Patent Prosecution Update

March 2013

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A Claim Construction Excluding the Preferred Embodiment Is "Rarely, If Ever, Correct"

by Elliot C. Cook

Patent applications that describe a "preferred embodiment" often include claims directed to that embodiment. After all, if an embodiment is "preferred," it is likely worthy of claim coverage. Nevertheless, applicants are not required to focus their claims on a preferred embodiment; they are free to claim any alternative embodiments described in the specification. A special issue of claim construction arises, however, when an application describes a "preferred embodiment," but a question is raised as to whether that embodiment is covered by the claims.

The Court of Appeals for the Federal Circuit recently considered this issue in *Accent Packaging*, *Inc*. *v*. *Leggett & Platt*, *Inc*., No. 2012-1011 (Fed. Cir. Feb. 4, 2013). In the district court, Accent alleged that Leggett infringed U.S. Patent Nos. 7,373,877 ("the '877 patent") and 7,412,992 ("the '992 patent"). The patents, which are related and have nearly identical specifications, describe and claime a wire tier device used to bundle trash or recyclables. According to the written descriptions, the wire tier includes four "elongated operator bodies" capable of gripping a wire, twisting two ends of the wire together using a "knotter," cutting the wire, and ejecting the wire from the knotter so that the trash or recyclables being bound can be moved away and a new bundle can be tied. Importantly, the written descriptions set forth a preferred embodiment where two elongated operator bodies are operably coupled to both the knotter and the cover.

Leggett's accused product included only two elongated operator bodies. Thus, Leggett argued that it did not infringe the '877 patent because its product did not meet the claim limitation of "each of the operator bodies being operably coupled with a respective one of said gripper, knotter, cutting element and cover." Leggett argued that the terms "each of" and "a respective one" required four elongated operator bodies, each operably coupled to one and only one of said gripper, knotter, cutting element, or cover. Leggett made separate arguments regarding noninfringement of the '992 patent. The district court agreed with Leggett regarding the '877 patent and granted summary judgment of noninfringement.

On appeal, Accent argued that the district court erred by construing the claims to require that each elongated operator body be coupled to one and only one operator element. The Federal Circuit agreed with Accent and reversed the district court's ruling on summary judgment regarding the '877 patent. The court explained that, "in the preferred embodiment of the invention, two elongated operator bodies are operably coupled to both the knotter and the cover," and, thus, Leggett's position that each elongated operator body must be coupled to one and only one operator element must be incorrect. *Accent Packaging*, slip op. at 12. "Put differently, the preferred embodiment features an elongated operator body that is operably coupled to *one or more* operator elements." *Id.* The basic principle invoked by the court was that "a claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct." *Id.* (citation omitted). The court also noted that the "indefinite article 'a,'" as used in Accent's claims, generally carries the meaning of "one or more" in open-ended claims containing the transitional phrase "comprising," unless the patentee has shown a clear intent to limit "a" to "one." *Id.*

Accent Packaging illustrates that care must be taken in deciding whether or not to describe an embodiment as "preferred" in a patent application. The case demonstrates that courts are generally inclined to read claims to cover a preferred embodiment unless a convincing reason to exclude the embodiment is provided. For practitioners, this can have positive and negative implications. Describing an embodiment as "preferred" in an application may help, as it did for Accent, if an accused infringer seeks to limit the claims in a manner arguably inconsistent with the preferred embodiment. However, including a preferred embodiment in a specification can also pose risks, as it may anchor the claims to a single embodiment and potentially limit the patentee's ability to argue that alternative embodiments are covered. While practitioners should carefully consider the tradeoffs in describing an embodiment as "preferred," *Accent Packaging* also suggests that use of the open-ended transitional phrase "comprising" and the indefinite article "a" remains a good practice if claim breadth is desired.

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In re EMC Corp.: the Federal Circuit Offers Thoughts on Joinder and Transfer in Multidefendant Litigations

by Clara N. Jimenez

On January 29, 2013, the U.S. Court of Appeals for the Federal Circuit issued its second mandamus decision in *In re EMC Corp.*, 2013 WL 324154 (Fed. Cir. Jan. 29, 2013) ("*EMC II*"). While affirming the denial of a motion to transfer from the U.S. District Court for the Eastern District of Texas, the court offered judges and litigants helpful guidance on the appropriate time frame to decide motions to transfer. The decision comes after, in response to the first mandamus petition, the court clarified the proper analysis for joinder of accused infringers under Fed. R. Civ. P. 20(a)(2). *In re EMC Corp.*, 677 F.3d 1351, 1357 (Fed. Cir. 2012) ("*EMC I*"). Understanding the Federal Circuit's reasoning in the *EMC* decisions may be useful to practitioners, at least because its interpretation of the joinder rules has been adopted by lower courts as persuasive guidance for interpreting the new joinder statute under the American Invents Act (AIA). *See, e.g.*, *Golden Bridge Tech., Inc. v. Apple Inc.*, 2012 WL 3999854 (C.D. Cal. Sept. 11, 2012); *ChriMar Sys., Inc. v. Cisco Sys., Inc.*, 2013 WL 828220 (D. Del. Mar. 6, 2013); *Norman IP Holdings, LLC v. Lexmark Int'l, Inc.*, 2012 WL 3307942 (E.D. Tex. Aug. 10, 2012).

Multidefendant patent litigation is most commonly employed by nonpracticing entities that seek to enforce one or more patents against multiple parties in a single action. The strategy is attractive to plaintiffs because the single proceeding streamlines the litigation, substantially reduces the litigation cost associated with managing multiple cases in multiple jurisdictions, and avoids inconsistent outcomes. For example, in *Technology Patents LLC v. T-Mobile (UK) Ltd.*, 700 F.3d 482, 489 (Fed. Cir. 2012), the plaintiff filed a patent-infringement lawsuit against more than 100 foreign and domestic defendants. For defendants, however, the picture can be less appealing. In many cases, accused infringers make different products or processes, and their only common characteristic is the alleged infringement of the asserted patents. Thus, these differently situated defendants are faced with the challenges associated with reaching agreement on a defense strategy with other defendants that may have conflicting interests. Coordinating the case strategy with other defendants also may add significant costs. These obstacles often outweigh any potential benefit of "splitting" the cost of defending the lawsuit and dividing the burden of discovery and validity challenges.

Acknowledging the burden posed by costly multidefendant patent litigations where defendants only share the tenuous connection created by the alleged infringement of the same patents, the AIA enacted a new joinder statute for patent-infringement actions effective September 16, 2011. Under the statute, codified as 35 U.S.C. § 299, joinder is only proper where the right to relief arises out of "the same transaction, occurrence, or series of transactions or occurrences relating to the making, using, importing into the United States, offering for sale, or selling of the same accused product or process, and questions of fact common to all defendants or counterclaim defendants will arise in the action." 35 U.S.C. § 299(a).

Prior to the AIA enactment, joinder of multiple defendants in a single lawsuit was dependent on each district court's interpretation of Rule 20, which permits joining defendants in a lawsuit if "[1] any right to relief is asserted against [the defendants] . . . with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences; and [2] any question of law or fact common to all

defendants will arise in the action." Fed. R. Civ. P. 20(a)(2). The second prong of the inquiry was generally met by virtue of the common questions that would arise during claim construction and validity. But, if the accused infringers had different accused products or processes, and acted independently in making, selling, or using their different accused products, the first prong of the rule, requiring that the right to relief against each defendant arises from the "same transaction," may be harder to meet. Indeed, the interpretation and application of the "same transaction or occurrence" requirement of Rule 20 resulted in disagreement between the district courts. A majority of courts read the first prong of Rule 20 as requiring more than simply allegations of infringing the same patents. Other courts, and particularly the Eastern District of Texas, read the rule more broadly, such that a shared allegation of infringement could be sufficient to meet the first prong of Rule 20. For example, in *MyMail, Ltd. v. America Online, Inc*., 223 F.R.D. 455 (E.D. Tex. 2004), the Eastern District of Texas held that the same transaction or occurrence requirement was satisfied in a patent-infringement case involving several unrelated defendants, because the record allegedly did not show that the defendants' methods or products were *dramatically different*. *Id.* at 456-57.

To address inconsistent views among the district courts, the AIA joinder statute provides that accused infringers may not be joined in one action as defendants or counterclaim defendants, or have their action as defendants or counterclaim defendants, or have their actions consolidated for trial, based solely on allegations that they each have infringed the patent or patents-in-suit. 35 U.S.C. § 299(b).[1]

This changing environment was the background in which the Federal Circuit decided the first mandamus petition in *EMC I,* 677 F.3d at 1357. The plaintiff, Oasis, originally filed its complaint on August 30, 2010, against eighteen defendants, including EMC Corp., Decho Corp., Carbonite, Iron Mountain, and GoDaddy.com. Oasis alleged infringement of four patents directed to off-site computer data storage. The defendants in the case were all alleged to offer services that provide online backup and storage for home or business computer users. Several defendants moved to sever claims and transfer the severed cases to more convenient venues. The district court denied the motions to sever and declined to rule on the motions to transfer. The petitioners filed a petition for writ of mandamus seeking severance and transfer. In *EMC I*, decided May 4, 2012, the Federal Circuit granted the writ in part, holding that the district court had applied an "incorrect test" on the issue of joinder, but remanded to the district court for reconsideration of the venue-transfer issue.

In deciding to reverse in part and remand in part the lower court's decision, the Federal Circuit decided that the Rule 20(a)(2) "same transaction or occurrence" inquiry requires the sameness of the accused products of processes. *EMC I*, 677 F.3d at 1359. Specifically, the court held that claims against independent defendants (i.e., where the defendants are not acting in concert) cannot be joined under Rule 20's transaction-or-occurrence test unless the facts underlying the claim of infringement asserted against each defendant share an "aggregate of operative facts." *Id*. The court went on to explain that, to be part of the "same transaction" requires shared, overlapping facts that give rise to each cause of action. *Id.* The mere sameness of the accused products is not enough to establish that claims of infringement arise from the "same transaction." *Id.* at 1357. According to the court, unless there is an actual link between the facts underlying each claim of infringement, independently developed products using differently sourced parts are not part of the same transaction, even if they are otherwise coincidentally identical. *Id*. at 1359. The court clarified that, where defendants are alleged to be jointly liable, joinder under Rule 20 is proper because jointly liable defendants share an aggregate of operative facts that satisfies the transaction-or-occurrence test of the rule. *Id* at 1356.

Acknowledging the changes in the multidefendant-litigation landscape prompted by the AIA, the court explicitly noted that it did not need to decide whether the sameness test in the AIA is identical to the sameness requirement under Rule 20 for litigations filed before the AIA became effective. *Id*. at 1360 n.4. Nevertheless, a growing number of district courts that have faced questions of proper joinder of defendants post-AIA have found the *EMC I* standard persuasive to resolve the issue. *See, e.g.*, *Golden Bridge Tech.*, 2012 WL 3999854, at *2; *ChriMar Sys.*, 2013 WL 828220, at *2; *Norman IP Holdings*,

2012 WL 3307942, at *2.

On remand, the district court severed Oasis's claims into separate cases. Nevertheless, the district court judge denied the transfer motions. This time, the district court concluded that after the case had been pending in the court for two years, judicial economy considerations "weighed heavily" against transfer, and noted that a court may deny motions to transfer based on "judicial economy alone." *See EMC II*, 2013 WL 324154, at *2 (Fed. Cir. Jan. 29, 2013). For a second time, defendants EMC and Carbonite petitioned for a writ of mandamus with regard to the district court's denial of their motions for transfer.

This time around, the Federal Circuit rejected the lower court's rationale for refusing to grant the motions to transfer, but denied the petition for writ of mandamus, finding that other factors weighed in favor of keeping the case in Texas. The court took the opportunity to emphasize the importance of addressing motions to transfer at the outset of litigation. According to the court, "Congress'[s] intent 'to prevent the waste of time, energy and money and to protect litigants, witnesses and the public against unnecessary inconvenience and expense' . . . may be thwarted where . . . defendants must partake in years of litigation prior to a determination on a transfer motion." *Id.* (citation omitted). The court noted that judges should rule on motions to transfer quickly and cannot use their familiarity with a case as a reason to deny transfer. *Id.* According to the court, while judicial-economy considerations are proper in the assessment of whether a motion to transfer is appropriate, their relevance is determined based on the situation that existed at the time the suit was filed, not on judicial considerations that arise after filing the suit. *Id*. In other words, a district court cannot rely on judicial-economy principles that arise from any familiarity with the case that the court may have gained while the transfer motion was under consideration. *See id.*

The environment of multidefendant litigation will continue to change. While 35 U.S.C. § 299 and the court's interpretation of Rule 20(a)(2) promise defendants an easier challenge to joinder, the burden imposed by a significant increase of serially filed infringement lawsuits may create a new pattern of consolidation of pretrial proceedings, which continues to be allowed under Fed. R. Civ. P. 42. For now, litigants must wait until some post-AIA cases are decided on joinder issues to better assess the true impact of the new statute.

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[1] Notwithstanding, under § 299(c), defendants may voluntarily waive the nonjoinder provisions of subsection (b) and be joined with other defendants that may not otherwise meet the "same transaction or occurrence" requirement.

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Rule Review

The Grace Period Under the USPTO's Final FITF Rules and Guidelines

by Adam M. Breier

The U.S. Patent and Trademark Office (USPTO) has now issued final rules and examination guidelines for implementation of the first-inventor-to-file (FITF) provisions of the America Invents Act (AIA) that take effect on March 16, 2013. *Changes to Implement the First Inventor to File Provisions of the Leahy-Smith America Invents Act*, 78 Fed. Reg. 11024 (USPTO Feb. 14, 2013) ("*Final FITF Rules*"); *Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act*, 78 Fed. Reg. 11059 (USPTO Feb. 14, 2013) ("*Final FITF Guidelines*" or "*Guidelines*").

As revised by the AIA, 35 U.S.C. § 102 provides the general standards for novelty and prior art in paragraph (a), and also provides certain exceptions in paragraph (b). Under these exceptions, certain disclosures made one year or less before a claim's effective filing date may not qualify as prior art. In particular, § 102(b)(1)(A) provides essentially that a disclosure traceable to an inventor[1] is not prior art, and § 102(b)(1)(B) provides essentially that another's disclosure is not prior art if there was an earlier "shielding" disclosure of the subject matter traceable to an inventor. Notably, for the § 102(b)(1)(B) exception to be relevant, an inventor's prior disclosure must not itself qualify as prior art, meaning that it must also have occurred one year or less before the effective filing date. *See Final FITF Guidelines*, 78 Fed. Reg. at 11076.

The *Final FITF Guidelines* provide the USPTO's interpretation of the AIA and the *Final FITF Rules*, including § 102(b)(1) and 37 C.F.R. § 1.130, but like the Manual of Patent Examining Procedure do not constitute official rulemaking or have the force of law. 77 Fed. Reg. at 11059. Nonetheless, the *Guidelines* reflect a clarified and broader interpretation of when the § 102(b)(1)(B) "grace period" can be relied upon than the version of the *Guidelines* originally proposed in July 2012. The earlier-proposed *Guidelines* had stated flatly that "the exception under 35 U.S.C. 102(b)(1)(B) does not apply" if there "are mere insubstantial changes, or only trivial or obvious variations" between the putative prior art and an inventor's prior disclosure. 77 Fed. Reg. at 43767. This interpretation, if adopted, would probably have made the § 102(b)(1)(B) grace period essentially unavailable unless the subsequent disclosure was a virtual replica of an inventor's previous disclosure. In contrast, the *Final FITF Guidelines* state the following:

- "There is no requirement . . . that the mode of disclosure by" an inventor "be the same as the mode of disclosure of the intervening" disclosure. For example, the former could be a technical article and the latter could be a sale or public use, or vice versa.
- Where an inventor "had publicly disclosed elements A, B, and C, and a subsequent" disclosure contains "elements A, B, C, and D, then *only element D*" of the intervening disclosure "is available as prior art." (Emphasis added.)
- If a subsequent disclosure "is simply a more general description" of subject matter previously publicly disclosed by an inventor, the § 102(b)(1)(B) exception applies, such as if an inventor "had publicly disclosed a species, and a subsequent intervening" disclosure simply contains "a genus (i.e., provides a more generic disclosure of the species)." The disclosure of an "alternative

species not also disclosed" by an inventor would, however, "be available as prior art."

78 Fed. Reg. at 11077.

Thus, according to the *Final FITF Guidelines*, the § 102(b)(1)(B) exception can apply despite the presence of certain differences between an inventor's disclosure and a subsequent intervening disclosure. Nonetheless, it remains unclear how the grace period will be applied in practice, so practitioners may want to avoid relying on it, except in rare circumstances. Instead of making a public disclosure and relying on the § 102(b)(1)(B) grace period, filing a fully enabled U.S. provisional or foreign priority application to establish an early effective filing date would provide far more certainty and protection. Consider, for example, a scenario where an inventor publicly discloses subject matter that is later identically claimed, but an intervening public disclosure is made between the inventor's public disclosure and the inventor's filing date. Assume the intervening disclosure contains an alternative species, which differs slightly from the inventor's first disclosure. The alternative species may well render the inventor's claim obvious, and may not be subject to disqualification under the grace period. According to the USPTO, whether the exception of § 102(b)(1)(B) applies "does not involve a comparison of the subject matter of the claimed invention to either the subject matter disclosed by" an inventor or by the intervening disclosure. 78 Fed. Reg. at 11077. Rather, the inquiry is limited to whether the subject matter of the intervening disclosure was previously publicly disclosed by an inventor. *Id*. Additionally, there is no guarantee that a court would adopt the broader USPTO interpretation from the *Final FITF Guidelines* as opposed to a narrower interpretation, such as the interpretation that the USPTO initially proposed. In contrast, obtaining the earliest possible effective filing date would prevent all subsequent disclosures, such as of an alternative species, from qualifying as prior art under § 102(a)(1).

The *Final FITF Rules* also revise 37 C.F.R. § 1.130 (Rule 130) in light of § 102(b)(1). Paragraph (a) provides that a declaration can be submitted to disqualify a disclosure by showing that it was made by or obtained directly or indirectly from the inventor or a joint inventor. Paragraph (b) provides that a declaration can be submitted to disqualify prior art by establishing prior disclosure under § 102(b)(1)(B). Such a declaration "must identify the subject matter publicly disclosed and provide the date" of disclosure. 37 C.F.R. § 1.130(b). Additionally, if the disclosure was in a printed publication, a copy must be provided; otherwise, the declaration "must describe the subject matter with sufficient detail and particularity to determine what subject matter had been disclosed on that date . . . ." *Id*. It is unclear what amount of evidence will be required to satisfy the amended Rule 130 requirements for disqualifying an otherwise prior art disclosure from applying in a given instance, but certainly collecting and arguing this evidence will frequently be more difficult than the Rule 131 "swearing behind" practice employed in pre-AIA (first-to-invent) applications to allege earlier invention.

Paragraph (c) of the amended Rule provides that Rule 130 declarations are unavailable against a rejection based on disclosures made more than a year before the effective filing date and may not be available against a rejection based on a U.S. patent or published application naming another inventor, where the patent or application claims substantially the same subject matter. In this case, if the subject matter claimed by the other named inventor was obtained from the inventor of the rejected claim, then relief may be had through a derivation proceeding. Paragraph (d) provides that revised Rule 130 applies to any application or patent containing a claim with an effective filing date on or after March 16, 2013, or a specific reference under 35 U.S.C. §§ 120, 121, or 365(c) (essentially, a domestic or PCT priority claim) to any patent or application that contains, or that contained at any time, such a claim.

Final Rule 130 has several differences from the version the USPTO initially proposed. *Compare* 77 Fed. Reg. 43742, 43758-59 (USPTO July 26, 2012) (proposed version of Rule 130) *with* 78 Fed. Reg. at 11058 (final Rule 130). In particular, the USPTO omitted a requirement for "a satisfactory showing that the inventor or a joint inventor is the inventor of the subject matter of the earlier disclosure." In its accompanying remarks, the USPTO stated that in response to public comments on the proposed rules, it revised and streamlined Rule 130 to more closely track the statutory language and to set forth only

procedural requirements, and it recognized that, in some cases, it would be readily apparent that the inventor or a joint inventor is the inventor of the subject matter of the earlier disclosure, e.g., based on authorship of a publication. 78 Fed. Reg. at 11044. The *Final FITF Guidelines* also state that the sufficiency of evidence in or accompanying a Rule 130 declaration will be evaluated on a case-by-case basis. *See, e.g.*, 78 Fed. Reg. at 11076. Such case-by-case treatment is generally consistent with current practice concerning disqualification of an inventor's own prefiling disclosure.

Additionally, the USPTO dropped a provision of the proposed rule stating that the USPTO "may require" the filing of a derivation petition where a declaration asserts that subject matter in a U.S. patent or published application naming another inventor was obtained from the inventor or a joint inventor of the claimed subject matter. Instead, paragraph (c) provides that Rule 130 "may not be available" under such circumstances. The USPTO remarked that under the final rule, an applicant or patent owner has discretion as to whether to file a derivation petition. 77 Fed. Reg. at 11045. While it is true that the USPTO cannot require the filing of a derivation petition under final Rule 130, doing so may nonetheless be the only remaining means for disqualifying certain references when Rule 130 is held inapplicable.

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[1] The statutory language has been summarized for brevity, at the cost of some precision. For example, the (b)(1)(A) exception applies to, and the (b)(1)(B) exception can be triggered by, disclosures made by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor. In the remainder of this article, "an inventor" is used as shorthand for the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

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EPO Practice

European Filing Strategies on the Eve of the Unitary Patent

by Martin D. Hyden and Eric P. Raciti

Europe, since the 1970s, has been blessed—or cursed, depending on your perspective—with two avenues toward procuring patent rights. The European Patent Convention (EPC), when ratified in 1973, created the European Patent Office (EPO) as a regional patent examination and granting authority. EPC Member States also retained national patent systems, which coexist with the EPO. Patent applications passed to grant by the EPO are recognized by EPC Member States as national patents. Each EPC Member State where a European Patent is electively placed into force (i.e., "validated") takes over enforcement issues and post-grant validity challenges (except for Oppositions in the EPO) under its national law, in the same way as it would with a nationally granted patent. Most applicants are accustomed to the idea of having both the EPO and the national offices available for their European filing strategies, although relatively few deviate from the simpler one-stop approach of filing only in the EPO.

The creation of the European Unitary Patent adds another layer of complexity to filing decisions, because it provides yet another route to obtain patent protection in at least some portion of the European Union (EU).

To begin with, the Unitary Patent (officially the "European Patent with unitary effect") is an EPO-examined patent that, when issued, has unitary effect in all participating countries, rather than becoming a bundle of national patents like the classical European Patent.

The implementation of the Unitary Patent includes the provision that all European Patents will fall under the jurisdiction of the newly created Unified Patent Court (UPC). The legislation creating the Unitary Patent includes a transitional period, which will last for at least seven years, and may be extended by up to a further seven years, for dealing with in-force EPO-granted patents. Article 83(3) provides that patentees may "opt out" of the UPC regime on a patent-by-patent basis. Because of the ability to opt back into the UPC system (Article 84(4)), it is widely speculated that many patentees will opt out in order to take a "wait and see" attitude toward the UPC. Owners of European Patents that have been validated in different countries are not accustomed to the prospect of central revocation, or a single decision of noninfringement for all of Europe, and many will prefer the *status quo* country-by-country system, notwithstanding its inefficiencies. The ability to opt back into the UPC system later does nothing to dissuade this approach.

At the time of this writing, it is not clear which states the Unitary Patent will cover. Spain has stated it will remain outside the Unitary Patent system. Italy, while signing up for the UPC has not signed on for the Unitary Patent, leaving that country's status up in the air. Further, because the system comes into effect when thirteen states have ratified (which must include the United Kingdom, France, and Germany), it is not clear which countries will be first to ratify and thus be included. Unitary Patents are covered only in the states that are part of the system when the patent grants, so later-joining countries are not added to the effective territory of an earlier-issued Unitary Patent.

During the transition period, it will be possible to get patent protection via national filing, EPO filing with national designations, and EPO filings with a Unitary Patent designation. After the transition period ends (in seven or fourteen years), the only options will be national filing and EPO filing with unitary designation.

The unitary designation will place the patent in an entirely new regime for enforcement and validity determination. The EPO-granted patents, as well as the nationally granted ones, were each subject to the same postissuance environments: the national authorities. The Unitary Patent, on the other hand, relies on a new system of adjudication that is yet unproven.

In advance of the changes that will be introduced by the arrival of the Unitary Patent, it will be useful to analyze some current practices that might need to be reconsidered when the Unitary Patent is available. For instance, it has become common practice for applicants from outside Europe to obtain European patent protection by means of a PCT application that later enters the EPO regional phase. In some cases, a different route may deliver better results in terms of cost, certainty, speed, and/or convenience.

The principal advantages of the EPO to the applicant are that it uses single applications, 80 percent of which are in English; and final decisions by the applicant on which countries are to be covered and translations (when needed) are required only when a patent is granted. Disadvantages to the EPO route include the relatively high official fees, and prosecution is often slow and complex. Also, because examination is centralized, refusal of the application by the EPO during prosecution or on post-grant opposition means that all rights are lost in one go.

In some cases, national filing(s) may have advantages that outweigh the convenience of the EPO system, but using national filings will need to employ different approaches country by country. For the most part, all EPC Member States have essentially the same substantive patent law, so questions of novelty, inventive step, and industrial applicability should not vary greatly or impact substantive prosecution strategy. That said, prosecuting applications in parallel before separate offices, and therefore different examiners, can always lead to different outcomes.

Some considerations that may bear on the choice between the EPO and national offices are discussed below.

Limited Territorial Scope

If protection in only a few (three to five) countries is required, the overall cost may not be much different between an EPO application and a handful of national ones. Official fees for most national filings are in the order of a few hundred dollars, many being around $500 in total (e-filing in France runs about €526 and about €440 in Germany). Another consideration might be the excess claims fees, which, while relatively expensive in the EPO (€200 from the fifteenth claim), are much less expensive in jurisdictions such as Germany and France (€20 and €40, respectively, from the eleventh claim), and zero in the United Kingdom.

The major cost in many cases is the cost of translation (about €75 to €85 per page). If the specification is relatively short, this may not be a significant cost. Many offices, however, accept applications filed in English, such as Switzerland, Sweden, Denmark, and Finland.

Speed of Prosecution

Some countries do not examine substantively (e.g., France, Italy, Spain, Switzerland, and Belgium), and an application can enter into force without the lengthy delays involved in EPO prosecution. A national filing will nevertheless be subjected to a search (and in France, this search is done by the EPO at a cost of €500 (or €250 for qualified small to medium-sized enterprises)). This is a big savings compared to about $1500 when the full search is done by the EPO for a European Patent application). A search can be undertaken in Switzerland, by examiners using the same resources as the EPO, for 700 CHF (200 CHF filing fee plus 500 CHF search fee). After the search, an opportunity is given to amend the claims,

but otherwise, an application will proceed to grant. With the recent law changes in European countries, all now allow amendment of patents post-grant so that invalidity issues can still be potentially addressed before attempts to enforce. Even those countries that do examine substantively will often respond to applicant's amendments and conclude prosecution more quickly than the EPO, especially if they are requested to do so. For example, the U.K. Intellectual Property Office has a rule that requires that prosecution must be complete within fifty-four months of the priority date, and will often complete examination within twelve months.

Many European countries have utility-model protection available as an option to or in addition to a full patent. These are usually unexamined and granted quickly for a shorter period. Germany, specifically, allows a utility-model application (or Gebrauchsmuster) to be filed from a pending European Patent application, a PCT application designating Germany or the EPO, or a German national application. This is true even when the language of examination is not German. Utility models offer the advantages of having protection issued without substantive examination, which can be desirable in countries that subject invention patents to substantive examination (like Germany, where registration can occur in six to eight weeks). Advantageously, a utility model is generally available for all patent-eligible subject matter in the jurisdiction, with the exception of methods of use.

Conversely, prosecution can be delayed (or deferred) in some countries. Germany, for instance, has a deferred examination system with low costs (e.g., a filing fee of €40) until a search and substantive examination is requested. This option allows an applicant to benefit from placing competitors on notice of its innovation without the attendant costs of prosecution. Naturally, no enforceable rights can result until examination is requested and completed—but in Germany, a utility model could be obtained in fairly short order and leveraged, where necessary.

Easier Prosecution

Where examination does take place, substantive prosecution can be less burdensome in national offices than at the EPO, especially in certain technology areas. Also, the level of argument needed in writing to overcome rejections can be less in national offices than at the EPO, with corresponding lesser potential impact on prosecution outside of Europe, particularly in the United States where arguments made in prosecution outside the United States can be relevant to U.S. claim scope or enforceability. Conversely, some countries are notoriously strict in certain areas of technology (e.g., the United Kingdom for computer-implemented inventions). Many countries are not so strict on the basis for amendments as the EPO, making prosecution easier.

Local Invalidity

An obvious advantage of national prosecution is that a refusal or abandonment in one country does not automatically affect the corresponding application or patent in another. The finding of invalidity of an issued patent in any jurisdiction is similarly not impactful on other national filings, although this can also be true of granted European Patents validated in different member countries. After grant, the provenance of a patent in a given jurisdiction (national or EPO) oftentimes does not matter, but the finding of invalidity of a validated European patent in one country, while not binding, might in some instances be used as evidence in a validity challenge in another EPC Member State.

Filing Route

While many EU countries allow a national application to be filed based on a PCT filing, there are eleven that have closed their national route; that is to say, these countries only allow protection to be obtained exclusively via the EPO if a PCT application is used (i.e., Belgium, Cyprus, France, Greece, Ireland, Italy, Latvia, Malta, Monaco, the Netherlands, and Slovenia). If national protection is to be sought in such countries by direct filing, it is necessary to do so within the twelve-month Paris Convention period, because the PCT option is not available.

If an applicant wants to take advantage of, for instance, the early and inexpensive European search given

to a French application, filing directly in France is the only way to accomplish this. This early EPO search can be of some importance as an indication of the course that prosecution will take in a parallel European application, so a national French filing may be useful as a companion filing. If the French application is used as a priority document for an EPO filing, that EPO search will be relied upon during EPO examination. Also considering the quick issuance that can be obtained in France because there is no substantive examination there, and the availability of remedies such as descriptive seizure, French national filings could provide valuable strategic tools otherwise not available.

These various potential benefits that may arise from the national-filing route should therefore be taken into account when deciding to file a PCT in order not to miss out on opportunities. Where it is useful to avoid the deficiencies of the Unitary Patent centralized system, national filing will become the only option available following the transition period. National filing may provide quicker, cheaper results that are less vulnerable to central attack.

The Patent Prosecution Highway and the USPTO

The use of the Patent Prosecution Highway (PPH) between the USPTO and the EPO is hampered by lengthy prosecution timelines in both jurisdictions. Another disadvantage, perceived or real, is that Articles 94(3) and 97 EPC do not really permit the EPO examiners to give much credence to what takes place in other offices, and the amendments introduced in U.S. practice will often cause issues at the EPO due to the limited ability to amend under Article 123(2) EPC. When these are taken into account, the long-standing PACE acceleration program will likely provide as much benefit of the USPTO-EPO PPH. The most recent data suggest that using PPH at the EPO makes no difference to prosecution time or outcome.

A still speedier overall outcome could result from using the PPH between a quick national office and the USPTO. National PPH agreements exist between the USPTO and Austria, the Czech Republic, Denmark, Finland, Germany, Hungary, Iceland, Norway, Portugal, Spain, Sweden, and the United Kingdom. In the authors' experiences, using U.K. prosecution as a vehicle to speed up U.S. prosecution has been favorable.

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At the Federal Circuit

Enablement: A Matter of Degree

by Rebecca Harker Duttry

That *some* experimentation might be required to make and use the full scope of a claimed invention does not necessarily mean that a patent is invalid due to lack of enablement; enablement is a matter of degree. *Cephalon, Inc. v. Watson Pharms., Inc.*, No. 2011-1325 (Fed. Cir. Feb. 14, 2013). A determination that a patent is invalid for lack of enablement because of undue experimentation requires a fact-specific analysis and clear and convincing evidence.

The *Cephalon* case centers on an appeal from a district court ruling that Cephalon's Khankari patents were invalid for lack of enablement. The patents-at-issue are directed to a method of administering tablets (or other dosage forms) via the mucous membrane lining or mucosa in the oral cavity. Such tablets include effervescent agents used as penetration enhancers, which influence drug absorption. Because the effervescent reaction occurring in the mouth affects the pH level of the saliva, the patents also disclose the use of an additional pH adjusting substance in combination with the effervescent agent to promote the absorption of the drugs. While both parties in the case agreed that the Khankari patents are enabled as to an effervescent "couple" (i.e., a soluble acid source plus a source for carbon dioxide) for generating the claimed effervescent reaction, the parties disputed whether the Khankari patents contain an enabling disclosure illustrating a dosage form having only a single compound effervescent agent.

Section 112, paragraph one, of the Patent Act requires an enabling specification to teach those ordinarily skilled in the art to make and use the full scope of the claimed invention without *undue experimentation*. *See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008). The Court in *Cephalon* emphasized that the question of undue experimentation is a matter of degree, pointing out that varying levels of experimentation are acceptable, depending on the circumstances. What is required is that the amount of experimentation not be "unduly extensive." Based on these guidelines, if a reasonable amount of routine experimentation is required to practice a claimed invention, the enablement requirement is not violated. For example, the Federal Circuit held that experimentation involving the repetition of known or commonly known techniques, even if extensive, is not necessarily categorized as undue experimentation. *See Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1988). Further, the mere fact that a clinician's involvement *may* be necessary to determine effective amounts of a single-compound effervescent agent and a separate, companion soluble acid source does not itself constitute undue experimentation. *See Ortho-McNeil Pharm.*, 520 F.3d at 1365-66. Therefore, the inquiry regarding undue experimentation is not a simple quantitative analysis. A considerable amount of experimentation is permissible as long as the experimentation is routine or if the specification provides sufficient guidance. *See PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996); *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988).

Even though this analysis seems somewhat vague and open-ended, the Federal Circuit has suggested some boundaries on the levels of reasonable experimentation. For example, in one case, the court found eighteen months to two years of experimentation to practice the patented invention

unreasonable. *See, e.g.*, *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788, 791 (Fed. Cir. 1983). Additionally, the court has provided some general guidelines, noting that the amount of experimentation may be undue where (1) the specification lacks guidance by teaching away from the subject matter that was eventually claimed; and (2) there is evidence of the patentee's own failures to make and use the later claimed invention at the time of the application. *See, e.g.*, *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

After analyzing the facts in *Cephalon*, the Federal Circuit found that the defendant failed to present sufficient testimony or documentary evidence showing the amount of experimentation that would be necessary to carry out the claimed invention. Specifically, the court found that the defendant did not present any evidence showing that the embodiment disclosed in the specification would not enable a person of ordinary skill to practice other permutations of the invention, or any evidence showing that the resulting experimentation would involve testing for an unreasonable length of time. Instead, the defendant solely relied on unsupported testimony from its expert that experimentation would be "difficult" and "complicated."

The Federal Circuit found the expert's testimony insufficient to constitute clear and convincing evidence of a lack of enablement. Further, the Federal Circuit found that the district court's emphasis on the inventor's testimony that some experimentation *may be* necessary was misplaced. The court pointed out that because the question of undue experimentation is a matter of degree, the fact that some experimentation may be necessary does not necessarily render the experiments unduly extensive, especially when the experiments involve repetition of known or commonly used techniques. *See Cephalon*, slip op. at 14 (citing *Johns Hopkins Univ.*, 152 F.3d at 1360). As explained above, the Federal Circuit has previously held that the potential need for clinical work, without more, is not dispositive on the issue of undue experimentation. *See AK Steel*, 344 F.3d at 1244. Therefore, the Federal Circuit reversed the district court's nonenablement determination.

Based on this renewed look at enablement, patent drafters should examine patent specifications prior to filing applications to ensure that all embodiments are fully enabled. While it is not necessary to explain in the specification how every embodiment of the claimed invention works, patent drafters should be careful to include enough instruction to make sure that all embodiments intended to be covered by the claims are fully enabled, particularly novel embodiments for which there is no guidance in the existing art.

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