PATENT HAPPENINGS *during September 2007 (Part I)* A publication by LATIMER, MAYBERRY & MATTHEWS IP LAW, LLP

A publication by LATIMER, MAYBERRY & MATTHEWS IP LAW, LLP on judicial, legislative, and administrative developments in patent law.

HIGHLIGHTS

<i>I. Lack of an enabling disclosure for one</i>	
embodiment of a means-plus-function limitation	
invalidated claim even though alternate	
embodiment was fully enabled1	
2. Purified form of a chemical found obvious where	
one of ordinary skill had the capability to purify	
the prior art composition	
<i>3. Purified form of a chemical found NOT obvious</i>	
where there was no reasonable expectation of	
success that the chemical could be purified 3	
1 0	
4. Disclaimer of equivalents found when applicant	
characterized prior art as being "less effective"	
than the claimed invention	
5. Failure to show actual infringing uses defeated	
claim of inducing infringement where accused	
product also had noninfringing uses	
6. "Ordinary observer" for assessing design	
patent infringement may be industrial purchaser	
of component part, rather than retail consumer,	
if the design only covers the component part 4	
7. Price disparity defeats a patentee's claim for	
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8. <u>Bell Atlantic</u> does not require patentee to plead	
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10.Named inventor, who had assigned patent, held	
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JUDICIAL HAPPENINGS

Enabling Distinctly Different Embodiments

Shaking up the law of enablement, a panel of the Federal Circuit held in Automotive Tech., Int'l., Inc. v. BMW of N. Am., Inc., No. 2006-1013, 2007 WL 2493281, *9 (Fed. Cir. Sept. 6, 2007), that where a claim covers "distinctly different" embodiments of the claimed invention, as opposed to various species of a single embodiment, the specification must provide an enabling disclosure for each of those "distinctly different" embodiments. The claimed invention at issue in Automotive Technologies covered a sideimpact-crash sensor. The claims included a meansplus-function limitation directed to a mechanism for initiating operation of a side air bag upon sensing vehicle velocity. To support a noninfringement position, the accused infringer argued that the corresponding structure of the means-plus-function limitation was limited to the mechanical sensor described in detail in the specification. The patentee argued that the claim was broader and covered electrical sensors since the specification disclosed an alternative embodiment of the invention that referred to the use of an electrical sensor. The Federal Circuit agreed with the patentee and held that in view of the patent's disclosure mentioning an electrical sensor, the corresponding structure of the means-plus-function limitation included both mechanical and electrical sensors.

Regarding the sufficiency of the patent's disclosure, the specification had extensive discussion on the construction of the mechanical sensor. Hence there was no question that the specification enabled the use of a mechanical sensor. But for the electrical sensor, the specification only provided a short conceptual description and a black-box depiction of the purported electrical sensor. Further, record evidence showed that electrical sensors for use in side-impact deployment systems were not commercially available.

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The inventor had testified that he had never built an electrical sensor for use in his invention. In view of this and other evidence, the Federal Circuit held that the district court properly granted summary judgment that the electrical sensor was not enabled by the patent specification. *Id.* at *7-*8.

Seeking to avoid the conclusion of invalidity, the patentee argued that because the specification fully enabled an embodiment of the invention using the mechanical sensor. the specification met the enablement requirement under the doctrine that an applicant must only enable any one embodiment of the invention.¹ The Federal Circuit rejected the patentee's argument. Following its recent decision in Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1378-80 (Fed. Cir. 2007),² the court held that in order to enable the full scope of the claimed invention, the specification had to provide an enabling disclosure of the mechanical sensor and the electrical sensor. The court noted that "[e]lectronic side impact sensors are not just another known species of a genus consisting of sensors, but are a distinctly different sensor compared with the well-enabled mechanical side impact sensor that is fully discussed in the specification." Id. at *9. Consequently, the failure to enable an embodiment of the invention with an electrical sensor resulted in a failure to enable the claim as broadly as it was claimed.

Similar to Automotive Technologies, the district court in Sprint Communications Co. L.P. v. Vonage Holdings Corp., 2007 WL 2572417, *3 (D. Kan. Sept. 4, 2007), denied a patentee's motion in limine seeking to exclude portions of the accused infringer's technical expert's testimony on lack of enablement where the expert opined that the asserted patents did not provide an enabling disclosure for the accused voice over internet protocol (VoIP) technology. The patentee argued that the expert's opinion was legally flawed since the specification only had to enable any one mode of the invention, and therefore it did not matter if the specification enabled VoIP technology if it fully enabled another mode of the invention. The district court rejected this argument. Instead, the court ruled that because the specification had to enable the full scope of the claim, and VoIP allegedly fell within the scope of the claim, the specification had to enable VoIP. Id.

Obviousness of Purified forms of Chemicals

Showing further that KSR has dramatically impacted the law of obviousness, the Federal Circuit in Aventis Pharma Deutschland GmbH v. Lupin, Ltd., No.2006-1530, 2007 WL 2593791 (Fed. Cir. Sept. 11, 2007), reversed a judgment of validity and held that claims to substantially pure form of a compound were invalid for being obvious over a § 102(g) prior invention of the compound in an impure state. Because one of skill in the art had the capability to purify the compound of the § 102(g) prior invention and knew of the benefit to be achieved by a pure form of the compound, the Federal Circuit found that a sufficient motivation to modify the prior art composition to create the pure form of the compound existed, and therefore the claims to the pure form of the compound were obvious.

The claims at issue in Aventis were directed to an isomer of ramipril with a 5(S) chemical structure and being "substantially free of other isomers." The prior art showed a 102(g) prior invention of ramipril with a 5(S) chemical structure, but not necessarily being substantially free of other isomers. In a bench trial conducted before KSR was handed down, the district court found that the accused infringer failed to show by clear and convincing evidence a motivation to modify the prior art composition to achieve a 5(S) form of ramipril that was substantially free of other isomers. The Federal Circuit reversed. It held that "[r]equiring an explicit teaching to purify the 5(S) stereoisomer from a mixture in which it is the active ingredient is precisely the sort of rigid application of the TSM test that was criticized in KSR." Id. at *6. Limiting the instances of when a purified form of a composition may be patentable over prior art of an unpurified form, the Federal Circuit instructed:

... [A] purified compound is not always prima facie obvious over [a] mixture [that existed in the prior art]; for example, it may not be known that the purified compound is present in or an active ingredient of the mixture, or the state of the art may be such that discovering how to perform the purification is an invention of patentable weight in itself. However, if it is known that some desirable property of a mixture derives in whole or in part from a particular one of its components, or if the prior art would provide a person of ordinary skill in the art with reason to believe that this is so, the purified compound is prima facie obvious over the mixture even without an explicit teaching that the

¹ See generally, Robert A. Matthews, Jr., 2 ANNOTATED PATENT DIGEST § 20:48 Enabling of any One Mode Suffices.

² Automotive Tech. and Liebel-Flarsheim were both written by Judge Lourie.

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ingredient should be concentrated or purified. Ordinarily, one expects a concentrated or purified ingredient to retain the same properties it exhibited in a mixture, and for those properties to be amplified when the ingredient is concentrated or purified; isolation of interesting compounds is a mainstay of the chemist's art. If it is known how to perform such an isolation, doing so "is likely the product not of innovation but of ordinary skill and common sense."

Id. at *7.

Applying the foregoing, the Federal Circuit noted that a *prima facie* case of obviousness existed since the prior art disclosed that ramipril with a 5(S) chemical structure provided therapeutic benefits and there was "no evidence that separating 5(s) and SSSR ramipril was outside the capability of an ordinary skilled artisan." *Id.* at *8. The patentee attempted to rebut the prima facie case with evidence of unexpected results but the Federal Circuit found the patentee's evidence failed since the patentee had not compared its claimed invention with the closest prior art, the § 102(g) prior art composition.

In sharp contrast to the outcome in Aventis, the Federal Circuit upheld the validity of claims to a substantially pure (+)-enantiomer of citalopram in Forest Labs., Inc. v. Ivax Pharm., Inc., No. 2007-1059, 2007 WL 2482122 (Fed. Cir. 2007). There, the accused infringer had argued that the claimed composition was rendered obvious by a paper that theorized the composition. However, the court found that the process to obtain a substantially pure form of the composition involved a "relatively new and unpredictable technique," that others, including the author of the prior art reference, had failed in their efforts to make the substantially pure form of the composition, and therefore there was no reasonable expectation of success that the claimed composition could be made. Id. at *2-*3,*6. Accordingly, the Federal Circuit affirmed the district court's judgment upholding the claims.

Disparaging Prior Art Surrendered Equivalent

Further eroding a patentee's ability to claim infringement under the doctrine of equivalents, the Federal Circuit held in *L.B. Plastics, Inc. v. Amerimax Home Prods., Inc.*, No. 2006-1465, 2007 WL 2660261, *5 (Fed. Cir. Sept. 12, 2007), that statements in a patent specification characterizing the prior art's use of adhesives as being "less effective" than the weld of the claimed invention operated as a disclaimer of adhesives being an equivalent to the claimed weld. The patent at issue concerned a gutter guard that included a continuous heat weld that connected a mesh component to a panel on the guard. The accused product used adhesives to connect its mesh component with its panel. The specification contained the following statements: "This novel construction facilitates an effective and secure attachment of the composite by ultrasonic or heat welding along the entire length of the gutter guard. The attachment means used in other prior art gutter guards incorporating multiple layers is generally less effective, and more costly, time consuming, and labor intensive." Based on these statements and the fact that the prior art gutter guards used adhesives, the Federal Circuit held that "the specification must be read to criticize the use of adhesives as attachment means." The court also found that the statements showed that the patentee "elected to distinguish prior art attachment means and to limit its claim to continuous welded attachments." Id. Following the principle that "when a specification excludes certain prior art alternatives from the literal scope of the claims and criticizes those prior art alternatives, the patentee cannot then use the doctrine of equivalents to capture those alternatives," the Federal Circuit found that the patentee had surrendered the use of adhesives as being an equivalent, and therefore affirmed the summary judgment of no infringement.

Necessity of Actual Acts of Direct Infringement

Where an accused product can operate in infringing and non-infringing modes, a mere inference that "at least some of the time" the users must use the product in an infringing manner without any further proof of actual infringing uses does not suffice to prove inducing infringement, so held the Federal Circuit in Acco Brands, Inc. v. ABA Locks Manufacturer Co., Ltd., No. 2006-1570, 2007 WL 2609976 (Fed. Cir. Sept. 12, 2007). In Acco, the Federal Circuit reversed a denial of an accused infringer's motion for JMOL of no inducing infringement because substantial evidence did not support the jury's verdict finding induced infringement where the patentee failed to proffer evidence of actual instances of direct infringement. The undisputed facts showed that the accused product, a laptop security lock, could be operated in an infringing mode and in a noninfringing mode. The accused infringer provided instructions to its customers only for using the device in a way that would lock in

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the noninfringing mode. The patentee failed to proffer any evidence of actual uses by customers in the infringing mode. The patentee's expert testified that the infringing mode was allegedly the "natural and intuitive way to employ the device." Relying on this, the patentee argued that the jury could infer that at least some of the time the customers used the accused lock in an infringing manner. The Federal Circuit rejected this argument. It stated that "[i]n order to prove direct infringement, a patentee must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit." Id. at *4. Since the accused lock was capable of infringing and noninfringing uses, it clearly did not "necessarily infringe" the patent. Id. Hence, the patentee had to come forward with evidence of actual uses by customers in the infringing configuration. The patentee, however, failed to proffer any instances of direct infringement except for the use by its expert. Further, the patentee failed to introduce any survey evidence of the accused infringer's customers to prove that they used the lock in an infringing manner at any time. Distinguishing Hilgraeve Corp. v. Symantec Corp., 265 F.3d 1336 (Fed. Cir. 2001), which holds that a product that meets a claim limitation only in some circumstances may nonetheless literally infringe, the Federal Circuit instructed that Hilgraeve does not alter the requirement that to support a claim of inducing infringement a patentee must prove specific instances of direct infringement or that the accused device necessarily infringes the patent in suit. Reiterating the holding of prior precedent, the Federal Circuit stated that "[h]ypothetical instances of direct infringement are insufficient to establish vicarious liability or indirect infringement." Id. at *5.

Industrial Purchasers as "Ordinary Observer"

claims In evaluating for design patent infringement, the Federal Circuit held in Arminak and Assoc., Inc. v. Saint-Gobain Calmar, Inc., No. 2006-1561, 2007 WL 2644562, *4-*6 (Fed. Cir. Sept. 12, 2007), that the "ordinary observer" is not always the end retail purchaser of the product containing the accused ornamental design. Where the ornamental design is found only in a component of a retail product, it may be proper to use as the "ordinary observer" the industrial purchaser who routinely purchases the component for a manufacturer's use in incorporating the component into a final retail product. This applies, even though the industrial purchaser likely will have a more sophisticated eye in viewing differences between

the ornamental designs than an ordinary retail consumer. Applying this standard, the Federal Circuit held that where the asserted design patent covered an ornamental design of spray-bottle trigger used in spray bottles, and the patentee only sold its spray triggers to manufacturers, and never directly to retail consumers, the district court properly used a manufacturer's industrial purchaser as the ordinary observer rather than the retail consumer of the completed spray bottle. In view of undisputed evidence that the similarities between the claimed design and the accused spray triggers would not deceive industrial purchasers into thinking that the accused spray triggers were the patentee's claimed ornamental design, the Federal Circuit affirmed the district court's grant of summary judgment of no infringement.

Price Disparity Precluded Lost-profits

The Federal Circuit affirmed a denial of lost-profit damages in Mitutoyo Corp v. Central Purchasing, LLC., No. 2006-1312, 2007 WL 2482137 (Fed. Cir. Sept. 5, 2007), because the patentee failed to prove that "but for" the infringement it would have made the accused infringer's sales where the patentee sold its patented product well above the sale price of the infringing product. More specifically, the patentee sold its patented product in the price range of \$40 to \$397 dollars, while the infringer sold its accused products in the range of \$19 to \$49 dollars. While there was some overlap in the price range, the patentee failed to proffer any direct evidence to show that there was an overlap among the consumers buying the patented product and the infringing product. Further, the accused infringer introduced testimony that its customers' preferred price point was \$21, which made most of the patentee's products well outside the price range for which the infringer's customers were likely to buy. Id. at *5. In view of this evidence, the Federal Circuit found that there was no basis from which a jury could have found that "but for" the infringement the patentee would have made the sales of the accused infringer or award lost-profit damages. Id.

Additionally, the Federal Circuit affirmed a reasonable royalty rate of 29.2%; a rate primarily based on the patentee's profit margin. The court held that under the circumstances, the rate did not show an abuse of discretion since the accused infringer itself had a 70% profit margin and the contentious history between the parties made it reasonable to conclude that the patentee would not license its patented technology for anything less than its profit margin. *Id.* at *6.

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Nonetheless, the Federal Circuit vacated the reasonable royalty award because the district court erred in permitting royalties to be awarded based on the price at which a customer of the infringer resold the infringing products, rather than the price the infringer charged the customer. Since the third-party customer and the infringer lacked any type of corporate relationship or course of dealings, it was not reasonable to assume that the infringer would have agreed to a royalty based on the customer's selling price. *Id.* The Federal Circuit noted that had a parent-subsidiary relationship existed between the infringer and the customer's selling price in the royalty base. *Id.*

Pleading Infringement Claims

McZeal v. Sprint Nextel Corp., No. 2006-1548, 2007 WL 2683705 (Fed. Cir. Sept. 14, 2007), is the Federal Circuit's first opinion to address the impact of the Supreme Court's opinion in Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955 (2007), on pleading patent infringement claims. Writing for the majority, Judge Archer, joined by Judge Michel, held that *Bell Atlantic* does not require a patentee to plead factual details showing how each element of the asserted claims of the patent is found in the accused product. Indeed, the court's holding effectively reaffirms that a patentee provides enough detail if its complaint provides allegations comparable to the level of detail shown in Form 16.³ Thus, a patentee's complaint for direct infringement need only identify the specific patent accused of being infringed and identify an accused product or a specific line of products that allegedly infringe. Id. at *2-*3. While McZeal specifically addressed an infringement complaint filed by a pro se litigant,⁴ the court's analysis of the impact of Bell Atlantic on pleading patent infringement claims appears applicable to all litigants.

The majority viewed *Bell Atlantic* as not altering the level of detail needed to plead a claim of infringement. *See id.* at *2 & n.4. It instructed that "a patentee need only plead facts sufficient to place the alleged infringer on notice as to what he must defend," and therefore, "a plaintiff in a patent infringement suit is not required to specifically include each element of the claims of the asserted patent." *Id.* at *2. Instead, the specifics of how an accused device infringes can be determined through discovery. *Id.* at *3. Nonetheless, the majority also stated that it did not condone this particular patentee's method of pleading, *id.* at *4; which perhaps signals that the court may be receptive to tightening the pleading requirements for litigants represented by counsel.⁵

Judge Dyk dissented. He stated that in his view complaints only pleading the minimal information shown in Form 16 do not meet the pleading standard under *Bell Atlantic*, but conceded that in view of Rule 84, such complaints must be deemed to adequately plead a claim of literal infringement. *Id.* at *5. He called for Form 16 to be abolished. *Id.* Judge Dyk also advocated that at the complaint stage, a patentee should be required to identify the specific claims of the patent it accuses of infringement and plead specific facts showing why there is infringement. *Id.* at *7.

Prosecution Disclaimer

Reaffirming the principle that "[t]he patentee is held to what he declares during the prosecution of his patent[,]" the Federal Circuit ruled that a district court erred in not limiting the scope of a claim term "outer surface" to exclude interior surfaces based on statements in the prosecution history in Gillespie v. Dywidag Sys. Int'l, USA, No. 2006-1382, 2007 WL 2493339, *5 (Fed. Cir. Sept. 6, 2007). The claim at issue concerned a mine-roof bolt and, specifically, a limitation reciting that the bolt have an "outer surface defining a drive head that accepts a driving mechanism." The accused product had an internal recess that accepted a driving mechanism and a smooth cylindrical exterior surface. During prosecution, the applicant distinguished over a prior art bolt having a cylindrical outer surface on the basis that the cylindrical surface could not engage a driving Based on these statements in the mechanism. prosecution history, the Federal Circuit ruled that one of skill in the art would understand that the term "outer surface" referred to the exterior of the bolt, and therefore the claim had to be construed as requiring literally that the exterior boundaries of the bolt could accept a driving mechanism. Id. at *4-*5. Consequently, the accused product having an interior

³ See generally, APD § 39:3 Form 16 – Sample of an Adequate Infringement Complaint.

⁴ A less demanding pleading standard generally apples to *pro se* litigants compared to a litigant represented by counsel.

⁵ *Cf. Anticancer Inc. v. Xenogen Corp.*, 2007 WL 2345025, *4 (S.D. Cal. Aug. 13, 2007) (applying *Bell Atlantic* in dismissing claims where patentee failed to "plead any . . . facts beyond a bare statement of direct and indirect infringement so as to demonstrate a plausible entitlement to relief").

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surface configured to engage a driving mechanism did not literally meet the claim, and the district court erred in concluding otherwise.

Personal Liability for Inequitable Conduct

A district court held in Armament Sys. & Proc., Inc. v. Emissive Energy Corp., No. 06-C-833, 2007 WL 2572304, *2-*3 (E.D. Wis. Sept. 5, 2007), that a named inventor who had assigned all ownership interest in his patent to another could, nonetheless, be joined to an accused infringer's declaratory judgment counterclaim for unenforceability where the named inventor had been previously found by the court to have personally committed inequitable conduct during the prosecution of the parent patent to the patents at issue. Relying on Nelson v. Adams USA, Inc., 529 U.S. 460 (2000), and other precedent, the district court ruled that since the named inventor's personal culpability for the alleged acts of inequitable conduct made the named inventor potentially liable with the patentee for any attorney's fees awarded under § 285, it was proper to join the named inventor to the declaratory judgment counterclaim.

LEGISLATIVE HAPPENINGS

On September 7, 2007, the House of Representatives passed by a vote of 220 to 175, H.R. 1908; its bill addressing patent reform. The House Bill includes provisions to move the U.S. to a first-to-file system, institute a post-grant review proceeding, and limit the scope of the estoppel from requesting an *inter partes* reexamination.

Despite opposition from the Federal Circuit, the federal executive branch, and numerous industry and trade groups, the House Bill contains the controversial provisions allowing interlocutory appeals of claim construction rulings, the requirement to apportion reasonable royalty damages where the entire market value rule does not apply, and limiting the venue for patent infringement actions and declaratory judgment actions involving patents. The House Bill tightens up the circumstances for a patentee to recover enhanced damages for willful infringement and when such claims can even be pled. It also gives the PTO authority to impose regulations requiring applicants to submit a "search report and other information and analysis relevant to patentability." Hence, this provision effectively gives legislative sanction to at least a portion of the PTO's new rules limiting the number of claims an applicant can file before having to submit an Examination Support Document.

The "best mode" requirement survived as something an applicant should disclose in the specification, i.e., the bill does not delete the requirement from § 112. But the bill amends § 282 to expressly exclude "best mode" as a grounds for asserting invalidity. It appears that a deliberate withholding of a best mode, done with an intent to deceive the PTO into issuing the patent, can still be asserted as a grounds for inequitable conduct. Hence, the bill may be viewed as bringing to fulfillment efforts of some members of the Federal Circuit to engraft an "intent to conceal" requirement to the standard for finding a best mode violation.⁶

The House Bill modifies the traditional consequences of inequitable conduct by giving the court discretion to choose from a variety of alternative sanctions including declaring the whole patent and any related patent unenforceable, declaring only some of the claims of the patent unenforceable, or denying the patentee any injunctive relief and limiting damages to only reasonable royalty damages. Should an attorney be found to have perpetrated the inequitable conduct, the district court must refer the matter to the PTO.

The bill also directs that the Administrative Office of the United States Courts conduct a study on the use of special masters in patent cases, whether special masters are beneficial in resolving patent litigation, and, if so, whether any special programs should be implemented to facilitate their use. The bill also requires that other studies be done, including having the PTO perform a study on reasonable royalty damages awarded in patent cases since 1990 and having the Comptroller study the work-place conditions at the PTO.

The Senate is still working on its bill addressing patent reform with further developments (and intense opposition) expected in October.

ADMINISTRATIVE HAPPENINGS

ESD Guidelines

The USPTO recently published guidelines concerning the content expected in an Examination Support Document (ESD).⁷ An ESD under 37 C.F.R. § 1.265 is now required in nonprovisional applications (filed on or after Nov. 1, 2007 or filed before but for which an Office Action was not mailed before Nov. 1,

⁶ See generally, APD § 21:44 Necessity of Intent to Conceal

⁷ http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/ esdguidelines090607.pdf

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2007), where more than five independent claims or more than twenty-five total claims are presented. The ESD must be submitted before issuance of a first Office Action on the merits. Amendments or the identification of additional references may trigger the requirement for a supplemental ESD.

Similar to the support document required for Accelerated Examination, the ESD must include: (a) preexamination search statement; (b) listing of references deemed most closely related; (c) identification of claim limitations disclosed by references; (d) detailed explanation of patentability; and (e) showing of support under 35 U.S.C. 112, first paragraph. Highlights of each of these requirements are detailed below.

Preexamination Search. The preexamination search must encompass all independent claim limitations and all dependent claim limitations separately. Searches from prior-filed nonprovisional applications, search reports from a foreign patent office, and international search reports will not automatically satisfy the preexamination search requirement. Templates for where and how to search are provided at http://www.uspto.gov/web/ patents/searchtemplates/.

Listing of Closest References. "Most closely related" references are references that: (a) disclose the most number of limitations in an independent claim; and (b) disclose a limitation of an independent claim or a dependent claim not found in any other reference. Applicants are encouraged to include references having a prior art date that is more than one year prior to the application filing date but which may be less closely related than another reference included in the ESD that has a prior art date less than a year prior to the application filing date. References identified to an applicant by means other than the preexamination search (e.g., identified in foreign search report) must also be included if deemed "most closely related." An applicant should use an Information Disclosure Statements (IDS) to submit references that do not qualify as "most closely related," but the applicant, nonetheless, wants the PTO to consider. An applicant will have to submit a supplemental ESD if any "as closely" or "more closely" related references are brought to the applicant's attention at a later date. A supplemental ESD may also be necessary if it adds new claim limitations that require a new search. The PTO wants all applicants to use the PTO Form SB/211 when available in October.

Identification of Claim Limitations in References. Applicants must identify at least one appearance in the reference that supports why the reference is being cited for each relevant element of the claims, but need not identify all relevant portions of the reference. Small entities, as defined by the Regulatory Flexibility Act, may claim exemption from this requirement upon filing a certification of such entitlement with the ESD. For applications originally filed by small entity applicants who no longer qualify as small entities, however, no certification can be made, as the small entity status must be applicable at the time of certification. This is unlike 37 C.F.R. § 1.27, which allows for applicants to continue to reap the benefits of paying reduced fees for small entities (up until payment of the issue fee), even when there has been a change in status.

Detailed Explanation of Patentability. Applicants must explain why the claimed subject matter is not described in the cited references, why there is no motivation to combine the features of one reference with the features of another reference, and why the claim limitations of the independent claims are novel and non-obvious over the cited references. General statements (*i.e.*, conclusory statements) purporting patentability will not be acceptable.

Showing of Support under 35 U.S.C. §112, First Paragraph. Applicants must show where each element of the claims, independent and dependent, is found in the specification. If the application claims the benefit of a prior-filed application, then the applicant must also point out where support for each element of the claims can be found in the prior-filed application. This includes any benefit or priority application, including provisional, foreign filed, international, or other nonprovisional applications. General statements that the claims are supported by the entire specification will be insufficient.

The PTO will notify applicants of non-compliant or omitted ESDs. For non-compliant ESDs, applicants will be notified of the defect and, to avoid abandonment, be given two months (not extendable) to: (a) file a corrected or supplemental ESD or (b) amend the application to contain less than 5/25 claims. For inadvertently omitted ESDs, one of the following three situations will occur. (1) For applications filed before November 1, 2007, applicants will be notified in situations where an ESD was omitted but is required, and applicants will be given two months (extendable up to a total of six months) to:

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(a) file an ESD; (b) file a suggested restriction requirement (SRR); or (c) amend the claims to less than the 5/25 claims threshold. If, however, the PTO combines the notice with a restriction requirement, then the applicant will not have the option of submitting an SRR. (2) In applications filed on or after November 1, 2007, applicants will be notified of the ESD omission and, if the notice was mailed before a first Office Action on the merits, the applicant will be given two months (not extendable) to avoid abandonment to: (a) file a compliant ESD or (b) to amend the application to contain less than 5/25 claims. (3) For applications filed on or after November 1, 2007 and in which a notice of omitted ESD is sent after the issuance of a first Office Action on the merits, applicants will be given two months (not extendable) to avoid abandonment, but their only choice is to amend the claims to less than 5/25 claims. ESD noncompliance, for applications filed on or after November 1, 2007, may result in negative Patent Term Adjustment consequences for the period of noncompliance.

UK Prosecution Highway

On September 4, 2007, the USPTO and United Kingdom Intellectual Property Office (UK IPO) announced that they are now accepting applications for participation in a pilot Patent Prosecution Highway (PPH) project established between the two offices. The PPH builds on the work of a similar pilot scheme between the USPTO and Japanese Patent Office, established in July 2006.

The PPH program seeks to expedite prosecution

and allow applicants in both countries to obtain corresponding patents more efficiently. Under the program, each office can benefit from the work previously performed by the other office, easing workload and reducing duplication of efforts. For the U.S. application to be eligible to participate in the PPH program, (1) the UK IPO application must have at least one claim that was determined by the UK IPO to be allowable/patentable; (2) the claims in the U.S. application must sufficiently correspond to the allowable/patentable claims in the UK IPO application; and (3) examination of the U.S. application must not have begun. If the U.S. application is eligible, the Applicant must file a request for participation in the PPH pilot program and a petition to make the U.S. application special under the PPH pilot program.

The PPH program is set to expire after one year but may be extended or terminated early depending on the level of participation and other factors.

New Final Rules for PCT Applications

The USPTO revised certain rules in title 37 of the Codes of Federal Regulations to conform to amendments made to the PCT regulations earlier this The amendments: (1) provide a means for year. applicants to restore a priority claim in applications meeting certain requirements; (2) provide a mechanism for applicants to insert a missing portion of the international application without losing the international filing date; (3) clarify the circumstances and procedures for correcting an obvious mistake; and (4) revise the search fees for international applications.

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