Patent Prosecution Update

January 2014

Written Description Support for Genus Claims in Mechanical Inventions: When Is a Single Species Enough?

The inquiry into the sufficiency of written description support turns on whether the disclosure of the application reasonably conveys to those skilled in the art that the inventor has possession of the claimed subject matter as of the filing date. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). But when the claim is directed to a genus, is disclosure of a single species sufficient to support the claim? That issue was addressed by *Synthes USA, LLC v. Spinal Kinetics, Inc.*, 734 F.3d 1332, 1338 (Fed. Cir. 2013).
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New Simpler and Easier PPH Formalities

The new Global Patent Prosecution Highway (PPH) pilot is the next step in an effort to harmonize and simplify the PPH platform. The pilot program launched on January 6, 2014, features a single-form and common set of guidelines by all the participating offices. The current list of participating offices includes Australia, Canada, Denmark, Finland, Hungary, Iceland, Israel, Japan, Korea, Norway, Portugal, Russia, Spain, Sweden, the United Kingdom, the United States, and the Nordic Patent Institute. It is expected that other offices that already participate in the PPH or PPH 2.0 programs will join Global PPH as results from the pilot become available. Under Global PPH, any earlier, positive results by any of these offices are now available as a basis for PPH at another participating office, so long as the applications share a common earliest date and support the claimed subject matter. Additional information, including the most up-to-date list of participating offices, is available at http://www.jpo.go.jp/ppph-portal/globalpph.htm. The PPH was discussed in the November 2013 edition of *Full Disclosure* here.

Supreme Court News

The U.S. Supreme Court agreed on January 10, 2014, to hear a patent case involving indefiniteness of claim language, the first case to reach the high court on this issue in decades. The Court granted certiorari in the case of *Nautilus, Inc. v. Biosig Instruments, Inc.* (No. 13-369), in which Nautilus

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raised on petition the following questions:

- Does the Federal Circuit's acceptance of ambiguous patent claims with multiple reasonable interpretations—so long as the ambiguity is not "insoluble" by a court—defeat the statutory definiteness requirement?
- Does the presumption of validity after grant dilute the requirement of definiteness?

The Supreme Court also granted certiorari in the case of *Akamai Technologies, Inc. v. Limelight Networks, Inc.* (No. 12-786), covered in the October 2012 edition of *Full Disclosure*. Click here. The Court will consider whether a party may be liable for infringement under either 35 U.S.C. § 271(a) or (b) where two or more entities join together to perform all of the steps of a process claim.

Certiorari has already been granted in *Alice Corp. Pty. Ltd. v. CLS Bank International* (No. 13-298), regarding patent-eligible subject matter. The *CLS Bank* decision was covered in the June 2013 edition of *Full Disclosure*. Click here.

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Written Description Support for Genus Claims in Mechanical Inventions: When Is a Single Species Enough?

by Clara N. Jimenez

The inquiry into the sufficiency of written description support turns on whether the disclosure of the application reasonably conveys to those skilled in the art that the inventor has possession of the claimed subject matter as of the filing date. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). But when the claim is directed to a genus, is disclosure of a single species sufficient to support the claim? That issue was addressed by *Synthes USA, LLC v. Spinal Kinetics, Inc.*, 734 F.3d 1332, 1338 (Fed. Cir. 2013).

Synthes sued Spinal Kinetics (SK) for infringement of claims directed to an intervertebral implant. The claims at issue in the litigation were added by amendment almost five years into the prosecution of the patent and after SK's accused infringing devices were on the market. *Id.* at 1341. In relevant part, the claims recite "a central part substantially located between the third and fourth plates, the central part including a flexible core and a fiber system, . . . wherein the fiber system . . . is at least partially received within the plurality of openings formed in the third and fourth plates so that the fiber system is joined to the third and fourth plates." *Id.* at 1336 (citation omitted). With these new claims, Synthes introduced the concept of "openings." The "opening" limitations were important because SK's devices thread their core fibers through circular slots within the cover plates to anchor the fiber system. The patent specification, on the other hand, disclosed only "grooves" on the perimeter of the plates. The parties agreed that "groove" is a type of "opening," but did not agree that it constitutes adequate disclosure to claim all openings located anywhere on the plates. *Id.* at 1342.

During litigation, the district court construed a number of terms, including "the third plate including a plurality of openings." As expected, SK argued that "plurality of openings" should be limited to "grooves on the circumference of the cover plate that radially penetrate into the lateral surface of the plate," as described in the specification. *Id.* at 1338. The court adopted a broader construction closer to Synthes's proposal: "the third plate including two or more openings to allow the fiber system to be joined or anchored to that plate." *Id.* at 1339 (citation omitted).

The jury concluded that the accused devices did not infringe the asserted claims, and that SK proved by clear and convincing evidence that the claims were invalid for lack of written description support for four limitations, including "plate including a plurality of openings." Synthes moved for judgment as a matter of law (JMOL) or new trial as to invalidity. The district court denied-in-part Synthes's motion, finding that SK had produced substantial evidence to support the jury's conclusion that two limitations, including "plate including a plurality of openings," lacked written description support, and were therefore invalid.

In a split opinion, the Federal Circuit affirmed the district court's conclusion. While broadening claims during prosecution is not improper, even to capture a competitor's product, the broadened claims must be adequately supported by the specification. *Id.* at 1341 (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 909 n.2 (Fed. Cir. 2004)). The court reiterated that a "disclosure of a species *may be* sufficient written description support for a later claimed genus including that species." *Id.* at 1344

(quoting *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1124 (Fed. Cir. 2004)). But if the difference between members of a species is such that a person skilled in the art would not readily discern that other species of the genus would perform similarly to the disclosed members, i.e., if the art is unpredictable, then disclosure of more species may be necessary to adequately show possession of the entire genus. *See id*. (citing *Bilstad*, 386 F.3d at 1125).

Here, SK's expert testified that there were "significant biomechanical property differences between using peripheral grooves and interior slots." *Id.* at 1342. SK's research and development manager also explained that SK began its development process with peripheral grooves and ended with internal slots, finding that the peripheral grooves and that the shape and location of the slots were important design decisions that affected the rate of wear on the system. *Id*. at 1342-43. He also noted that SK "had to overcome technical hurdles through its development process." *Id.* at 1343. Synthes argued, in contrast, that the art in this case was not unpredictable and that "the 'mechanical world' is a 'fairly predictable field.'" *See id*. at 1345 (quoting *Bilstad*, 386 F.3d at 1126). The court sided with SK and found "at least circumstantial evidence" that "the written description did not support the broad claim limitations in the asserted claims." *Id.* at 1343. The court clarified that while *Bilstad* stated that the mechanical field was "fairly predictable," it did not hold that "*all* inventions that may be characterized as 'mechanical' allow claiming a genus based on disclosure of a single species." *Id*. at 1345 (discussing *Bilstad*, 386 F.3d at 1126).

Writing in dissent, Judge Taranto concluded that SK failed to present the proof required to show an insufficient written description. *Id*. at 1348 (Taranto, J., dissenting). To prevail on a written description challenge of structural claim language, the challenger must identify the differences between the claim language and the disclosed embodiments, and demonstrate, at a minimum, that the particular differences have a material effect on whether the products would achieve the aim of the claim at issue. *Id.* According to Judge Taranto, SK failed to prove that the difference between the claimed "openings" and the disclosed "grooves" had any material effect on the ability of the invented implants to fulfill their purpose to prevent sideways movement of the fibers, along the perimeter of the plate, as they hold the components of the implant together. *Id.* at 1349.

For patent drafters, *Synthes* is a reminder that describing several alternative common features, or a range of alternative representative species, can help ensure written description support for later-added genus claims. This approach requires the inventor and the patent drafter to think about potential alternative embodiments of the invention when preparing the application. From a litigation standpoint, the case also calls for careful analysis of the proposed claim construction. While a broad construction may be useful to advance infringement theories, broad constructions can also make the claims more vulnerable to enablement and written description challenges, as well as to prior art challenges. The case is also useful to remind practitioners in the mechanical arts that, while predictability of the art is generally not an issue that appears as prominently as in chemical or biotechnological cases, it should still be taken into account in considering the patentability of the claims.

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Rule Review

New Grounds of Rejection at the USPTO Patent Trial and Appeal Board

by Eric P. Raciti

Patent applicants are entitled to fair treatment by the U.S. Patent and Trademark Office (USPTO) under the Administrative Procedure Act (APA), a federal law that governs how administrative agencies are permitted to take certain actions. 5 U.S.C. § 500 et seq. When deciding a contested matter, such as the patentability of an applicant's patent claims, the APA requires that an applicant be provided with an opportunity to respond to a ground of rejection. In other words, if the Patent Trial and Appeal Board (PTAB or the Board) relies on a new ground of rejection denying patentability of an applicant's claims, that applicant has a right to argue against those new grounds.

Since the Supreme Court's decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), patent applicants have been faced with steepening challenges arguing patentability. The *KSR* decision permitted the USPTO to rely on "common sense" in formulating obviousness rejections, which can sometimes be vexing and difficult to overcome. *See id*. However, the PTAB may not overstep the requirement to treat applicants fairly by taking procedural shortcuts that deprive an applicant the right to respond fully to a rejection, on the record.

Two recent decisions of the United States Court of Appeals for the Federal Circuit define when a ground of rejection by the PTAB is new. It has long been the case that the Board can supplement the findings of a patent examiner. The central question is whether the Board and the examiner properly relied on the same factual underpinnings and articulated reasoning in rejecting an applicant's claims or whether the Board made new findings and adopted different reasons to create a new ground of rejection under 37 C.F.R. § 41.77, thereby depriving the applicant of an opportunity to respond.

In *Rambus v. Rea*, 731 F.3d 1248 (Fed. Cir. 2013), the court considered a case where claims filed by Rambus directed to certain dynamic RAM memory operations were determined to be invalid on grounds of obviousness during reexamination. The technology in question allowed memory write operations to take place during an entire microprocessor clock cycle, whereas in the prior art only half of the cycle was commonly used for writing to memory. The examiner rejected the claims based on a certain combination of two references. The examiner's rejection, however, was factually flawed, and all parties to the reexamination and appeal conceded that the rejection was in error. The Board modified the examiner's reasoning that certain features of the primary reference could be replaced with teachings from a secondary reference by replacing it with a new finding that certain features of the primary reference could simply be dropped. The Board justified its approach by stating that the rationale was obvious, and that Rambus had never shown that the application's claims were not obvious. Rambus argued that this was a new ground of rejection and that it was not afforded the opportunity to fully respond. Rambus also argued that the Board had improperly shifted the burden onto Rambus to prove patentability, rather than keeping the burden on the USPTO to show unpatentability.

The Federal Circuit, citing *In re Leithem*, 661 F.3d 1316, 1319 (Fed. Cir. 2011), held that the Board may not rely on new facts and post-hoc rationale not previously raised to the applicant. The court restated the

existing law that the Board is not required "to recite and agree with the examiner's rejection *in haec verba*" and that the Board may elaborate on the examiner's findings, as long as the applicant had an adequate opportunity to respond during the USPTO proceeding.

By changing the specific finding of the examiner—that one skilled in the art would have been motivated to modify the primary reference in a certain way—the Board issued a new ground of rejection. Because the findings were completely new, the Board was obliged to issue a new ground of rejection under 37 C.F.R. § 41.77(b).

In *In re Biedermann*, the court considered claims directed to an orthopedic bone screw having a holding portion that connects to other bone screws. 733 F.3d 329 (Fed. Cir. 2013). The holding portion has an inner thread that cooperates with the outer thread of a locking element to hold screws securely together. The configuration of the screw threads was at issue in this case. In the prior art, the threads on the holding portion of the primary reference were of a certain "saw-tooth" configuration. In contrast, the claimed apparatus used square threads.

During examination, the examiner rejected the claims for obviousness. The examiner reasoned that one of ordinary skill in the art would have substituted square threads, as taught by a secondary reference, for the "saw-tooth" threads in the bone screw of the primary reference in order to provide "for efficient load transfer." The secondary reference applied by the examiner was based on machine parts used to transfer heavy loads, and taught that square threads were desirable because of their large cross-section.

The Board modified the examiner's rejection to state that the substitution of threadforms could be made based on an additional reference (the *Machinery's Handbook*), which stated that the "saw-tooth" threadform of the primary reference was a type of "buttress" thread that could be used for load translation. Because both square threads and buttress threads can be used for load translation, the Board concluded they would have been interchangeable to one of ordinary skill in the art. Specifically, the Board pointed to the elimination of the radial component of a load when screwing components together.

The Federal Circuit refused the Board's substitution of the rationale for combining the teachings. The substitution of "interchangeability" for the examiner's "load transfer efficiency" constituted a new ground of rejection because the rationale for combining the prior art references had been modified. The court also found that the Board had ignored evidence in the primary reference stating that square threads (used in the claimed invention) were in fact difficult to cut, undercutting the Board's argument of interchangeability of the threadforms.

The reminder for patent prosecutors is that the procedural requirements imposed on the USPTO are designed to ensure fair treatment of patent applicants. If at any time during the prosecution of a patent application, an applicant is confronted with a prematurely final rejection, the applicant should object in a timely manner. Applicants almost always have an opportunity to call an examiner's attention to their right to respond to any grounds of rejection. Although the cases discussed here pertain to actions before the PTAB, analogous arguments could be made during prosecution. *See* 37 C.F.R. § 1.113; M.P.E.P. § 706.07 et seq.

A new ground of rejection is likely to be accompanied by the citation of a new reference, which should be treated as a yellow flag. As held by the Federal Circuit's predecessor court, the citation and reliance on a new reference to support a rejection will usually be an indication of a new ground of rejection. *In re Biedermann*, 733 F.3d at 338 (quoting *In re Boon*, 439 F.2d 724, 727-28 (CCPA 1971)). There are possible exceptions, such as when the reference is a standard work, cited only to support a fact that was previously judicially noticed or plays a minor role, such as filling in any gaps which might exist in the evidentiary showing made by the examiner to support a particular ground for rejection. But the recent teaching of the Federal Circuit makes it clear that the Board errs when it relies on new grounds of

rejection.

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EPO Practice

A Strict View of Priority in the UK's Court of Appeal

by Martin D. Hyden and J. Derek McCorquindale

A recent decision in the United Kingdom suggests that the strict priority approach applied in the European Patent Office (EPO) Boards of Appeal will also be enforced in that jurisdiction against patentees relying on the filing dates of earlier applications. The Court of Appeal in *Hospira UK Generics Ltd. v. Novartis AG*, [2013] EWCA Civ. 1663 (Dec. 19, 2013), held that a claim directed to use of a specific compound to treat osteoporosis at a certain dosage was not entitled to the earlier priority date of a U.S. patent application, notwithstanding that all the claim elements appear to be disclosed in the U.S. application, when read as a whole.

UK Priority Law

Applicants may benefit from the filing date of a foreign application under the terms of the Paris Convention for the Protection of Industrial Property. In the United Kingdom, Section 5 of the Patents Act 1977 (PA 1977) provides for reliance on an earlier priority date. The corresponding provision of the European Patent Convention (EPC) is Article 87(1). While Section 5 PA 1977 uses different language from Article 87 EPC, the Court of Appeal has held that the UK statute and the EPC article mean the same thing.[1]

Article 87(1) EPC governs priority in this context, stating that

> *[a]ny person who has duly filed, in or for . . . any State party to the Paris Convention . . . , an application for a patent* . . . shall enjoy, for the purpose of filing a European patent application in respect of *the same invention*, a right of priority during a period of twelve months *from the date of filing of* the first application (emphases added).

Thus, under Article 87(1) EPC, an applicant's claim will benefit from a right of priority of an earlier application if for the "same invention." *See id.* Importantly, this has been interpreted by the Enlarged Board in *G02/98* to mean that priority is effective "only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole."[2] This standard requires, at minimum, that all elements from the claim be disclosed, explicitly or implicitly, in the earlier application. *See id*.

The UK courts have also recognized the significance of *G02/98*, finding its approach not inconsistent with leading UK decisional law on priority.[3] On the one hand, in *Pharmacia Corp. v. Merck & Co.,* [2002] R.P.C. 41, priority was lost by narrowing down from the disclosure of the priority document so that the invention could not be directly and unambiguously derived from it. On the other hand, in *Beloit Technologies Inc. v. Valmet Paper Machinery Inc.*, [1995] R.P.C. 7005, priority was lost by overgeneralizing from the disclosure of the priority document.[4]

Background

The patent-at-issue in *Hospira UK Generics* was European Patent (UK) 1 296 689, belonging to

Novartis. [2013] EWCA Civ. 1663, ¶ 1. The Novartis patent related to the use of a particular member of the bisphosphonate class of drugs. *Id*. Specifically, Novartis's claim 7 claimed the use of a zoledronate medicine for the treatment of osteoporosis and adapted for intravenous administration in a unit dosage form which comprises from about 2 to 10 mg of zoledronate, administered about once a year. *Id*. Claim 7 covered Novartis's commercial drug product ACLASTA, a successful, once-yearly infusion product. *Id*. ¶ 3. Claim 7 was argued to have the priority date of an earlier U.S. application filed June 20, 2000. *Id*. ¶ 2. The main issue with respect to this claim was whether the disclosure in the U.S. application contained the subject matter, because, if not, the parties agreed that an intervening publication would be invalidating. *Id*. ¶ 3.

The High Court held that, although the elements of claim 7 were disclosed in the U.S. application, "there was nothing to link the dosage sizes and intervals there claimed with the other features of the claims, such as treatment of osteoporosis and intravenous administration." *Id*. ¶ 22. Mr. Justice Arnold explained that

> [t]he nearest one gets is the abstract, which links zoledronate, osteoporosis and six monthly administration, but does not mention intravenous administration . . . . As for Example 5, this is limited to the intravenous administration of particular doses of zoledronate to post-menopausal osteoporosis patients six monthly and yearly . . . ."[5]

Since the court found that there was no linkage of the elements in the disclosure, Novartis was deemed to lack priority for claim 7 and the patent was invalidated in the first instance.[6]

Court of Appeal Decision

On appeal, Novartis argued that the High Court erred by reading the relevant passages in isolation. Had the High Court properly read the disclosure as a whole, Novartis contended, it would have credited, inter alia, the "2-10 mg once a year" passage[7] as containing a clear and unambiguous disclosure for the claim. *Id*. ¶ 23. Although the critical "2-10 mg once a year" passage does not expressly mention osteoporosis or a particular mode of administration, Novartis explained that treatment of osteoporosis was the very focus of the U.S. application. *Id*. Further, according to Novartis, intravenous administration appears throughout the disclosure as a principle route taught. *Id*.

For a unanimous court, however, Lord Justice Floyd succinctly stated "that the problem for Novartis in seeking to establish that claim 7 is entitled to priority from [the U.S. application] is that the disclosure . . . is either too general or too specific." *Id*. ¶ 32. When focused on the priority disclosure for zoledronate, the "'2-10 mg once a year' passage tells the skilled reader nothing about the dosage range for any particular method of administration . . . [and] does not tell the reader about dosage range for any particular condition, such as osteoporosis," meaning that it was too general to support priority. *Id*. When focused on the priority disclosure for mode of administration, "Example 5, on the other hand, is specific[,] . . . teach[ing] that 4 mg, once a year, administered intravenously to patients with post-menopausal osteoporosis is effective, but nothing about what other doses could be used at that dosage interval." *Id*.

The Court of Appeal acknowledged Novartis was correct that intravenous administration is one of the preferred methods of administrations in the disclosure and that osteoporosis is highlighted in the disclosure as one of the conditions targeted. *Id*. ¶ 33. But the Court of Appeal rejected the notion that the "2-10 mg once a year" passage must be read to teach that no matter how one administers zoledronate, and no matter what condition one administers it for, 2-10 mg is always suitable dosage range. *Id*. "To put it another way," if Novartis's theory were adopted, "it would be read as saying that this particular dosage range can be used independently of the condition being treated and independently of the method of administration." *Id*. ¶ 35. Instead, Lord Justice Floyd explained that a skilled person would read the "2-10 mg once a year" passage quite differently, "namely that, depending on the method of administration and the condition being treated, some doses within this range may be suitable." *Id*. ¶¶ 35-

36.

Supporting this conclusion, the Court of Appeal cited the following: (1) the specification elsewhere expressly states that the dosage is dependent on method of administration and condition; (2) the skilled person knows from common general knowledge that dosage is critically dependent on method of administration and condition; (3) the fact that other dosage ranges are given in the patent could not be taken as saying that they were suitable for every condition and every means of administration; and (4) the expert testimony that a 2-10 mg would be "in play" for intravenous administration was "well short" of what is required, such that "nothing in the expert evidence . . . displace[d] the view that there is no disclosure in [the U.S. priority application] of using 2-10 mg zoledronate once a year by intravenous administration to treat osteoporosis." *Id*. ¶¶ 36-40.

Accordingly, claim 7 could not rely on the disclosure of the U.S. application and its earlier priority date. The trial court's invalidity judgment was approved and the appeal was dismissed, with Lord Justice Patten and Lord Justice Tomlinson in accord. *Id.* ¶¶ 42-44.

Conclusions

In fact, all elements of claim 7 were in some fashion disclosed in the U.S. priority application, as the Court of Appeal acknowledged. *See id*. ¶ 33. But these disparate elements were deemed insufficiently linked to the claimed invention to find it directly and unambiguously disclosed to a person of skill. Novartis's main contention that "*reading the document as a whole*, one sees a disclosure of the whole package of claim 7," was scarcely addressed and did not persuade the court. *Id*. (emphasis added). The resulting strict approach to priority means that U.S. practitioners need to be aware in preparing priority filings that will be relied on later at the EPO or in EPO member states. A clear linking statement for all claimed subject matter is now advisable to avoid losing priority.

[1] *See, e.g.*, *Unilin Beheer BV v. Berry Floor NV*, [2004] EWCA Civ. 1021, ¶ 39 ("The UK 1977 Patents Act, seeking to implement this, does so in the unhelpful mode of "re-write" rather than "copy out." The provisions are to be found in s[ection] 5. . . . They are supposed to mean the same as Art. 87 . . . .").

[2] Enlarged Board of Appeal in *G02/98*, [2002] EPOR 167 (deciding that the basic test to determine whether a claim is entitled to the date of a priority document is the same as the test of whether an amendment to an application satisfies the requirement of Art. 123(2) EPC).

[3] *Pharmacia Corp. v. Merck & Co.*, [2002] R.P.C. 41 (finding that the leading UK authority on priority, *Biogen Inc. v. Medeva PLC*, [1997] RPC 1, is consistent with *G02/98*, even though decided before).

[4] *See also Unilin Beheer*, [2004] EWCA Civ. 1021.

[5] *Novartis AG v. Hospira UK Ltd.*, [2013] EWHC 516 (Pat.), ¶ 137.

[6] Subsequent to the invalidity determination by the High Court, a preliminary injunction was granted by the Court of Appeal until the case could be reviewed. *See Novartis AG v. Hospira UK Ltd.*, [2013] EWCA Civ. 583.

[7] U.S. Application No. 60/267,689 states that "a unit dose of from about 1 up to about 10 mg may be used. For example . . . from about 1 to about 5 mg may be used for dosing once every 6 months; whereas a dose of from about 2 up to about 10 mg may be used for once a year dosing."

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At the Federal Circuit

Secondary Considerations: Of Primary Importance in Defending Against an Obviousness Challenge

by Elizabeth A. Doherty, Ph.D.

To determine whether a claim is obvious, the decision-maker must:

1. determine the scope and content of the prior art;
2. determine the differences between the prior art and the claim at issue;
3. assess the level of ordinary skill in the pertinent art; and
4. evaluate evidence of "secondary considerations" (also known as "objective indicia of nonobvousness").

See Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

A patentee or applicant may rely upon several types of secondary considerations, including teaching away, unexpected results, solving a long-felt but unmet need, acclaim or praise of the claimed invention by others in the field, copying of the claimed features by competitors in the field, and commercial success. For evidence of secondary considerations to be given weight, there must be a nexus between the evidence and the merits of the claimed invention. *See, e.g.*, *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 n.42 (Fed. Cir. 1985). But secondary considerations, such as unexpected results, do not need to be mentioned in the patent disclosure or recited in the claims.[1]

In spite of its name and its place as the last of the four *Graham* factors, "*secondary*" considerations of nonobviousness can be of primary importance in demonstrating the patentability of a claim. Such evidence "can establish that 'an invention appearing to have been obvious in light of the prior art was not'" and "may be 'the most probative and cogent evidence in the record.'" *Rambus Inc. v. Rea*, 731 F.3d 1248, 1256 (Fed. Cir. 2013) (citations omitted). The Federal Circuit has emphasized that this evidence guards against the use of hindsight because "[i]t helps 'turn back the clock and place the claims in the context that led to their invention.'" *Id.* (citations omitted). As the Federal Circuit explained in three cases from August and September 2013, the USPTO and other tribunals cannot ignore evidence of secondary considerations offered by a patentee or applicant.

Apple Inc. v. International Trade Commission, 725 F.3d 1356 (Fed. Cir. 2013), for example, concerned a patent claim covering Apple's transparent, multitouch screen used in the iPhone® and other devices. The claimed screen is both transparent and able to detect and respond to multiple, simultaneous touches of a user's fingers, unlike prior art screens that were either transparent but not multitouch or multitouch but not transparent. *Id*. at 1364-65. The International Trade Commission (ITC) found Apple's claimed transparent, multitouch screen to be an obvious combination of the multitouch and transparency features described in two items of prior art. *See id.* Apple had offered several types of secondary consideration evidence to support the patentability of its invention, namely, praise from the industry, including news articles describing the claimed screen as "brilliant" and "the most impressive feature of the new iPhone"; evidence that nearly every competitor copied the screen shortly after Apple introduced it; and evidence of

commercial success of iPhones including the inventive screen. *Id.* at 1366 (citations omitted). But the ITC did not consider this evidence. *Id.* The Federal Circuit criticized the ITC for not mentioning, let alone weighing, this secondary consideration evidence, and stated that, by failing to consider the evidence, the ITC did not follow precedent and made an error that was "not harmless." *Id.* at 1365-66. The court reiterated that secondary consideration evidence, in fact, "may be 'the most probative and cogent evidence [of patentability] in the record,'" and found that "Apple presented compelling secondary considerations evidence that may have rebutted even a strong showing under the first three *Graham* factors, and the ITC failed to grapple with it." *Id.* at 1366 (alteration in original) (citation omitted). As a result, the Federal Circuit vacated the ITC's decision and remanded for further consideration. *Id.* at 1367. Judge Reyna, in dissent, argued that the secondary consideration evidence was so strong that the court need not even send the case back to the ITC for further proceedings. *Id.* at 1375 (Reyna, J., dissenting).

Rambus v. Rea stemmed from a reexamination proceeding at the USPTO on a patent held by Rambus concerning dynamic random-access memory (DRAM) technology. Like Apple, Rambus submitted evidence of several types of secondary considerations to the USPTO, including satisfaction of a long-felt but unmet need, industry praise, and commercial success. The Federal Circuit held that the USPTO had not properly considered this evidence in concluding that the claims were obvious. For example, the court found that the USPTO did not address evidence of industry praise, including a press release by a competitor calling Rambus's invention "revolutionary and pioneering technology." *Rambus* 731 F.3d at 1256-57 (citation omitted). The court also found that the USPTO erred in concluding there was a lack of nexus between the evidence and the claimed invention, applying too strict a standard in judging nexus. *Id.* The court pointed out that "[o]bjective evidence of non-obviousness need only be '*reasonably* commensurate with the scope of the claims.'" *Id.* (emphasis added) (citation omitted). Accordingly, as in *Apple*, the court vacated the USPTO decision and remanded for reconsideration.

The final case in this trio, *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346 (Fed. Cir. 2013), also an appeal from a USPTO reexamination, emphasizes that secondary consideration evidence can be crucial in defending claimed inventions that, on their face, appear to encompass only small changes from the prior art or appear to be simple combinations of known elements. That case concerned a pharmaceutical formulation that appeared to be a simple mixture of three ingredients—two active agents and a solvent. The claim also recited the result-oriented limitation that the formulation is "storage stable." *Id*. at 1349-50. The USPTO found the claims invalid over a combination of three references, two reciting prior compositions comprising mixtures of the two active agents, and the third disclosing the claimed solvent. *Id.* at 1350-51. The Federal Circuit reversed, noting that, while formulations containing both active agents had been made previously, Leo Pharmaceuticals had provided evidence to the USPTO that those prior formulations would not have been able to remain stable in storage because the two active ingredients require different and incompatible conditions, and that this storage stability problem was not recognized in the prior art. *Id.* at 1354-55. During proceedings before the USPTO, Leo Pharmaceuticals had also provided evidence of unexpected results, teaching away, and commercial success. *Id.* at 1353-54, 1358. The court agreed with Leo Pharmaceuticals that the three cited references taught away from the claimed invention, and found its evidence of secondary considerations compelling. *Id.* at 1355-56. The court also noted that, while it had been known for a long time that using the two claimed active agents together was beneficial, the evidence suggested that Leo Pharmaceuticals was the first to develop a formulation comprising both active agents that was storage stable. *See generally id.* at 1358-59. The decision pointed out that "[t]he length of the intervening time between the publication dates of the prior art and the claimed invention can also qualify as an objective indicator of nonobviousness," and that the fourteen- to twenty-two-year gap in this case "speaks volumes to the nonobviousness of the . . . patent." *Id.* at 1359.

These three cases highlight that bodies such as the USPTO and ITC are required to consider and weigh evidence of secondary considerations when presented by an applicant or patentee, and that such evidence can in some cases be the best evidence of patentability. Accordingly, patent applicants, for

example, should ensure that the examiner has properly considered secondary consideration evidence, and should consider bringing these cases to the examiner's attention, if not. Applicants or patent holders defending claims that, on their face, may appear to be noninventive should be prepared to provide secondary consideration evidence to the USPTO or other tribunal as, in such cases, it might well be the best evidence to support patentability.

[1] Although reciting unexpected results expressly in the claims can be helpful in withstanding a validity challenge, as noted in another article in this issue of *Full Disclosure*. *See also Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731 (Fed. Cir. 2013).

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