persuasion to the patent owner, 37 C.F.R. § 42.20(c), and Aqua Products has presented no sound argument against giving *Chevron* deference to that regulation.

The following summarizes the positions of the participating judges:

Five judges (O'Malley; Newman; Lourie; Moore; and Wallach) concluded that 316(e) specified that the petitioner had the burden to prove by a preponderance of the evidence that substitute claims are not patentable.

Six judges (Taranto; Prost; Chen; Hughes; Reyna; and Dyk) concluded that the statute did not specify who had the burden of proof on patentability of substitute claims.

Four of these six judges (Taranto; Prost; Chen; and Hughes) concluded that rule 42.20(c) was entitled to *Chevron* deference and specified that patent owner had the burden of proof to show patentability of substitute claims in an IPR proceeding and that rule 42.20(c) was entitled to *Chevron* deference.

Two of these six judges (Reyna and Dyk) concluded that the PTO had not promulgated in a rule in compliance with the APA specifying that the patent owner had the burden of persuasion by a preponderance of the evidence to show substitute claims patentable in an IPR proceeding, and the default rule of law did not place that burden on the patent owner. These two judges found the PTAB decision a nullity because it relied upon a rule contrary to the default, and these two judges would have vacated and remanded, requiring the PTAB to assign only the burden of production and not the burden of persuasion on the patentee on the issue of patentability of substitute claims.

This leaves open the likelihood that these two judges would accord *Chevron* deference to an agency rulemaking that resulting in allocation of the burden of persuasion of patentability of substitute claims in an IPR proceeding on the patentee. Therefore, the likelihood that these two judges would affirm such a regulation as valid, is relatively high.

The judgment in this case is confused. Judges O'Malley and Reyna disagree on whose opinion represents the judgment of the court. The portions of their opinions representing majority views that have common points appear below.

Judge O'Malley, writing for seven judges, stated:

...The final written decision of the Board in this case is vacated insofar as it denied the patent owner's motion to amend. The matter is remanded for the Board to issue a final decision under § 318(a) assessing the patentability of the proposed substitute claims *without placing the burden of persuasion on the patent owner. The Board must follow this same practice in all pending IPRs unless and*

until the Director engages in notice and comment rulemaking. At that point, the court will be tasked with determining whether any practice so adopted is valid. [Aqua Products, Inc. v. Matal, 2015-1177 (Fed. Cir. 10/4/2017) (Judge O'Malley's en banc plurality opinion).]

Judge Reyna writing for six judges, stated (italics added for emphasis):

Third, I conclude that § 316(d) and 37 C.F.R. § 42.121 *place a default burden of production on the patentee*. This last part of the opinion is joined by Chief Judge Prost and Circuit Judges Dyk, Taranto, Chen, and Hughes, collectively representing a majority view of the court. ***

It is important to note that Aqua has not challenged two important aspects of the Board's practice pertaining to the burden of production. First, the *obligations the Patent Office may impose on the patent owner to produce evidence pertinent to the required assessment of patentability*. See *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 100 n.4 (2011) (distinguishing burdens of persuasion from burdens of production); *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378–79 (Fed. Cir. 2015). The other is the *assignment of various pleadings or argument duties, i.e., the scope of obligations the Patent Office may impose on the patent owner to address particular patentability issues in its motion to amend*. See *Veritas Techs., LLC v. Veeam Software Corp.*, 835 F.3d 1406, 1414–15 (Fed. Cir. 2016) (noting that issue of what patent owner must address in its motion to amend is distinct from the issue of the ultimate burden of persuasion on the evidence). Section 316(e) does not address either aspect. ***

There is no disagreement that the patent owner bears a burden of production in accordance 35 U.S.C. § 316(d). Indeed, the Patent Office has adopted regulations that address what a patent owner must submit in moving to amend the patent. 37 C.F.R. §§ 42.20(a), 42.22(a), 42.121(a)(2)(I). *** These regulations are not called into question by today's decision. *** Part III of this opinion sets forth the judgment of this court on what the Board may and may not do with respect the burden of production on remand in this case. To that extent, a patent owner is not excused from assisting the Board to perform its statutory obligation to “issue a final written decision with respect to the patentability of . . . any new claim added under section 316(d).” 35 U.S.C. § 318(a).

A rule of law apparent from the O'Malley majority is that, at least until the PTO promulgates a rule stating otherwise, the PTAB cannot place the burden of persuasion on patentability of amended claims on the patentee.

A rule of law apparent from the Reyna majority is that, the patent owner bears the burden of production. The Reyna majority appears to construe this production burden to have two components. First, "*obligations the Patent Office may impose on the patent owner to produce evidence pertinent to the required assessment of patentability*." Second, "*pleadings or argument duties, i.e., the scope of obligations the Patent Office may impose on the patent owner to address*

particular patentability issues in its motion to amend." This second component appears to correspond to the rule requirements, such as 42.121. However, the first requirement corresponds with the PTO case law requirement that a motion to amend the patent disclose all "prior art known to the patent owner" that is material to the motion to amend. (*See Masterimage 3d, Inc. v. Reald Inc.*, IPR2015-00040, paper 42 (PTAB 7/15/2015) (Precedential): "The reference to 'prior art known to the patent owner' in the above quoted text, as well as everywhere else in *Idle Free*, should be understood as no more than the material prior art that Patent Owner makes of record in the current proceeding pursuant to its duty of candor and good faith to the Office under 37 C.F.R. § 42.11, in light of a Motion to Amend.") It appears that the PTO case law requirement that the patent owner must come forward with this class of prior art in a motion to amend remains valid law.

The Court generally passed on this second question. This is not surprising given its inability to decide the first question. On this second question, Judge O'Malley's opinion states:

Our en banc order also asks whether the Board may *sua sponte* raise patentability challenges to a proposed amended claim. Having fully considered the record, however, we conclude that the record does not present this precise question. We believe it should be reserved for another day, as, apparently, do the other members of the court.

Judge Reyna minority opinion addresses this question in footnote 8, which reads:

This same reasoning [sic; why "the default rule is that the patent owner does not bear the burden of persuasion"] applies to the second question presented: whether the Board can *sua sponte* raise patentability issues if the petitioner does not raise a patentability [sic; unpatentability] argument. The Patent Office has not fully considered whether the *inter partes* review statute can be reasonably interpreted to give the Board this kind of broad discretion, in particular where, as here, the petitioner remains in the *inter partes* review proceeding.

[Sanofi-Aventis U.S. LLC v. Immunex Corporation, IPR2017-01129, paper 19 \(PTAB 10/4/2017\).](#)

This is a decision of a PTAB panel. Sanofi-Aventis (et al) petitioned for IPR. The PTAB denied institution.

Legal issue: 37 CFR 42.104(b)(3) petition requirement to show how "the challenged claim is to be construed."

The PTAB noted that the petitioner's claim construction in the IPR petition (specifying no claim construction) was inconsistent with its position in the district court litigation specifying a MPF construction and that the Federal Circuit specified that MPF construction was the same in the PTO and in district courts. In part, on that basis, the PTAB found the petition failed to meet the "reasonable likelihood" burden necessary for institution, and denied institution.

... Petitioner argues the challenged claims are broad, and the '816 application does not support the challenged claims because it "fails to describe a

single isolated human antibody species that falls within that genus, let alone common structural features that would allow a POSITA to visualize or recognize all covered species.” *** Specifically, Petitioner argues that the ’816 application fails to describe a single antibody that competes with a “reference antibody” or MAb 12B5, as required by the claims. *** We are troubled by Petitioner’s failure to inform us of its contention before the district court that the claims should be construed under 35 U.S.C. § 112 ¶ 6. As the Federal Circuit has held, “no distinction is made in [§ 112] paragraph six between prosecution in the PTO and enforcement in the courts . . . [P]aragraph six applies . . . whether as part of a patentability determination in the PTO or as part of a validity or infringement determination in a court.” *In re Donaldson Co.*, 16 F.3d 1189, 1193 (Fed. Cir. 1994) (en banc); *see also Facebook, Inc. v. Sound View Innovations, LLC*, Cases IPR2017-00998 and IPR2017-01002, slip op. 14–18 (PTAB Sept. 5, 2017) (Paper 13) (finding “troubling” Petitioner’s failure to inform the Board that it was arguing 35 U.S.C. § 112 ¶ 6 applies to challenged claim in district court). That the broadest reasonable interpretation applies to construing claims in inter partes review proceedings does not justify taking a different position with respect to § 112 ¶ 6 before the district court. Thus, Petitioner’s failure to expressly construe the term “antibody” calls into question the Petition’s compliance with 37 C.F.R. § 42.104(b)(3), which requires that the Petition identify “[h]ow the challenged claim is to be construed,” particularly with respect to § 112 ¶ 6. [Sanofi-Aventis U.S. LLC v. Immunex Corporation, IPR2017-01129, paper 19 (PTAB 10/4/2017).]

Legal issue: 35 USC 314(a), requirement of a petition to meet the "reasonable likelihood" burden, impact of failure to address incorporated by reference material on the issue of written description support.

The petition and its expert witness did not address the incorporated by reference material when concluding that the claims lacked written description support in the patent. In part, on that basis, the PTAB found the petition failed to meet the "reasonable likelihood" burden necessary for institution, and denied institution.

Although Petitioner asserts the ’816 application fails to describe or enable the challenged claims, Petitioner fails to address the references expressly incorporated by reference in the ’816 application specification. Moreover, the list of references considered by Dr. Robinson does not include the patents incorporated by reference in the ’816 application, suggesting he did not consider the references, either. Ex. 1012 ¶ 28. *** “Incorporation by reference provides a method for integrating material from various documents into a host document . . . by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein.” *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). Thus, by failing to consider the patents incorporated by reference in the ’816 application, Petitioner and Dr. Robinson have failed to consider the full

scope of the disclosure for purposes of written description and enablement. We, therefore, give Dr. Robinson's opinion regarding priority little weight. [Sanofi-Aventis U.S. LLC v. Immunex Corporation, IPR2017-01129, paper 19 (PTAB 10/4/2017).]

The PTAB concluded that:

Having considered the arguments and evidence, we determine the Petition is deficient in view of: (1) the failure to consider the Office's prior determination of priority; (2) the ambiguity of Petitioner's position regarding whether 35 U.S.C. § 112 ¶ 6 applies to the construction of "antibody," and (3) the failure of Petitioner's expert to consider the full scope of the '816 application disclosure in rendering his opinion on written description and enablement. Thus, under the circumstances of this case and without reaching whether the disclosure of the '816 application satisfies § 112 ¶ 1, we are not persuaded that Petitioner has shown sufficiently that the challenged claims are not entitled to the benefit of the filing date of the '816 application. As a result, we are not persuaded that Petitioner has shown sufficiently that Stevens constitutes prior art or that it is reasonably likely to prevail at trial on its challenge based on that reference. [Sanofi-Aventis U.S. LLC v. Immunex Corporation, IPR2017-01129, paper 19 (PTAB 10/4/2017).]

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