Intellectual Property Litigation
FROM THE SECTION OF LITIGATION INTELLECTUAL PROPERTY LITIGATION COMMITTEE
Winter 2012, Vol. 23 No. 2

TABLE OF CONTENTS

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ARTICLES

Inter Partes Review: The New *Markman* Hearing?

By Robert M. Asher – February 20, 2012

The U.S. Supreme Court did not impose *Markman* hearings on patent litigation. In the case of *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), the court merely held that "claim construction is a matter of law for the judge to decide." District courts have since experimented with a variety of ways of handling patent litigation to give effect to this governing law. Depending on the court, claims have been construed by the judge before trial, after trial, and in the context of summary judgment motions. Over time, claim-construction hearings have become the most widely accepted approach to patent litigation.

The America Invents Act (AIA) may revolutionize patent litigation again through the introduction of *inter partes* review proceedings. *Inter partes* review has the promise of a swift contested administrative patent review with estoppel effect in which the proper meaning of claims will be determined. As of September 16, 2012, one may seek *inter partes* review of any U.S. patent. This new procedure replaces and eliminates the existing *inter partes* reexamination process. *Inter partes* reexaminations have suffered from a protracted timetable that discourages district court stays of litigation, and they thus make the prospect of preclusive effect remote.

The final determination of claim patentability or unpatentability in an *inter partes* reexamination creates an estoppel effect against the parties in civil litigation. However, that estoppel does not become effective until the termination of all appeal rights. *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 648 (Fed. Cir. 2011) ("[W]e hold that the estoppel provision of 35 U.S.C. § 315(c) applies only after all appeal rights are exhausted, including appeals to this court."). *Inter partes* reexamination can take years before the examiner, years before the board of appeals, and a year at the Federal Circuit Court of Appeals. As a result, it often takes five or more years before it has an estoppel effect. District court judges hesitate to stay a litigation for several years to wait for the results of a proceeding that might not even resolve the litigation.

Inter partes review has the potential to resolve these issues and thereby significantly enhance the prospect of making a substantive impact on litigations and obtaining a stay of district court litigation. An *inter partes* review is quick to reach a decision with estoppel effect. Moreover, the statute prevents the delayed filing of an *inter partes* review more than one year after being served with a complaint alleging infringement of the patent.

Inter partes review will be conducted before the Patent Trial and Appeal Board (PTAB). The PTAB will replace the Board of Patent Appeals and Interferences. Expert declarations may be submitted, and any declarant may be deposed. Either party has the right to an oral hearing before

the board. The patent owner will be allowed one motion to propose a reasonable number of substitute claims. Any further motions to amend and the specifics as to how *inter partes* reviews will be handled await Patent and Trademark Office (PTO) rulemaking over the coming year. Any appeal goes directly to the Federal Circuit Court of Appeals. Finally, the statute sets out time limits that should keep *inter partes* reviews to about 1.5 to 2 years in duration. In particular, the statute gives the board one year, extendible by not more than six months, after a PTO notice agreeing to institute an *inter partes* review, to issue its final written decision.

Whereas estoppel is not triggered in an *inter partes* reexamination until patentability has been "finally determined" (which includes all appeals), *inter partes* review triggers estoppel on receiving the "final written decision" from the PTAB. Because an *inter partes* review decision may be reversed on appeal to the Federal Circuit, courts will presumably stay or continue to stay a litigation during such an appeal. Such a stay remains discretionary with the courts. Given the hope of an estoppel-triggering decision in less than one year from institution of an *inter partes* review, even more aggressive judges may consider staying a litigation until the completion of a co-pending *inter partes* review. The prospect of staying litigation and averting the associated enormous costs of discovery and motions could provide a major incentive for the filing of *inter partes* reviews.

Another advantage of *inter partes* review over court litigation, at least for the petitioner, is the standard of proof. While an *inter partes* review petitioner needs to show anticipation or obviousness only by a preponderance of the evidence, a litigant must prove invalidity by a clear and convincing showing. In other words, the presumption of validity does not apply in *inter partes* reviews. On appeal to the Federal Circuit, underlying factual findings will be reviewed under a substantial-evidence standard for both *inter partes* reviews and appeals from jury decisions. Appeals from factual rulings made by judges may apply the slightly stricter "clearly erroneous" standard.

What Does the AIA Mean by the "Proper Meaning" of a Patent Claim?

Questions remain as to how claims will be construed in *inter partes* review proceedings. Reexaminations have long been attractive to requesters because of the comfort of knowing the PTO applies the broadest reasonable interpretation to claim language. As recognized by the Federal Circuit, "unlike in district courts, in reexamination proceedings [c]laims are given their broadest reasonable interpretation, consistent with the specification." *In re Swanson*, 540 F.3d 1368, 1377–78 (Fed. Cir. 2008) (internal quotations and citations omitted).

The differences between court proceedings and reexaminations can be dramatic. The Federal Circuit noted that "if the district court determines a patent is not invalid, the PTO should continue its reexamination because, of course, the two forums have different standards of proof for determining invalidity." *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1428–29 (Fed. Cir. 1988). In reviewing board decisions in reexaminations, the Federal Circuit, while reviewing claim construction de novo, "must determine whether the Board's construction of the term was reasonable." *In re NTP, Inc.*, 654 F.3d 1279, 1287 (Fed. Cir. 2011). This may all change with the AIA.

Instead of referring to "broadest reasonable interpretation," the new statute tasks the PTO—in ex parte reexamination, *inter partes* review, and post-grant review—to determine "the proper meaning of a patent claim." 35 U.S.C. § 301(d). The proper meaning of a claim has normally been the province of litigation. "To determine the proper meaning of claims, we first consider the so-called intrinsic evidence, i.e., the claims, the written description, and, if in evidence, the prosecution history." *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998). "The proper construction of a patent's claims is an issue of Federal Circuit law. . . . To ascertain the scope and meaning of the asserted claims, we look to the words of the claims themselves, the specification, the prosecution history, and any relevant extrinsic evidence." *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1129 (Fed. Cir. 2011) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315–17 (Fed. Cir. 2005)).

To better understand what the AIA means when it refers to the "proper meaning" of a claim, let's examine the phrase in context. Section 301 is amended to allow any person to cite to the PTO at any time "statements of the patent owner filed in a proceeding before a Federal court or the Office in which the patent owner took a position on the scope of any claim of a particular patent." The statement may be accompanied by "documents, pleadings, or evidence from the proceeding in which the statement was filed that addresses the written statement." Such statements and accompanying information "shall not be considered by the Office for any purpose other than to determine the proper meaning of a patent claim in a proceeding that is ordered or instituted pursuant to section 304, 314, or 324." *See* 35 U.S.C. § 301.

Thus, as of September 16, 2012, positions taken by a patent owner on claim scope may be used in determining the "proper meaning" of a claim in ex parte reexaminations, *inter partes* reviews, and post-grant reviews, but not in reissue proceedings.

Will Proper Claim Construction Be Redefined?

The courts are left to determine how a patent owner's positions on claim scope should influence "the proper meaning of a patent claim." Moreover, courts must define "the proper meaning of a patent claim." While reissue proceedings and original patent prosecutions will continue to apply the "broadest reasonable interpretation, consistent with the specification, and limitations appearing in the specification are not to be read into the claims," *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984), presumably Congress intends that in the new review proceedings and in ex parte reexamination, "the proper meaning" will be applied.

The proper meaning in *inter partes* reviews, post-grant reviews, and ex parte reexaminations will be informed in part by statements made by the patent owner in litigation. Arguments for a broad scope may inform the "broadest reasonable interpretation," and arguments in favor of a narrowed scope might suggest which interpretations are consistent with the specification. Alternatively, a patent owner's arguments for a broad scope may incur what might come to be called litigation history estoppel. The broad construction proposed in litigation might be adopted by the PTO,

thereby subjecting the patent to a wider prior art attack and an increased risk of cancellation or amendment. Many questions remain. Must the claim construction be reasonable to be applied by the PTO? Does the position taken in court have weight if the court did not adopt the position?

On the other hand, courts have been referring to the *Phillips* claim-construction approach as the proper claim construction. Might not the Federal Circuit interpret the statute as asking the PTO to apply the *Phillips* approach when handling review proceedings or ex parte reexaminations? Statements regarding claim scope made by the patent owner in patent litigation could then be considered extrinsic evidence, and the courts would need to determine how the PTO should weigh and apply such evidence. The PTO has limited experience applying *Phillips*, doing so only in reexaminations of patents that have expired. If this approach is followed, it will be interesting to see if the PTAB has any better success than the district courts in arriving at claim constructions ultimately approved by the Federal Circuit.

Proposal for a Unitary Approach to Claim Construction

Although Congress created a single U.S. Court of Appeals to handle patent appeals from both the district courts and the PTO, a uniform standard for determining patent invalidity has been elusive. The validity of patents currently depends on one approach to claim construction in the district courts and an entirely different approach in the PTO. A unitary approach to claim construction of issued U.S. patents should create greater certainty and enhance confidence in the judicial system. Under current law, the validity of a patent can depend on whether it reaches the Federal Circuit from a district court decision or from the Board of Patent Appeals and Interferences, rather than on a consistent measure of the merits of the invention.

Litigators can play a big role in inviting courts to determine whether the framework for construing claims should be revised in view of the AIA. At some point, a litigator in district court will demand that the claims in litigation be construed according to their “proper meaning.” If the PTAB is determining the “proper meaning” of a claim pursuant to the AIA, shouldn’t the court also be deciding patent disputes on the basis of the “proper meaning” for the claims? Can courts decide a case on the basis of a claim construction that is not proper? The language of the AIA appears to cry out for a unitary approach to claim construction.

This is a great opportunity for courts to take a fresh look at determining the best framework for claim construction. In arriving at a preferred, uniform approach, would there not be far greater certainty if courts determined the scope of a patented invention on the basis of the claim language as set forth in *In re Yamamoto* requiring consistency with the specification rather than relying heavily and unpredictably on the specification to interpret the claim language when trying to apply *Phillips*? Patent claims are examined and amended during patent prosecution to arrive at a scope that constitutes a patentable invention relative to the prior art according to the PTO. If this broad patentable interpretation of the claims were also applied by the courts, the doctrine of equivalents would become less necessary. Courts could be encouraged to revisit the

debate between those who saw a need for a doctrine of equivalents to protect the incentive for innovation and those who favored the competing desire to make the scope of patents more certain. Perhaps the use of the doctrine of equivalents under such a new claim-construction framework could be more strictly limited. Patent owners can still pursue equivalents outside the scope of their claims by seeking broader claims in continuations and broadening reissues. A patent would only be entitled to such scope if that scope was still novel and not obvious.

Greater certainty would result if courts could adopt a claim-construction framework in which the incorporation of limitations from the specification does not occur unexpectedly and the use of the doctrine of equivalents is limited. This would provide greater predictability and would increase the availability of summary judgments of noninfringement. If the patent owner finds that its claims are too broad, the patent laws offer numerous options to seek narrower claims, including in continuation applications, reissue applications, and ex parte reexamination.

Will *Inter Partes* Review Replace *Markman* Hearings?

If courts decide to adopt a uniform claim construction for review proceedings and litigation, then a review proceeding could serve as a *Markman*-like hearing. Unlike a *Markman* hearing in court, the PTAB *inter partes* review decision can be reviewed on appeal by the Federal Circuit before the district court case proceeds to trial. Thus, by staying a litigation for an *inter partes* review, the court may benefit from a Federal Circuit-approved construction of the patent claims.

Stays will be further beneficial because *inter partes* review can result in a settlement. This is not the case with reexaminations, which continue even without the involvement of the parties. *Inter partes* review also offers the customary possibility of a cancellation of some or all of the patent claims or confirmation of the patentability of some of the claims with estoppel effect. Thus, stays should be more readily granted. If the PTAB is able to issue its final decisions in a timely manner, *inter partes* review is likely to be a big hit and may even replace *Markman* hearings as the defining moment in many patent litigations.

A uniform and more predictable claim-construction approach would enhance our patent system and the economy. Litigators can play a critical role in shaping the law by urging new approaches and dramatic changes or arguing to preserve a semblance of the status quo. Interpreting the AIA will bring a new world for patent law.

Keywords: litigation, intellectual property, America Invents Act, *inter partes* review, claim construction

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Joinder Limitations in the America Invents Act: Big Change?

By Chandran B. Iyer and Ryan M. Corbett – February 20, 2012

The newly enacted America Invents Act (AIA) is the most radical change to U.S. patent laws in 60 years. One of the more significant aspects of this act is the addition of section 299, titled "Joinder of parties." This provision, which took effect immediately on the enactment of the AIA, sets forth the circumstances under which accused infringers may be joined in a single patent infringement suit and when they may not.

New Joinder Rule
Section 299(a), in relevant part, provides:

> parties that are accused infringers may be joined in one action . . . *only if*—
>
> > (1) any right to relief is asserted against the parties jointly, severally, or in the alternative with respect to or arising 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
> >
> > (2) questions of fact common to all defendants or counterclaim defendants will arise in the action.

(emphasis added). In other words, section 299 delineates two conditions that must be satisfied before accused infringers may be joined in a single civil action. Specifically, different accused infringers can be joined in one case if the relevant questions of fact are common to all accused infringers and either the right to relief is asserted against the accused infringers jointly or severally or if one of the asserted causes of action is with respect to or 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.

In addition, section 299(b) also contains a specific joinder prohibition.

> (b) ALLEGATIONS INSUFFICIENT FOR JOINDER.—For purposes of this subsection, accused infringers may not be joined in one 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.

Specifically, joinder of accused infringers is expressly prohibited if it is based solely on allegations that each defendant has infringed the asserted patent(s).

It should be mentioned, however, that section 299 is not compulsory in that an accused infringer may "waive the limitations set forth in this section with respect to that party." *See* § 299(c).

One noticeable exception to the new joinder provision is that it does not apply to Hatch-Waxman litigations (also called abbreviated new drug application or ANDA litigations)—in other words, allegations of infringement under 35 U.S.C. § 271(e)(2). This specific carve-out in section 299 would allow plaintiffs in ANDA cases (typically branded drug makers) to join multiple defendants (typically generic drug makers) in a single lawsuit, even though each generic manufacturer would be sued for marketing, offering to sell, or selling their own generic version of the branded drug. In other words, generic drug makers can be sued in one lawsuit, even though the asserted cause of action is not with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences.

Interpretation of the New Joinder Rule

Although the new joinder standard in the AIA has gotten much attention, it is worth noting that the section 299 standard is nearly identical to the permissive joinder standard set forth in Rule 20 of the Federal Rules of Civil Procedure. In fact, like section 299, Rule 20 also provides that persons may be joined as defendants in one action if:

> (A) any right to relief is asserted against them jointly, severally, or in the alternative with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences; and
> (B) any question of law or fact common to all defendants will arise in the action.

In other words, the joinder provision of Rule 20 sets forth two conditions that are substantively identical to the conditions set forth in section 299. Accordingly, practitioners trying to anticipate how section 299 will be applied by courts need only look at how courts have interpreted Rule 20. In fact, many accused infringers in patent cases have already used Rules 20 and 21 for severing defendants from multiple-defendant patent suits on the basis that the defendants have been misjoined. While ruling on the accused infringer's misjoinder motion, courts have interpreted the scope of the phrase "arising out of the same transaction, occurrence, or series of transactions or occurrences."

For example, in May 2011, Judge Alsup from the U.S. District Court for the Northern District of California ruled that the eight defendants named by the plaintiff patent holder were misjoined because the alleged infringement did not arise from "related activities." *See EIT Holdings, LLC v. Yelp!, Inc.*, 2011 U.S. Dist. LEXIS 64034, at *2–3 (N.D. Cal. May 12, 2011). In *EIT Holdings*, the court noted that the unrelated defendants operate different accused websites that implement different functionalities through different software and that the plaintiff had not alleged any conspiracy or that any defendant induced another to infringe. *See id.* at *3–5. Although the accused products in *EIT Holdings* contained completely different software that allegedly

performed the infringing acts, the fact that unrelated products may contain the same component that performs the alleged infringing act may not be sufficient to establish joinder.

Likewise, in another recent order, the U.S. District Court for the Northern District of California found that five defendants were misjoined even though the defendants' accused products included the same processor that performed the allegedly infringing acts. *See Optimum Power Solutions, LLC v. Apple Inc.*, 2011 U.S. Dist. LEXIS 106436 (N.D. Cal. Sept. 20, 2011). In *Optimum Power Solutions*, the defendants' accused computers all contained Intel processors that were allegedly the basis for the plaintiff's infringement claims. *See id.* at *4–5. According to the plaintiff, the fact that the accused products shared a common processor that allegedly performed the infringing acts was sufficient to join the defendants. *See id.* at *7. The court disagreed, noting that the shared processor may establish a question of law or fact common to all defendants, but does not establish that the defendants' infringement involved the same transaction, occurrence, or series of transactions or occurrences. *See id.* at *10–11.

In light of, among others, *Optimum Power Solutions* and *EIT Holdings*, it appears that the Ninth Circuit defines "same transaction, occurrence, or series of transactions or occurrences" very narrowly to require a high degree of factual commonality underlying the claims before multiple parties can be joined as defendants in one lawsuit. *See Coughlin v. Rogers*, 130 F.3d 1348, 1350 (9th Cir. 1997).

The stringent standard used by the Ninth Circuit for joining defendants in one patent case has also been adopted by courts in other jurisdictions. For example, in *Phillips Electronics v. Contec Corp.*, the U.S. District Court for the District of Delaware found that two defendants were not properly joined where they sold different accused products manufactured by different third parties, even though the accused products were sold to the same customer. *See Phillips Elecs. N. Am. Corp. v. Contec Corp.*, 220 F.R.D. 415 (D. Del. 2004). The foregoing cases from two of the busiest patent dockets in the country demonstrate that courts have started to require a plaintiff to meet a very high standard for joining multiple, unrelated defendants in one patent case. This trend will certainly continue with the enactment of section 299.

Furthermore, the legislative intent behind the AIA also provides some support for the proposition that section 299 will require the plaintiff in a patent case to put forth a strong showing of factual commonality before multiple defendants are allowed to remain in one suit. More specifically, the legislative history of the act explicitly states that the new joinder provision legislatively abrogates the interpretation of Rule 20(a) taken by some jurisdictions in cases such as *MyMail, Ltd. v. America Online, Inc.*, 223 F.R.D. 455 (E.D. Tex. 2004), in which joinder was found proper simply on the basis that the accused products were similar and were alleged to infringe the same patent, but otherwise unrelated. *See* H.R. Rep. No. 112–98, pt. 1, at 55 n.61. Moreover, given the common belief that the new joinder provision may have been enacted in part to stop nonpracticing entities (NPEs) from suing multiple defendants in a single lawsuit, a more

stringent joinder standard was most likely contemplated by Congress. In fact, prior to passage of the act, Congress heard testimony from multiple witnesses decrying NPEs' allegedly abusive practice of naming dozens of defendants in a single lawsuit to extort settlements over questionable patents. *See, e.g.*, *Review of Recent Judicial Decisions on Patent Law: Hearing Before the Subcommittee on Intellectual Property, Competition, and the Internet of the House Committee on the Judiciary*, 112th Cong. 68–69 (2011) (statement of John Boswell, Senior Vice President and General Counsel, SAS Institute).

One unintentional consequence of requiring a high degree of factual commonality is that, while limiting the number of defendants that may be sued at one time by an NPE, the new joinder provision also unfairly limits the ability of practicing entities to efficiently seek a remedy against multiple infringers. For example, a small company that owns a patent and practices the invention claimed in that patent would be at a disadvantage if its patent is being infringed by several of its larger competitors because of the increased cost of being forced to sue each infringer separately. Unfortunately, there may be no other way for such an entity to enforce its patent rights.

Maintaining Judicial Efficiency and Economy

One issue that the AIA fails to contemplate is the effect of having multiple lawsuits involving the same patent(s). In other words, what happens when a plaintiff is required to file multiple lawsuits against various defendants on the same patent, as opposed to naming the different defendants in one lawsuit? Under this scenario, it is entirely possible for one plaintiff to litigate an infringement case involving one patent in different venues across the country. This could, in turn, result in duplicative discovery—such as discovery on conception, reduction to practice, and other issues pertinent to an inventor—and contradictory claim constructions from different courts. In such an instance, how can judicial economy and efficiency by achieved? One option to circumvent this inefficiency is to enter into a multidistrict litigation (MDL) proceeding.

Litigating patent cases in an MDL setting is not uncommon. To enter into an MDL proceeding, the moving party must show that there are "one or more common questions of fact" between the civil actions pending in various venues, that the transfer "will be for the convenience of parties and witnesses," and that the transfer "will promote the just and efficient conduct" of the actions to be consolidated. *See* 28 U.S.C. § 1407(a). Moreover, although the MDL statute expressly requires common questions of fact, the MDL panel may also consider common questions of law, such as claim construction, when it applies this standard. *See, e.g.*, *In re Cygnus Telecomm. Tech., LLC, Patent Litig.*, 177 F. Supp. 2d 1375 (J.P.M.L. 2001).

Also, although section 1407 does not specifically set forth how the appropriate forum for an MDL action is determined, the MDL panel has offered its own guidance on the issue. In particular, the MDL panel has chosen a venue based on several factors, such as the venue where the majority of the actions are pending; the actual location of the patentee, defendants, and witnesses; the venue of the first-filed action; and the docket backlog in various forums. Using

these factors, it is entirely possible for the MDL panel to select a venue that is not contemplated by any of the parties. This fact should certainly be considered before an MDL proceeding is sought.

Conclusion

The joinder provision in the AIA, section 299, has received much attention. However, section 299 is nearly identical to the existing Rule 20, which patent defendants have successfully used to sever themselves from multi-defendant cases. As a result, while section 299 does not change the existing standard for joining multiple defendants in one lawsuit, its impact will certainly be felt given its prominent placement in the U.S. patent laws.

Keywords: litigation, intellectual property, joinder, America Invents Act, multidistrict litigation

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How the America Invents Act Revived the Prior-User Defense

By Jeff Mikrut – February 20, 2012

In general, a "prior-user defense" is a defense to a claim of patent infringement that permits a person to continue their use of an invention even if that invention is subsequently patented by another. One specific area where this defense may be particularly applicable is where the dominions of trade secrets and patents intersect. For example, suppose that a manufacturer discovers a specialized process for making a product. The manufacturer can choose to keep the process as a trade secret or divulge its discovery in an attempt to obtain a patent on the process. If the manufacturer chooses to keep the process as a trade secret, then the manufacturer could potentially be liable for patent infringement if that process is subsequently patented by another entity. In many foreign jurisdictions, a prior-user right or defense exempts the manufacturer from liability for patent infringement because the manufacturer used the patented process prior to the other entity obtaining a patent on it. Until recently, however, the United States did not provide for any meaningful prior-user defense to prevent such manufacturers from incurring this liability.

The law in the United States on prior-user defenses has fluctuated between providing a broad, strong defense to omitting it entirely. The policy debates have generally been framed according to the issues demonstrated by the above example—whether to protect the interests of those entities who invented something first and were secretly commercially exploiting the invention versus promoting disclosure through the patent process. The Leahy-Smith America Invents Act of 2011 (AIA), Pub. L. No. 112-29 (2011), readjusted the prior-user defense once again. In particular, section 5 of the act substantially expanded the scope and applicability of the prior-user defense beyond the previous version codified at 35 U.S.C. § 273 (2010). The current modifications to section 273 provide for a more robust prior-user defense that will likely have far-reaching effects that impact both patentees and accused infringers.

The History of Prior-User Defense Rights

As noted above, the prior-user defense has had a continually shifting position in U.S. patent law. The first explicit appearance of the prior-user defense occurred in the Patent Act of 1839. 5 Stat. 353–55 (1839). This act included a broad prior-user defense that encompassed any machine, manufacture, or composition of matter that was obtained, constructed, or purchased prior to an application for a patent. *Id.* at § 7. Modified forms of this prior-user defense continued until the defense was explicitly repealed by the Patent Act of 1952. *See* Kyla Harriel, "Prior User Rights in a First-to-Invent Patent System: Why Not?," 36 *IDEA* 543, 547–50 (1996) (discussing the history of prior-user defense up to the Patent Act of 1952).

Following the major reforms implemented by the Patent Act of 1952, the prior-user defense lay largely dormant until the 1990s. The defense came back to the forefront of U.S. patent law when

the World Intellectual Property Organization attempted to harmonize the varying global patent laws through a proposed patent law treaty. In an attempt to spur the United States to join the harmonization efforts, members of each chamber of Congress introduced bills to implement the major substantive provisions involved in the patent law treaty—primarily switching to a first-to-invent system and including prior-user rights. *See* Patent Harmonization Act of 1992, S. 2605, 102d Cong. § 3 (1992); Patent Harmonization Act of 1992, H.R. 4978, 102d Cong. § 3 (1992). Each of these bills would create a new section, section 273, defining a prior user's right or defense to patent infringement. While these attempts to harmonize U.S. patent law with the world proved unsuccessful, Congress continued to endeavor to revive the prior-user defense with varying degrees of success. *See, e.g.*, Omnibus Patent Act of 1997, H.R. 400, 105th Cong. § 302 (1997) (passed by the House of Representatives only); Patent Prior User Rights Act of 1994, S. 2272, 103d Cong. (1994) (passed by the Senate only).

The Enactment and Scope of the Previous Section 273

Though Congress made prior attempts to enact varying iterations of the prior-user defense, it was not until the Federal Circuit's unexpected decision in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), that incited legislators into action. In brief, the Federal Circuit's decision in *State Street* upended the commonly held belief that methods of doing business were not subject to patenting. *Id.* at 1375. Prior to *State Street*, novel business processes and procedures could only be protected as trade secrets. Following the *State Street* decision, however, the Patent and Trademark Office (PTO) was awash with new business-method patent applications. To alleviate concerns that business-method patents would issue that covered methods of doing business corporations and individuals had long held as trade secrets, Congress enacted the American Inventors Protection Act of 1999, which was incorporated into the Consolidated Appropriations Act of 2000, Pub. L. No. 106–13 § 4302 (2000). Section 273, titled the "Defense to infringement based on earlier invention," thus revived the prior-user defense, albeit in an extremely narrow and convoluted context.

In brief, the previous section 273 provided that an accused infringer could assert a prior-user defense against a claim of infringement of a business-method claim only if the accused infringer had actually reduced the subject matter to practice one year prior to the effective filing date of the patent and commercially used the subject matter before the filing date of the patent. *See* 35 U.S.C. § 273 (2010) (prior to amendment in 2011). Both of these prongs needed to be proven by clear and convincing evidence. In addition to these strict requirements, the defense was also subject to a series of limitations that substantially narrowed the scope and applicability of the defense. For instance, the term "commercial use" was limited to commercial use in the United States (§ 273(a)(1) (2010)), abandonment of the use would reset the time requirements (§ 273(b)(5) (2010)), and the defense was limited to the person who performed the infringing acts and was rarely transferable (§ 273(b)(6) (2010)). These extensive limitations severely restricted the use and applicability of the prior-user defense.

One of the most restrictive limitations to the prior-user defense—limiting the defense to only business methods—was done as a direct reaction to the Federal Circuit's *State Street* decision. In response to a question about limiting the defense to business methods, Representative Howard Coble of North Carolina, the sponsor of the American Inventors Protection Act, stated that the defense "is limited . . . to the State Street Bank case. There was some discussion early on that perhaps the first inventive defense should apply to processes as well as methods, but we finally concluded that we would restrict it to methods only, and that, by having done that, we were able to satisfy some folks who were opposed to the bill otherwise." 145 *Cong. Rec.* H6942 (daily ed. Aug. 3, 1999) (statement of Rep. Coble). Additional statements by other members of Congress confirmed this strict limitation. 145 *Cong. Rec.* H6943 (daily ed. Aug. 3, 1999) (statement of Rep. Rohrabacher) (stating that the prior-user defense is limited to business methods only). Despite the enactment of a form of the prior-user defense, the restriction limiting its applicability to business methods severely hampered any effective use.

Case Law Following the Enactment of the Previous Section 273

Though the prior version of section 273 was effective for more than a decade, only a handful of cases invoked or even mentioned the section. In fact, the most prominent case involving section 273, *Bilski v. Kappos*, did not even apply it as a defense, but used the existence of the section as part of the Court's justification for the patentability of business methods. 130 S. Ct. 3218, 3228–29 (2010). Moreover, the first case to discuss section 273 as a defense, *Seal-Flex, Inc. v. W.R. Dougherty*, 179 F. Supp. 2d 735 (E.D. Mich. 2002), did not reach any substantive analysis of the prior-user defense. In *Seal-Flex*, the defendant asserted the prior-user defense only after the district court entered summary judgment for the plaintiff. Therefore, the court found that the defense was untimely and did not rule on its merits. *Id.* at 741–42. The next case addressing section 273 as a defense, *PB Farradyne, Inc. v. Peterson*, No. C 05-3447, 2006 U.S. Dist. Lexis 67281 (N.D. Cal. Sept. 6, 2006), did not occur until four years after *Seal-Flex*. Though the defendant technically was successful in asserting the defense, this was only because the plaintiff failed to oppose the defense in the plaintiff's response to a motion for summary judgment. *Id.* at *11–12. This win, by technicality, was the only successful assertion of the prior-user defense of section 273 since its revival.

The first and only case to substantively discuss the provisions of the prior-user defense was *Sabasta v. Buckaroos, Inc.*, 507 F. Supp. 2d 986, 1002–5 (S.D. Iowa 2007). In *Sabasta*, the patent at issue was directed to a roll-bending die used to make saddles for pipe insulation. *Id.* at 988. In attempting to assert the prior-user defense, Buckaroos contended that the term "business method" applied to their use because they were "in business, and [were] using a roll-bending process as part of conducting [their] business." *Id.* at 1002 (internal quotes omitted). The court ultimately rejected Buckaroos's broad interpretation of "business method" and concluded that "[t]he fact that Buckaroos is in business and uses a process to manufacture ribbed pipe saddles does not, in light of the legislative history and the *State Street* case, bring it within the intended

purview of § 273." *Id.* at 1005. Thus, the first court to substantively address section 273 confirmed that the scope of the defense was limited to the kinds of business methods that resulted from the *State Street* decision. The defense did not encompass all methods or processes that were used by a business. However, while the foregoing cases demonstrated the limited effectiveness of the prior-user defense enacted by the American Inventors Protection Act of 1999, legislation to overhaul the U.S. patent laws, including an expanded prior-user defense, was pending in Congress.

The New Prior-User Defense and Its Enactment

The recent enactment of the AIA both broadened and narrowed different aspects of the prior-user defense of section 273. While the act modified a number of aspects of section 273, there are four significant changes:

- the expansion of the subject matter to which the defense applies;
- the slight broadening of the personal-defense aspect;
- the requirement that commercial use is made one year prior to the effective filing date of the patent; and
- the university exception.

In general, an accused infringer may now assert the amended prior-user defense of section 273 against any claimed invention provided that the accused infringer commercially used the subject matter in the United States at least one year prior to the effective filing date of the claimed invention. 35 U.S.C. § 273(a). According to the act, every patent that issues on or after September 16, 2011, is subject to this new prior-user defense, provided that the accused infringer also meets the additional requirements of section 273. One particular hurdle that carried over from the previous section 273 is that the defense must still be proven by clear and convincing evidence.

The most notable change in the new section 273 is the expanded scope that exposes almost all patents to the prior-user defense. One specific reason for this broadening amendment was to specifically insulate businesses from having to disclose their internal processes or manufacturing materials. Both of the named sponsors of the bill, Representative Lamar Smith of Texas and Senator Patrick Leahy of Vermont, discussed this reasoning during the debate over the bill. *See, e.g.*, 157 *Cong. Rec.* H4483 (daily ed. June 23, 2011) (statement of Rep. Smith) ("The prior-use defense is not overly expansive and will protect American manufacturers from having to patent the hundreds or thousands of processes they already use in their plants."); 157 *Cong. Rec.* S5426 (daily ed. Sept. 8, 2011) (statements of Sen. Blunt and Sen. Leahy) (discussing that "the prior user rights provided under section 5 of H.R. 1249 will allow developers of innovative technologies to keep internally used technologies in-house without publication in a patent"). In addition, the remarks from Senator Jon Kyl of Arizona explain that "[t]he prior-commercial-use defense provides relief to U.S. manufacturers . . . [by] allowing them to make long-term use of a

manufacturing process without having to give it away to competitors or run the risk that it will be patented out from under them." 157 *Cong. Rec.* S5430 (daily ed. Sept. 8, 2011). Accordingly, it is clear that a major driving factor for the broadening of the prior-user defense was to shield manufacturers who owned trade secrets from subsequent patent-infringement claims.

In addition, the new prior-user defense also broadened the entities that can assert the defense. As noted above, under the prior section 273, the defense was by and large limited to the person who performed the infringing acts of the business method. Section 273(e)(1)(A) now expands the defense to "the person who performed or directed the performance of the commercial use described in subsection (a), or by an entity that controls, is controlled by, or is under common control with such person." While the previous personal-defense limitation was never interpreted by a court, the new provision is intended to expand the defense to include contractors, vendors, or other third parties over whom the person asserting the defense had control. *See* 157 *Cong. Rec.* S5430–31 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl).

While some features of the prior-user defense expanded, other changes to section 273 narrowed the defense. In particular, the amended commercial use requirement slightly narrowed the applicability of the defense. While the previous requirement only required commercial use any time prior to the effective filing date, now, the prior user is required to demonstrate commercial use one year prior to the effective filing date of the patent. The extension of the commercial-use requirement is intended to account for the grace period that has been enacted as part of the first-to-file amendments. *See* 157 *Cong. Rec.* S5430 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl) (discussing the increased commercial-use time requirement as addressing concerns that the prior-user defense would lead to a "morass of litigation over whether an infringer was entitled to assert it" or not). Additional commentary in the congressional record provides further insight regarding the commercial-use requirement. In particular, portions of the record imply that the commercial-use requirement may encompass the creation of prototypes (157 *Cong. Rec.* S5427 (statement of Sen. Blunt)) and that seasonal or infrequent commercial use may not constitute an abandonment of the use, 157 *Cong. Rec.* S5431 (statement of Sen. Kyl).

Finally, the amendments to section 273 include a specific exception to preclude assertion of the defense to certain patents developed by universities. 35 U.S.C. § 273(e)(5). Specifically, the "University Exception" precludes an accused infringer from asserting the prior-user defense against patents that were, at the time the invention was made, owned or subject to an assignment to a university or technology transfer organization for the university (for example, the Wisconsin Alumni Research Foundation). Congress added this exception because of the publication and disclosure requirements needed to advance scientific research. *See* 157 *Cong. Rec.* S5427 (daily ed. Sept. 8, 2011) (statement of Sen. Kohl). One exception to the broad University Exception explicitly permits the assertion of the defense against university-developed inventions that "the federal government is affirmatively prohibited, whether by statute, regulation, or executive order, from funding research in the activities in question." 157 *Cong. Rec.* S5431 (daily ed. Sept. 8,

2011) (statement of Sen. Kyl). Despite this exception to the exception, the immunity provided to university-owned patents effectively excludes a large swath of patents from the prior-user defense.

The Potential Impact of the New Prior-User Defense

Though the ultimate impact of the new prior-user defense will not necessarily be known for some time, the amendments to section 273 provide a solid foundation for a more expansive and useful prior-user defense. For current patent holders, the new section 273 defense has no substantial effect because the new defense is limited to patents issued on or after September 16, 2011. For current trade-secret owners, the expanded prior-user defense appears to provide a longed-for shield to defend against those who might acquire a patent on a process the trade-secret owner may have been using for decades.

Going forward, however, the new section 273 defense will likely have a larger impact. For example, inventors of a new manufacturing process may now be better served by maintaining the process as a trade secret instead of pursuing patent protection. While there is a risk that a court may limit the prior-user defense to exclude trade-secret uses, the extensive legislative history addressing this point may guide courts to resolve the issue in favor of protecting those uses under the new prior-user defense. Inventors of other patentable subject matter, such as machines, compositions of matter, and manufactures, will likely be less affected by the new prior-user defense because the commercial-use requirement for a machine, composition of matter, or manufacture will likely prevent the subsequent patent from issuing under the new first-to-file system. In the rare instance that an inventor of a device uses it only during the internal manufacturing of a different product—for instance, the patented die from *Sabasta v. Buckaroos*—the inventor may be able to advantageously maintain its market position by only using the invented device internally. In the end, the new prior-user defense provides innovators with a clear and functional defense that will hopefully spur more innovation rather than less.

Keywords: litigation, intellectual property, prior-user defense, trade secrets, America Invents Act

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Intellectual Property Litigation
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Words Method vs. Invention Method of Claim Construction

By Brad Lyerla – February 20, 2012

While the pundits will debate the importance of the America Invents Act (AIA) for months to come, one thing is clear: The AIA did nothing to address the most persistent and pernicious problem in patent litigation—namely, claim construction. There is reason to hope, however, that this problem will receive the attention it deserves some time soon. After simmering for years, it may now be that the core problem in claim construction is coming into sharp focus for review by the Court of Appeals for the Federal Circuit.

Many have come to understand that the rules for claim construction are ill-defined and applied inconsistently. *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 2011 WL 5222835 (Fed. Cir. Oct. 31, 2011). Patent litigators know that claim construction is unpredictable in the trial courts and that the rate of reversal in the court of appeals is too high. Professor David Schwartz has studied whether trial judges improve at claim construction with experience and discovered that—as a group—they do not improve as they gain more experience construing patents. David L. Schwartz, "Practice Makes Perfect? An Empirical Study of Claim Construction Reversal Rates in Patent Cases," 107 *Mich. L. Rev.* 223 (2008). Among other possible explanations for the observed data, Professor Schwartz hypothesizes that claim construction may be inherently "indeterminate." *Id.* at 267. So claim construction, which is of crucial importance to patent litigation, is ill-defined, unpredictable, inconsistent, and possibly (like quantum mechanics) indeterminate! What is going on here?

There is an explanation, and it is simple. There are two competing methods for doing claim construction. They likely are irreconcilable. However, the case law does a poor job of recognizing the two methods. Both methods are used by members of the Federal Circuit and by trial judges. There is little predictability as to which method will be used in which situation. In some cases, the methods are conflated and used together, leading to even further confusion.

The Two Methods

When a patent claim is ambiguous, a court must resolve the ambiguity by choosing one of its possible meanings. The court looks first and foremost to the patent documents to discern the correct meaning of the claim. But what is the court looking to find in the patent documents? The answer to that question is different depending on the method of construction that the court employs. Some judges will study the patent documents to try to understand what the inventor has invented. Such a judge will then choose the claim meaning that best fits the invention. For simplicity, I will call this the invention method of claim construction. Other judges will take a very different approach. They will focus on the claim language and will rely on the words of the

claim and rules of construction, which are largely linguistic, to choose the meaning to assign to the claim. This method of construing claims can be called the words method.

At first blush, it may seem that these methods are simply two different ways of getting to the same thing. They are not. In fact, they are profoundly different and often result in dramatically different outcomes in litigation.

An Example from the Federal Circuit

Arlington Industries, Inc. v. Bridgeport Fittings, Inc., 632 F.3d 1246, decided in early 2011, provides a good illustration of the two methods as applied in the same case. There, the patent claimed an improved electrical connector that could be snapped into an electrical box using only one hand. The connector featured a spring metal adaptor. The parties disputed whether the adaptor could be a continuous, unbroken circle or whether it must be a noncontinuous circle with a split so as to allow it to expand and contract. The trial judge held that the claims required the split limitation and granted summary judgment of noninfringement. The Federal Circuit panel reversed, but with a dissent. And the disagreement between the majority and the dissenting opinions is an excellent example of the difference between the words method and the invention method of construing patent claims.

Chief Judge Rader wrote for the majority. He analyzed the question first by asking whether the ordinary meaning of the phrase "spring metal adaptor" would include the concept of a split as understood by one of ordinary skill. He concluded that it would not. This suggested to him that the trial court imported the split limitation from the specification. He found corroboration for this conclusion by invoking the doctrine of claim differentiation. Because a dependent claim actually calls out the split limitation, he reasoned that the independent claim must not be so limited. On the basis of this reasoning and a review of the file history where Judge Rader used the patent documents essentially as a lexicon, the majority held that the trial court erred in construing the claims to include the split limitation, and it vacated the summary judgment granted below. This is a classic example of the words method.

In Judge Lourie's concurrence and dissent, he noted that one of the patents in suit disclosed only adaptors with splits and concluded that the claims of that patent should be construed to include the split limitation. He reasoned as follows: "[A]t bottom, we are reading a patent specification to see what the inventors invented, what they disclosed, and how they conveyed that information. A patent is a teaching document. In almost all cases, the inventors, and their patent solicitors, knew what was invented and generally disclosed their invention in competent language. . . . I believe the inventors in this case contemplated that their invention consisted only of spring metal adaptors with a [split]." *Id.* at 1257–58. Judge Lourie would have affirmed the trial court's claim construction because it fits what was invented. This is a classic example of the invention method.

Both methods have a legitimate claim to be the correct method. And both have an argument that the other method brings with it too many problems. That is so because each method has its own advantages and disadvantages. Each emphasizes different evidence. Each speaks to different policies in the patent laws. But neither has gained sway over the other—and that is the problem.

The Invention Method

Let's consider the invention method first. It offers serious advantages. First among the advantages is that this is the method that persons of ordinary skill use to understand a patent. They do not wordsmith the claims. Laymen read the whole patent document to understand what the inventor has invented. Laymen are familiar with the prior art, and they try to discern what the inventor has contributed that is new. If a layman is not doing what is new in the patent, then he will conclude that he does not have a problem with potential infringement. If he is doing something close to what is new in the patent, then he knows that he may have a problem. The nuances and rules of construction that lawyers use to divine the meaning of a claim are ignored by laymen. Laymen do not understand those rules, unless they have been tainted by too much patent litigation. Instead, they read a patent like an engineering or science document. This is the essence of the invention method.

Of course, all judges say that they are construing a patent as would one of ordinary skill. But judges using the invention method are probably more faithful to this principle than are words-method judges. As in the majority opinion in *Arlington Industries*, the words method focuses on the abstract meaning of words to a person of skill in the art, not on the meaning of the patent document as a whole to a person of skill.

A second advantage of the invention method is that it fits with what the public understands a patent to be. The public believes that there is a physical thing that corresponds to what is claimed in the patent. The invention method approaches a patent the same way. It assumes that there is something described in the patent that can be understood from the disclosure of the patent and protected by the court. Because that makes sense to the public, the invention method tends to reinforce the legitimacy of the patent system in the mind of the public—an important deterrent to infringement.

A third advantage of the invention method is that it minimizes the influence of the claims draftsman who may have planted seeds of confusion in the claims to create potential arguments for greater breadth in the event the patent is litigated. A common example of this is to claim the invention broadly in an independent claim reading on all of the disclosed embodiments and then to recite a limitation in a dependent claim that is present in every embodiment, thus implying that the independent claim is broader than the dependent claim, even though both claims are coextensive with the disclosed invention. It is no secret that claims are sometimes deliberately drafted to include some uncertainty as to their scope for the precise reason that it may give the

patentee an advantage if the patent is litigated. The invention method tends to minimize the effectiveness of such claim-drafting strategies.

But the disadvantages of the invention method are also profound. Discerning what has been invented is not something that judges are trained to do. Judges are at a great disadvantage because they have no first-hand knowledge of the prior art and are not capable of reading a patent with the same understanding as one of ordinary skill. Moreover, judges are discouraged from considering extrinsic evidence, which presumably might supply some of the information known to persons of skill. This is a very serious practical problem with the invention method.

A second disadvantage of the invention method is that it ignores that fact that the inventor often claims less than the full scope of his invention. That is true of every—or almost every—dependent claim. In such cases, the invention method alone may not enable us to resolve a dispute about an ambiguity concerning the scope of a claim that is less than the inventor's disclosed invention.

A third problem is that the invention method can lead to claim meanings that are susceptible to the charge that limitations from the specification have been read into the claims. This is, perhaps, the greatest weakness of the invention method and may be the biggest reason why those who favor the words method distrust the invention method.

The Words Method

The words method offers serious advantages too. It is far easier for courts to use. Judges are trained to apply rules of construction to a legal document. It helps in claim construction that the exercise is limited primarily to the four corners of the patent documents—the so-called intrinsic evidence. Judges who employ the words method are not required to understand the technology with any sophistication. Nor must they compare what the inventor discloses as his invention to the state of the art that existed before the disclosure. They simply step through the rules of construction (which are formal and linguistic, not scientific) and apply the meaning that the rules require. This approach is not much different than the process a court uses to construe a contract, a will, or a deed—though the rules vary a bit.

Notice that in using the words method, the court will read the specification and file history for a very different purpose than when using the invention method. If the judge is a words method judge, he will use the specification and file history to understand how the inventor uses the words that are found in the claims. The patent documents are, for him, a lexicon that informs him concerning the vocabulary of the claims. When employing the words method, he is not reading the intrinsic evidence to understand the invention. He is reading it to understand the words that the claim draftsman used to set out the legal rights that the claim represents.

The words method also is very good at avoiding the mistake of reading a limitation into a claim, which is forbidden in patent law. By shifting the focus away from the specification, except to the extent the specification can be used as a lexicon, the process of construing a claim is removed from the actual teaching of the invention and the danger of imposing a limitation from the teaching of the specification is minimized.

But that is also the greatest shortcoming of the words method. It deemphasizes the actual teaching of the patent in the claim-construction process. This can result in claim meanings that are disconnected from the actual invention. It also creates opportunities for some patentees to argue for claim scope that exceeds the inventor's contribution to the art. That this happens, and often with great publicity, erodes the credibility of the patent system in the mind of the public. This is arguably a principal reason why the patent system is held in low regard in certain industries. There is no legitimate social purpose served by awarding a patentee claim scope that exceeds the inventor's contribution to the art, yet the words method creates opportunities for this to happen.

Words method partisans do not believe their method will result in patent claims that are overbroad. They believe sincerely that the court should not "fix" a claim that seeks greater scope than the disclosure warrants. Instead, they argue that the remedy in such a case is to invalidate the claim for lack of written support and not to narrow the claim during claim construction. That makes sense in the context of a set of rules that establish the words method as the law of the land. Indeed, if the words method were to emerge as the prevailing method, then one would expect to see the written description defense succeed more often than currently is true.

Deference May Depend on the Method of Construction

Of course, there now is a debate concerning whether and to what degree the court of appeals should continue to defer to the claim constructions of the trial judge. The prevailing rule, which comes from *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1463 (Fed. Cir. 1998) (en banc), is that the court should not defer, that claim construction is purely a legal question, and that the question is reviewed by the court of appeals de novo. The wisdom of that rule is now being questioned. *See* Dunner, "Time to Revisit the 'No Deference' Cybor Rule," *ABA Landslide* Vol. 4, No. 2 at 8 (Nov./Dec. 2011).

Notice that the method used to construe claims may influence our thinking as to whether the court of appeals should defer to the trial judge. If the claims are construed using the invention method, then the trial judge has done something akin to fact finding. He has made a determination—at least preliminarily—about what was invented. That is something that might warrant deference from a reviewing court. On the other hand, when the claims are construed using the words method, then there is no fact finding. What the trial court has done is simply construe a legal instrument according to legal rules. Typically, in our system of justice, we do not defer to the trial court on such matters. Thus, whether the court of appeals should defer to the

trial court on issues of claim construction may depend on whether we choose the invention method or the words method of construing claims.

Can the Methods Be Harmonized?

Must we choose? Can the two methods coexist peacefully? This is doubtful. They have not so far. In fact, they are often conflated, leading to further confusion. Consider the Federal Circuit's en banc opinion in *Phillips v. AWH Corp*. There, the question was simple: Was the invention limited to internal baffles at acute angles to the outer surface of the walls in which they are placed, or did the invention also include baffles perpendicular to the surface of the walls? It seemed that the benefits of the invention required that the baffles be at acute angles, and the disclosed embodiments all featured baffles at acute angles. But there was a dependent claim that specifically recited that the baffles should be at acute angles, suggesting that the independent claim must include something more than acute angles. This was the full court's opportunity to choose between the invention method and the words method. What did it do? It invoked both methods and in the process missed its opportunity to make claim construction more certain and predictable.

In its opinion, the court warned against focusing on the abstract meaning of words and insisted that the focus should instead be on the invention: "The main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent. . . . The patent system is based on the proposition that claims cover only the invented subject matter." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (en banc). The court's opinion also made clear that judges are expected to learn the technology well enough to understand the invention: "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventor actually invented and intended to envelop with the claim." *Id.* at 1316. That is invention method reasoning at its finest.

But the court apparently did not mean what it said, because in the end, a majority of the court chose the words method to render a decision. Relying primarily on the formalistic doctrine of claim differentiation, the court held that the correct claim scope included the undisclosed perpendicular baffles, which would not deliver the main benefit that the inventor apparently understood his invention to provide. The reasoning of the majority opinion in *Phillips* favored the invention method, but the actual decision was rooted entirely in the words method. The court missed an opportunity to make claims construction more certain and clear.

Retractable Technologies v. Becton Dickinson

After gestating for several years, the issue of the two methods may be coming to a head in the Federal Circuit. On October 31, 2011, the Federal Circuit denied rehearing en banc in *Retractable Technologies*. Chief Judge Rader and Judge Moore dissented from the denial of the rehearing precisely because they thought that the time had come to confirm that the words of the

claim define the scope of the claim and not the disclosed invention. Judge O'Malley also dissented, but because she wanted to address the question of deference. This is something that they believe was resolved in *Phillips*, and they would have granted rehearing to reaffirm what they take to be the rule announced in *Phillips*.

I do not know how to interpret the fact that the court did not grant the petition. The question is of critical importance, and we should all hope that the court will take up the question soon and resolve it head-on. As we have seen, *Phillips* failed to address the question squarely, and nothing was settled in the aftermath.

Practical Tips

Here are some ideas for how to make practical use of your new understanding concerning the two methods of construing claims. First, it can be a powerful tool for explaining claim construction to neophytes. It can be used to introduce them to the process and how it works. You can also use it to explain why outcomes are difficult to predict when it comes to claim construction. The process is unpredictable because individual judges do not agree on the correct method for interpreting claims and often conflate the two ways of doing claim construction.

Second, use it to plan your advocacy in court. Judges' preferences are often well known. Do the research and pitch your claim-construction arguments to emphasize the approach that the judge has favored in his prior claim-construction rulings.

Third, don't be frustrated by the fact that judges sometimes conflate the two approaches and get lost in inconsistent reasoning. Use that to your advantage. Just beware of inconsistencies in your own arguments.

Lastly, when the opportunity presents itself, educate policymakers that there is a way to make claim construction better. Let's simply choose which method is primary. That way, when there is a conflict, the district court will know which method to use so that the constructions will be affirmed on appeal.

A Suggestion for How to Choose

If we are to choose between the words method and the invention method, how should we choose? One way might be to look at the costs that each method imposes and how each method would encourage behavior that will minimize those costs. That approach might lead us to favor the invention method. When the invention method is used poorly, the result can be that limitations are read into the claim from the specification. That imposes a cost on the inventor. In contrast, when the words method is used poorly, the inventor receives more claim scope than he deserves. The cost of that is borne by the public.

It is difficult to quantify the relative costs to compare them and then choose the method that imposes the lowest costs, but it is not difficult to see that while the public bears almost no ability

to avoid the costs of the words method in advance of litigation, the inventor has a great deal of control to avoid the costs of the invention method before there is litigation. The inventor and his legal representative prepare the patent and the claims. If the invention method is the law, then they can prepare claims that will be read accurately per that method. If there is doubt about the proper scope of the claim, it is not unfair that the costs of ascertaining the meaning should be borne by the party that created the ambiguous claim. By choosing the invention method, we can provide an incentive for inventors and their lawyers to tailor their claims more closely to the disclosure and reduce the costs of patent litigation by greatly simplifying claim construction.

The alternative would be to choose the words method, but invigorate the written description defense to police against claims with scope that exceeds the inventor's contribution to the art. This too would be a logical response to the problem, but it may do less to reduce the transactional costs of patent litigation than simply adopting the invention method.

Keywords: litigation, intellectual property, claim construction, America Invents Act

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Intellectual Property Litigation
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New Avenues for Hatch-Waxman and Biosimilar Litigation?

By Richard Pettus and David Joyal – February 20, 2012

Competition and success in the pharmaceutical industry is often defined by a winning patent strategy that most effectively addresses generic market entry. For both branded and generic drug manufacturers, this patent strategy centers around the Hatch-Waxman statutory scheme and associated abbreviated new drug application (ANDA) litigation. The Orange Book patent(s) protecting a company's branded product and a generic's Paragraph IV patent challenges to those patent(s) are the respective lifebloods of these competitors. The Hatch-Waxman Act, enacted in 1984 and amended in 2003, encouraged early entry of generic drug products and corresponding Orange Book patent challenges, thereby elevating the importance of patent strategies while ostensibly providing greater business certainty through early and expedited litigation.

Litigation, however, is an inherently uncertain process, and competition is an ever-evolving one. Since Hatch-Waxman's enactment more than 25 years ago, changes in the legal landscape (statutory amendments, obviousness/inequitable conduct jurisprudence, and so on) have compounded this uncertainty and caused Hatch-Waxman litigants on both sides to constantly rethink and adapt their strategies. So, too, have changes in the competitive landscape. For instance, over the years, the scope and prevalence of ANDA lawsuits has steadily increased. This increase has been driven by the expansion of both the number of generic manufacturers (including branded companies who have started generic businesses of their own) and the "size" of the products subject to such challenges. No longer are branded-generic ANDA battles reserved for "blockbuster" drugs. Drug products with annual sales well below $100 million are increasingly subject to ANDA challenges from one or more generics. Similarly, the 2009 Biologics Price Competition and Innovation (BPCI) Act has expanded the branded-generic patent battleground into the realm of so-called biologics, such as recombinant proteins, antibodies, and the like, by introducing a litigation framework for follow-on biologics (FOBs).

These and other strategic shifts in competitive dynamics have also altered the mindsets of competitors on both sides of the conflict. More and more often, despite still strongly held combative feelings, a fight to the finish is not seen as the only possible resolution; branded and generic companies increasingly explore cost-effective settlement mechanisms to even the most hotly contested disputes, such as pre-patent expiry and "authorized" generic launches—all under the watchful eye of the U.S. Federal Trade Commission (FTC). Accordingly, factors such as timing, scope/cost, and settlement of ANDA challenges have become more important in the patent strategic calculus.

President Obama signed the America Invents Act of 2011 (AIA) into law on September 16, 2011, signaling a potential further evolution of patent strategies related to the branded-generic

conflict. This patent reform represents the most significant revamping of U.S. patent law since the 1952 Patent Act. The new legislation introduces post-grant patent review proceedings that are designed to provide a clearer and more rapid path to clarifying patent scope and enforceability. These new post-grant administrative proceedings include modified *inter partes* reexamination, post-grant opposition, and supplemental reexamination.

Post-Grant Review and Supplemental Examination

Pre-Patent Reform Post-Grant Review Options

Challengers and owners of issued patents were previously restricted in U.S. Patent and Trademark Office (PTO) proceedings to raising validity issues through reexamination or reissue. Reexamination proceedings are procedures before the PTO where a requester seeks to address the validity of issued patents in view of particular types of prior art. A reexamination requester has needed to raise a "substantial new question of patentability" to have its reexamination request granted—a standard that has been met in more than 90 percent of the reexamination requests filed to date. Whether the proceedings are ex parte or *inter partes*, the prior art that can be used in such proceedings has historically been limited to two potential sources: issued patents or printed publications. Ex parte proceedings also limited a requester's participation to the initial request for reexamination, after which the patent owner engaged in ex parte prosecution with the PTO that resulted in the cancellation, reissuance, or amendment of the reexamined claims. *Inter partes* proceedings enabled requesters to participate in the PTO's evaluation process, but also estopped them from raising in federal court litigation any issues that were "raised or could have been raised" during the pendency of the reexamination proceeding.

Time to resolution of reexamination has weighed against its more prevalent use, despite what would seem to be high "success" rates; about 75 percent of ex parte and about 89 percent of *inter partes* reexaminations result in the cancellation or amendment of at least some claims in the reexamined patents. In theory, reexaminations are conducted with "special dispatch." In practice, however, reexaminations start quickly but can drag on, often for years, through potential appeals to both the Board of Patent Appeals and Interferences and then to the U.S. Court of Appeals for the Federal Circuit. The end result is that, while the proceedings are statutorily mandated to be started within 60 days, the average total pendency of an ex parte reexamination has been 25.6 months and the average pendency of an *inter partes* reexamination has been 36.2 months. *See* www.uspto.gov/patents/stats/Reexamination_Information.jsp

Since 2006, it has taken an average of around five years to complete the reissue application process. *See* www.patentlyo.com/patent/2011/01/reissue-patent-pendency.html.

Revamped and New Post-Grant Inter Partes *Review Proceedings*

The AIA created a new post-grant review process that differs in several important respects from preexisting reexamination proceedings. First, in terms of timing, *inter partes* post-grant review proceedings must be concluded within 12 months of filing, with an additional 6 months available

for good cause. The conduct and appeal of the proceeding will also be truncated, with the initial decision being rendered by a three judge panel rather than a patent examiner and a single appeal directly to the Federal Circuit. Within the initial nine months of patent issuance, a post-grant opposition review proceeding must be requested, but it cannot be requested if the would-be requester has already filed or counterclaimed for patent invalidity in federal court. After nine months, a post-grant *inter partes* review proceeding may be requested.

Second, in terms of scope, the new post-grant review proceedings allow a requester to attack the validity of a patent on any invalidating ground, including all relevant sources of anticipatory/obviousness prior art, as well as issues of enablement and/or written description. The standard for starting such a proceeding is whether it is more likely than not that at least one challenged claim is unpatentable. Alternatively, post-grant review proceedings may be initiated if the petition raises a novel or unsettled legal question important to other patents or applications. The post-grant review proceedings also allow for discovery of "evidence directly related to factual assertions advanced by either party in the proceeding," which will presumably include at least some limited document discovery and deposition practice. The Patent Office Director has been granted the authority to promulgate regulations governing the conduct of such discovery, so the ultimate scope and procedures are yet to be determined. Given the accelerated timeframe for completion of post-grant review and the new discovery provisions, the estimated cost for these proceedings is expected to be higher than preexisting reexamination proceedings (the total average cost of which is estimated at about $280,000), but not as high as full-blown federal district court patent litigation (the estimated averages of which are $3–6 million, depending on the stakes). *See* American Intellectual Property Law Association, 2011 Report of the Economic Survey. As with preexisting *inter partes* reexamination, post-grant review requesters will be estopped from asserting invalidity of the patent in a later litigation with respect to issues that were "raised or could have been raised" during the pendency of the post-grant opposition proceeding, no matter the result of the proceeding.

Last but not least, the parties have broad latitude to terminate the new post-grant review proceedings due to settlement agreements. In such instances, termination by settlement will not create an estoppel in subsequent litigation.

Supplemental Examination: Avoiding the "Plague" of Inequitable Conduct
Before the AIA, both patentees and third parties were restricted to the use of reexaminations and reissues in submitting additional prior art after patent issuance. During prosecution of patent applications, the PTO has established rules concerning when information material to patentability must be submitted to the office. Failure to meet this "duty of disclosure" during prosecution has resulted in issued patents subsequently being held unenforceable. In dealing with material information discovered after a patent issued, however, patentees have long faced an unpalatable choice of requesting reissue or reexamination of their patents, thereby reopening examination of their patents on all fronts, just to have the PTO consider the newly discovered

prior art. Reissue requires the patentee to declare an error on which reissue is based—which may not be in the bests interests of or even available to patentees seeking consideration of additional prior art without any change to the patent itself—and places the ultimate fate of the patent in great uncertainty, particularly given the long pendency of reissue proceedings. Reexamination likewise typically involves a long pendency, only allows the narrowing of issued claims, and carries a real risk of claim amendments resulting from the reexamination process, which, in turn, may result in intervening rights and limit a patentee's ability to collect damages prior to the issue date of the new claims or at all.

New supplemental examination proceedings permit a patent owner to submit potentially material prior art to the PTO after its patent is granted and to potentially avoid reexamination and reissue proceedings entirely. In terms of timing, the patentee can have additional prior art considered by the PTO without the need for reissue or reexamination by essentially allowing the filing of an additional information disclosure statement (IDS). The PTO then has three months to conduct a supplemental examination of the patentability of the issued claims in the patent in light of the newly submitted prior art and to then issue a certificate. This supplemental examination request must be filed prior to any inequitable conduct allegation regarding the prior art at issue being pled with particularity in a federal-court litigation or being raised in a Paragraph IV notice letter.

In terms of scope, the PTO may conduct a supplemental examination or initiate an ex parte reexamination proceeding if and only if the patentee's submission indicates that the newly submitted prior art raises a substantial new question of patentability. In either case though, no error need be alleged by the patentee. And, if the patent is issued, the cited prior art cannot serve as the basis for a later claim of inequitable conduct by a third party. Thus, supplemental examination allows the patent holder to eliminate a potentially costly defense/counterclaim of inequitable conduct and associated antitrust concerns that could be asserted later by third-party federal court litigants.

A comparison of the salient features of each of these strategic options is summarized below.

	Inter Partes Review	Post-Grant Opposition	Supplemental Reexamination
Scope	Patents and Printed Publications Only "More likely than not" invalid standard to grant	All invalidity grounds (§§ 102, 103, 112, inequitable conduct)	All information
Timing	Starting 9 months after patent issuance	Within 9 months of patent issuance	Prior to allegation of inequitable conduct;

	May be filed any time Must be completed within 12 months of initial filing (w/ possible 6-month extension)	Cannot be filed after declaratory judgment or counterclaim for invalidity asserted in federal court Must be completed within 12 months of initial filing (w/ possible 6-month extension)	PTO must make a determination of no action or reexamination within 3 months of filing If reexamination is ordered, reexamination must be completed within 18 months of order
Estoppel	Yes All issues raised or could have been raised	Yes All issues raised or could have been raised	N/A
Ability to Settle	Yes with estoppel effect (e.g., entry of stipulation by district court judge)	Yes Without estoppel effect	N/A
Discovery/3rd Party Participation	No discovery 3rd-party participation	Discovery 3rd-party participation	No discovery No 3rd-party participation

Evaluating the AIA's Potential Effect on ANDA and/or FOB Litigation

A brief overview of ANDA and FOB litigation helps illustrate some of the aspects of these unique branded-generic litigation pathways that may make the AIA post-grant review proceedings a potential new strategic option in the branded-generic arsenal.

Hatch-Waxman and ANDA Litigation

The Hatch-Waxman Act established a regulatory framework designed to balance incentives for continued innovation among research-based pharmaceutical companies with opportunities for market entry by generic drug manufacturers by providing an accelerated pathway to market for "bioequivalent" versions of pharmaceuticals. This accelerated pathway is balanced by two different forms of exclusivity that were established for the branded company—data exclusivity and patent exclusivity.

The purpose of data exclusivity is to protect the research data that branded/innovator pharmaceutical companies file with the regulatory agencies to obtain marketing approval for new drug products. Reliance on this data, including pharmacokinetic, safety, and the like, is what enables the abbreviated nature of a generic's application for regulatory approval so that they do

not need to invest the substantial time and expense to independently generate such studies. In return for the filing of such data with the Food and Drug Administration (FDA) in its nondisclosure agreement (NDA), a branded company is given five years of data exclusivity for submission of a new chemical entity (NCE), seven years of exclusivity for an orphan drug, and three years of exclusivity for a new condition of use (new dosage form and so on). During this period of exclusivity, the FDA cannot issue final approval of a generic's ANDA. With respect to an NCE, the FDA may not accept submission of an ANDA containing a Paragraph IV challenge for four years. These data exclusivities are a major component of the complex timing calculus of branded-generic competitors, because generic companies must wait to attack the listed Orange Book patent(s) and clear a pathway to market for their product. Data exclusivity does not prevent the use of post-grant patent review proceedings against these or any other patents.

Patent exclusivity is what ANDA litigation is all about. A branded company, often the patent owner, must list all of its patents that cover the branded drug product in the FDA's Orange Book. Often, more than one patent covering the drug product is listed. The expiration dates for these patents may vary widely. For instance, a patent covering the drug compound itself may have been filed for and/or issued long before the branded drug product was launched or the NDA was filed. Branded companies also continue developing their patent portfolio with respect to new therapeutic indications, pharmaceutical compositions, improved performance, and so on. Some of these patents may be issued and added to the Orange Book much later and could significantly complicate or undermine a generic's product development and litigation strategies. Finally, patent term extension may also be sought for one of the patents covering the approved product up to a maximum of five years past expiry (in other words, beyond the standard 20-year patent lifetime to account for marketing time lost due to clinical development and FDA regulatory delays). This too can impact the competitive scenario.

If a generic company wishes to enter the market prior to the expiration of one or more of the listed Orange Book patents, it can challenge those patents, so long as the applicable marketing-exclusivity periods have run. Generic companies are incentivized to file ANDAs, as the first Paragraph IV ANDA filer with respect to a particular pharmaceutical composition can receive its own 180-day generic marketing exclusivity. These so-called Paragraph IV challenges start with a notice letter to the branded competitor certifying the generic company's beliefs with respect to the invalidity, noninfringement, or unenforceability of the Orange Book-listed patent(s) and providing a detailed basis for each such belief. The branded company then has 45 days to sue the Paragraph IV-certifying generic company in federal district court. On filing of the lawsuit, the approval of the generic company's ANDA will be delayed for up to 30 months so as to give the parties time to resolve their patent dispute.

The costs of ANDA patent litigation can be high for both parties (e.g., multiple millions of dollars). In ANDA federal district court lawsuits, the litigants can deploy their full array of infringement, validity, and enforceability arguments and seek full discovery on those issues. For

a blockbuster drug product, the value of exclusivity may justify the costs, but this analysis can change significantly when dealing with smaller products (for example, annual sales in the $30 million range), where the very real question of whether the candle is worth the flame is asked by both sides.

The BPCI Act and Follow-On Biologics

Biologic products developed over the past three decades and approved by the FDA now provide important therapeutic options for a variety of conditions. From a sales base of $243 million in 2010, biosimilar global sales are expected to reach $3.7 billion by 2015 (per Reuters, March, 2011). The BPCI Act of 2009 has created an ANDA-like "abbreviated pathway" for submission of a FOB application regarding biologics that are "biosimilar" to already-approved products. These products must be biosimilar to (with no clinically meaningful differences in safety, purity, and potency) and interchangeable with (it provides the same clinical result with no additional risk if the patient is switched between products) a branded product to be automatically substituted by a pharmacy.

The BPCI Act's statutory scheme for resolution of biosimilar patent disputes differs from the ANDA process in several respects. First, the data exclusivity given to a branded company is a significantly longer period of 12 years. This means that a generic application can not be filed for at least 12 years after approval of the branded product. Likewise, a first-to-file FOB application certificate holder is entitled to a longer period of generic exclusivity—a full year—but only with respect to other interchangeable biosimilar products.

The timing of when patent rights are asserted is also fundamentally different. The FOB application pre-litigation ramp-up is a much less straightforward and a more deliberate, iterative process that has been characterized as "a very slow game of chess." www.ftc.gov/os/comments/healthcarecompissues/537778-00010.pdf [PDF]. At the outset, a generic applicant provides a copy of the biosimilar application to the branded company within 20 days of filing, including a description of the process by which the generic company intends to manufacture its biosimilar product. This transmittal starts an information exchange between the parties whereby the branded company provides a list of its patent rights, including in-licensed rights, that it believes to be infringed by the generic's biosimilar product/process within 60 days. The generic responds with its position on why each patent is believed to be invalid, not infringed, and/or otherwise not relevant within 60 days. The parties have 15 days to negotiate which patents will be listed in the generic's Paragraph IV-like certification, which may form the basis for subsequent litigation to be filed within the following 30 days.

Thus, the total time from first notice to when a lawsuit is actually filed could be up to 205 days. Absent agreement on the list, the generic company determines the number of patents to be listed. However, the branded company gets a "second bite at the apple" on litigating its listed patents 60 days before approval of a FOB application. At that time, the branded company has the option of

filing for preliminary injunction with respect to any of its originally listed patents. Over the course of the FOB application litigation, there is no 30-month or other stay of approval on initiation of the lawsuit. Finally, it is worth noting that while hundreds of ANDA litigations have been fought out in the last two decades, as of the writing of this article, the FOB application litigation scheme stands virtually untested.

What Are the Benefits of Post-Grant Review?

Having reviewed some of the nuances of AIA post-grant review proceedings, the question is whether they present any tactical benefits to branded-generic competitors that warrant their utilization in the context of ANDA and FOB application litigation. Based on changes in timing, scope, and settlement, they very well may become part of a strategy to bring earlier business certainty on issues of utmost importance to both competitors.

Timing: Earlier Certainty?

In both the ANDA and FOB application litigation contexts, a generic may have to wait to challenge a branded company's patents on any grounds due to data exclusivities. Moreover, once such a challenge is instituted, the lawsuit may take an additional 30 months to obtain a judgment.

Data exclusivity has never restricted a generic company's ability to challenge an Orange Book patent in nonjudicial post-grant proceedings. In the past, however, reexaminations (up 30 months) and reissues (5 years) took too much time to resolve. The more streamlined, AIA post-grant review proceedings must, by statute, be resolved within 12 months (or at most 18 months). Accordingly, they could be utilized by a generic company as a vehicle for the early clearing of patents on invalidity grounds while they are waiting for data exclusivities to run. For instance, an invalidity challenge could be brought and resolved against one or more of the branded company's patents during the period of data exclusivity and before any ANDA or FOB application is submitted.

Because a generic company may prefer to ultimately prevail on a noninfringement defense as opposed to an invalidity attack that would also clear a pathway for its fellow generic competitors, this process could also be used in an attempt to narrow the scope of the branded company's patent claims in a way that could bolster a noninfringement defense for a generic's contemplated product at a time and in a forum where access to the details of that product would not be available to the branded company.

AIA post-grant proceedings also could be used as a more rapid alternative, or a co-pending companion, to federal district court litigation. For example, if a generic company believes that it has a strong noninfringement defense and a somewhat weaker invalidity defense against a particular patent, it may choose to pursue only its noninfringement challenge in the district court and present its invalidity arguments to the PTO. From a tactical and trial lawyer's standpoint, by separating the somewhat weaker argument from the perceived "best" argument, the risk of the

weaker argument tainting the stronger one would be removed. Such focusing of the district court litigation on only noninfringement arguments might also reduce the scope of discovery and enable a more rapid resolution of the district court litigation. Similarly, a generic company may believe that it has a stronger invalidity case against one Orange Book patent than it does against a second Orange Book patent and, thus, elect to attack one of the patents in district court and the other patent in a post-grant proceeding for the same reasons (to avoid any risk of the weaker invalidity case dragging down the stronger case, and to streamline discovery and trial in the district court litigation).

Scope: Heightened Certainty Through Expanded, Lower-Cost Proceedings?
A key question is how rigorous, consistent, and reliable these new post-grant proceedings will be in vetting the validity of biopharmaceutical patents. Until all of the rules governing discovery and the like are promulgated and the process is actually tested in operation, it is hard to say how effective the new proceedings will be in achieving the tactical objectives of generic companies.

What we do know, in addition to the expedited nature of the process, is that use of the new proceedings likely will be much more cost effective than federal court litigation. We also know that post-grant opposition filers will have the opportunity to participate fully in these new AIA proceedings and that these proceedings will frequently involve discovery, including depositions of fact and expert witnesses, and potentially extensive motions practice in a trial setting presided over by three administrative patent judges. Post-grant proceedings also now authorize a generic company to raise any and all grounds of invalidity of a patent, providing an opportunity for the generic company to fully present its invalidity theories to the PTO prior to the start of federal court litigation.

While a generic company will have to assume some downside risk in the form of an estoppel in subsequent litigation on the same issues, the availability of discovery and the expanded nature of the process, including the scope of the arguments that may be raised, should dampen such risk. Coupled with the PTO's lower "preponderance of the evidence" standard for invalidating patent claims and "broadest reasonable construction" of claim terms, and the fact that post-grant oppositions will proceed before administrative patent judges who specialize in patent proceedings, post-grant review may provide a new palatable forum for challenging a branded company's patents.

Settlement: Partial and/or Earlier Business Resolutions?
The AIA provisions that permit parties to settle post-grant review proceedings among themselves without any estoppel effect in federal court litigation may be the most important provisions of all. In the past, *inter partes* reexamination could only be terminated upon either the PTO making a final determination of patentability or the parties submitting a district court's final judgment on patentability. Like a runaway freight train, once started, the only way the parties could resolve an *inter partes* reexamination was through actual completion of the reexamination process or

through a stipulation of dismissal endorsed during district court litigation. The new provisions for settlement of AIA post-grant proceedings greatly expands the endgame possibilities and may make them much more effective vehicles for achieving business certainty.

Of course, one potential downside to the AIA post-grant review proceedings is that the requesting party must reveal its identity. Generic companies are normally careful to keep their plans for ANDA targets secret, as much to keep their branded opponent in the dark as the numerous generic competitors who may also be working on a challenge to the same patent(s). One of the concerns is that if the generic competition gets wind of the filing of a post-grant proceeding before any ANDAs have been filed, it may spur them to place the product(s)/patent(s) in question on a higher priority to better ensure their first-to-file status. The flip side is that until it becomes known who the challenger is and the basis for the challenge, there is virtually no avenue for pre-litigation settlement talks. An earlier threat of a post-grant review may prompt a business resolution that avoids costly litigation altogether for both parties.

Conclusion

Branded-generic company patent litigation is a high-stakes arena wherein the players are constantly adapting to changes in the legal/competitive landscape and adopting new strategies to help give them an edge. The AIA has brought some of the most sweeping changes to the patent law that our system has ever seen. New post-grant review proceedings have the potential to drive the earlier resolution of branded-generic company conflicts through expedited validity determinations and/or settlements that could avoid more costly litigation altogether or streamline such lawsuits in a meaningful way. Much will depend on the actual implementation and effectiveness of such proceedings. But, at the very least, it is certainly something worth keeping an eye on as these proceedings get up and running so as not to be caught by surprise when and if the competition chooses to test them out.

Keywords: litigation, intellectual property, America Invents Act, abbreviated new drug applications, follow-on biologics, Patent and Trademark Office

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Effects of the America Invents Act on Inventorship Disputes

By Janelle D. Waack – February 20, 2012

Collaboration can be an effective way to develop ideas and products in business and academia. As the saying goes, two heads are better than one. However, sometimes a cooperative pooling of resources or a friendly intellectual exchange can sour as the sweet prospects of commercial value are tainted by an inventorship dispute. Such disputes can impair business relationships, cloud intellectual property rights, and lead to litigation.

Inventorship disputes are more common in the United States because our patent laws require inventors of claimed subject matter to apply for a patent in their own names. This requirement arises from the intellectual property clause of the U.S. Constitution, which states that, "The Congress shall have power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and *Inventors* the exclusive Right to their respective Writings and Discoveries" (emphasis added, capitalization in original). Intentionally failing to name, or incorrectly identifying, inventors can result in a patent being held invalid.

Each inventor named on a patent has the right to assign the claimed invention. Those inventors are often obligated to assign those rights to their employer pursuant to a contract. Nonjoinder or misjoinder of an inventor can impact whether a company or university can capitalize on the intellectual property rights to the technology at issue, particularly in the context of a joint venture.

The Leahy-Smith America Invents Act of 2011 (AIA), enacted on September 16, 2011, changed many aspects of U.S. patent law, including inventorship disputes and their resolution. A key provision is the establishment of derivation civil actions and derivation proceedings under AIA section 3(h)–(k), which provides for resolution of derivation allegations between owners of patents (35 U.S.C. § 291) and applicants for patents (35 U.S.C. § 135). Patent-owner disputes will be addressed by civil action in a district court, whereas patent applicant disputes will be addressed by derivation proceedings in the U.S. Patent and Trademark Office (PTO) before the newly titled Patent Trial and Appeal Board (PTAB).

Before the AIA, derivation issues arose before the Board of Patent Appeals and Interferences in the context of interferences. Under 35 U.S.C. § 102(f), a person was not allowed to obtain a patent if "he did not himself invent the subject matter sought to be patented." Under the AIA, interferences will eventually be eliminated as U.S. patent practice moves to a modified first-to-file system. Derivation proceedings will remain and are expected to adopt many of the procedures employed in interferences. However, the AIA directs the PTO to prescribe further regulations setting forth standards for the conduct of derivation proceedings, and they are still under development.

As stated in section 3, the term "inventor" means the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention. The terms "joint inventors" and "coinventor" mean any one of the individuals who invented or discovered the subject matter of a joint invention. Joint inventors can exist even where one inventor contributed a majority of the work.

Initiation of Derivation Civil Actions vs. Derivation Proceedings

Under 35 U.S.C. § 291(a), to have relief by civil action for a claim of derivation, a party must own a patent. That patent must claim the same invention as another patent having an earlier effective filing date. The party must further show that the owner of the other patent derived the claimed invention from the inventor of the invention claimed in the patent owned by the person seeking relief. Such derivation civil actions are initiated by filing a complaint in federal district court and will be governed by the Federal Rules of Civil Procedure and the Federal Rules of Evidence.

The "effective filing date" for a claimed invention in a patent is generally the earlier of the actual filing date of the patent application underlying the patent or the filing date of the earliest application to which the underlying application has a right to priority. Note that the owners of two patents may be aware of a dispute, but only the patent owner with the later effective filing date can file a complaint to initiate the civil action. Under the first-to-file system, the patent with the earlier effective filing date could possibly have a different remedy of challenging the patent with the later effective filing date on the basis of prior art under 35 U.S.C. §§ 102(a)(2) or 103.

In contrast, under 35 U.S.C. § 135(a), to initiate a derivation proceeding before the PTAB, a party must have a pending patent application. The patent applicant files a petition in the PTO setting forth with particularity the basis for finding that an inventor named in an earlier application derived the claimed invention from an inventor named in the petitioner's application and the earlier application claiming such invention was filed without authorization. The petition must be made "under oath" and supported by "substantial evidence." Based on that petition, the PTO will determine whether to institute a derivation proceeding. That determination is final and not appealable. If a derivation proceeding is instituted, further steps would be taken under the PTO rules to develop the record in an *inter partes* context and reach a decision regarding derivation.

Timing for Derivation Civil Action and Proceedings

Although the AIA was enacted September 16, 2011, the patent-reform laws directed to derivation civil actions and proceedings will not become effective until March 16, 2013 (18 months from enactment). The effective date applies to patent applications or patents with an effective filing date on or after March 16, 2013. For patents and applications with pre-March 16, 2013, effective filing dates, issues of derivation will continue to be addressed in the context of interference proceedings.

For derivation disputes involving an issued patent that meets the AIA effective date provision, there is a one-year deadline to file a complaint for a derivation civil action. More specifically, a derivation civil action may be initiated only before the end of the one-year period beginning on the date of the issuance of the first patent containing a claim to the allegedly derived invention and naming an individual alleged to have derived such invention as the inventor or joint inventor.

For derivation proceedings involving pending patent applications, there is also a one-year deadline, but it is triggered by the publication of an offending patent application. More specifically, any petition alleging derivation may be filed only within the one-year period beginning on the date of the first publication of a claim to an invention that is the same or substantially the same as the earlier application's claim to the invention.

These one-year deadlines call for heightened awareness of competitors' patent applications and patent portfolios. Intellectual property owners and patent attorneys may elevate their monitoring efforts, for example, by regularly conducting searches on public databases such as the searchable databases of U.S. patents and applications provided on the PTO website at uspto.gov.

Preserving Your Right to Have a Derivation Proceeding

Some instances of derivation come to light after two parties have filed their own respective patent applications and one party subsequently becomes aware of the other application. Other times, a party becomes aware of a competitor's published patent application or patent and has no pending patent application covering that invention, and yet the party suspects the competitor derived the claimed invention from the party. Under the AIA, it may be possible for the party to have a derivation proceeding, as long as it acts within one year of the publication of the offending patent application.

Upon discovery of a published derived patent claim, a party may prepare a patent application claiming the same or substantially same invention and file it in the PTO with a petition for a derivation proceeding. Again, that application and petition must be filed within one year of the published claim.

In some cases, particularly those arising from a joint venture, the party may have difficulty obtaining all of the signatures to complete the required inventors' declaration. For example, imagine a dispute over whether solo inventor A (from company X) derived the invention from a joint inventorship of A (from company X) and B (from company Y). Company Y may want to preserve its rights by filing a patent application naming A and B as inventors, but Y may not be able to obtain A's signature—A may refuse to cooperate or may dispute the inventorship issue. Nonetheless, company Y believes that pursuant to a joint venture agreement A and B were under an obligation to assign the invention to company Y. In such a case, AIA section 4(b) may enable Y to file an application naming joint inventors A and B to preserve its rights. Section 118 of title 35 of the United States Code states a "person to whom the inventor has assigned or is under an

obligation to assign the invention may make an application for patent. A person who otherwise shows sufficient proprietary interest in the matter may make an application for patent on behalf of and as agent for the inventor on proof of the pertinent facts and a showing that such action is appropriate to preserve the rights of the parties."

Conducting Derivation Proceedings at the PTAB

Once the derivation proceeding is instituted, the PTAB will determine whether there was derivation. While the final rules governing such procedures have not yet been issued, they are expected in general to follow procedures for interferences. Derivation proceedings usually involve a timeline of facts evidenced by documents and declaration testimony of inventors, corroborators, and other witnesses, including technical experts. Persons submitting declarations in support of a motion are generally obligated to appear for a cross-examination deposition in the United States. Discovery is not as broad as that allowed in district court and generally must be authorized by the administrative patent judge.

The PTAB also has wide discretion to defer action on a petition for a derivation proceeding on two grounds. First, the PTAB may defer action on a petition until three months after the issuance of the patent that is the subject of the petition. Second, the PTAB can defer action on a petition for derivation or stay the proceeding after it has been instituted, until the termination of a concurrent ex parte reexamination, *inter partes* review, or post-grant review.

The decision will be rendered by a panel of technically trained administrative patent judges. When a final decision on the issue of derivation is reached, an adverse decision will generally result in the cancellation of the involved patent claims. In appropriate circumstances, the PTAB may correct the naming of the inventor in any application or patent at issue. The PTAB's decision can be appealed, and any such appeal must be filed within 30 days of the final decision.

Settlement of Derivation Proceedings

The parties to a derivation proceeding can terminate the proceeding through settlement. The parties would need to file a written statement reflecting the agreement of the parties regarding the correct inventors of the claimed invention in dispute. The PTAB will take action consistent with the agreement, unless the PTAB finds the agreement to be inconsistent with the evidence of record, if any. Any written settlement or understanding of the parties must be filed with the PTO; however, a party can request that the agreement be kept confidential and available only to government agencies on written request or to any person on showing of good cause.

Keywords: litigation, intellectual property, America Invents Act, inventorship, derivation civil actions, derivation proceedings

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NEWS & DEVELOPMENTS

The Situation vs. the Fitchuation

MTV's *Jersey Shore* reality show features Italian Americans living and working for the summer in Seaside Heights, New Jersey. In its four seasons on the air, viewers have watched the eight cast-member roommates live, drink, love, drink, work, and drink their way through life in Seaside Heights, Miami Beach, and Italy. The show quickly became a cultural phenomenon, spawning catch phrases and lingo that permeated the vernacular and catapulting the cast members to reality-show stardom and D-list celebrity status. For *Jersey Shore* viewers, "GTL" is understood to mean "gym, tanning, laundry." However, for Michael Sorrentino, better known as "The Situation," one of the show's breakout cast members, it now means "gym, tanning, litigation."

Sorrentino has flexed his muscles in three separate trademark-infringement disputes over the past year. First, in May, Sorrentino, through his company, MPS Entertainment, LLC, brought a trademark-infringement lawsuit in the U.S. District Court for the Southern District of Florida against his father, Frank Sorrentino, and his father's one-time business partner, Robert Fletcher, for the unauthorized use of the trademark "The Situation" and Sorrentino's name, image, and likeness. *MPS Entertainment, LLC v. Fletcher*, Case No. 1:11-cv-21765-PCH (S.D. Fla. May 16, 2011). The case was quickly settled, and the court permanently enjoined the defendants from using the trademark "The Situation," bolstering Sorrentino's claim to his nickname.

Sorrentino later confronted the website MyGTLFuel.com, the vendor of an energy drink purporting to "fuel" a lifetstyle that Sorrentino claimed referred to his exploits. Though Sorrentino may not own a trademark in GTL, the MyGTLFuel website was taken down.

Then, on November 15, 2011, Sorrentino filed suit against Abercrombie & Fitch Stores, Inc. ("A&F"), also in the U.S. District Court for the Southern District of Florida, asserting claims for federal and common-law trademark infringement and related unfair-competition claims under both the Lanham Act and the Florida Statutes. In response to an A&F publicity stunt wherein A&F offered to pay *Jersey Shore* cast members to stop wearing its clothes. *MPS Entertainment, LLC v. Abercrombie & Fitch Stores, Inc.*, Case No. 1:11-cv-24110-JAL (S.D. Fla. Nov. 15, 2011). Notably, at or around the time A&F made its offer to Sorrentino, it was selling T-shirts bearing the slogans "The Fitchuation" and "GTL . . . You Know The Deal," arguably references to *Jersey Shore* and Sorrentino in particular.

A&F responded on December 12, 2011, with a motion to dismiss and a separate motion to strike. A&F argues the complaint should be dismissed for failure to state a claim under Fed. R. Civ. P. 12(b)(6) because Sorrentino does not own a valid federal or state trademark registration for either asserted trademark, "The Situation" or "GTL;" Sorrentino does not own any valid, recognizable

common-law rights in any "GTL" trademark; A&F's use of "GTL" and "The Fitchuation" were not trademark uses; and the referenced T-shirts are permissible parodies.

Sorrentino asserts that MPS Entertainment owns federally registered trademarks for "The Situation" and "GTL;" however, as A&F points out, Sorrentino has only applied to register those marks with the U.S. Patent and Trademark Office. The only registration that Sorrentino owns is for a stylized mark, "Situation," Registration No. 3,635,203, that it acquired through an assignment from a third party and that A&F argues is invalid as an assignment in gross. Further, A&F alerts the court to Viacom International, Inc.'s (the parent company of MTV) ownership of the registration "GYM TANNING LAUNDRY," Registration No. 4,014,420, as well as a pending application, Serial No. 77/960,143.

A&F sought to strike 13 of the 17 trademark applications Sorrentino attached to his complaint, claiming such applications do not relate to clothing and are therefore irrelevant. Sorrentino has since entered an amended complaint, voluntarily withdrawing several claims, and A&F have since renewed their motion to dismiss, reasserting various defenses.

For all of the parties' bluster, the litigation raises various interesting trademark issues. Sorrentino's claim relates to a nickname very much tied to him, possibly invoking the well-known Bo Ball case. A&F asserts that MTV failed to "blur" the cast's clothing and may have suggested an endorsement, which in today's culture seems a rare error. But A&F's offer to pay the cast to *not* wear its brand could be seen as trading on the cast's likenesses for a sort of reverse endorsement, leading to A&F's first amended defense. Meanwhile, season five of *Jersey Shore* began airing in January 2012. The cast's latest T-shirt labels remain unknown.

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