

PATENT HAPPENINGS

during August 2007 (Part II)

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

HIGHLIGHTS

1.	PTO announces its final rules on continuation applications and examining claims
2.	Patentee's failure to produce a fully automated computer-aided design system as claimed showed lack of an enabling disclosure
3.	Points of novelty for design patents may lie in combinations that are a non-trivial advance over the art
4.	District court's claim construction order not binding on PTO during reexamination
<i>5</i> .	State-law fraud claim required jury to determine issues of conception for later use in § 256 correction of inventorship claim
6.	Foreign priority applied where foreign application had § 112 support for a species within the scope of the count
7.	PTO must meaningfully consider applicant's rebuttal evidence before finalizing an obviousness rejection
8.	Patentee's lost-profits claim negated its contention that its patent was not "essential" to an industry standard
9.	Pioneer drug manufacturer's settlement with generic manufacturers mooted re-seller's declaratory judgment claim
10	Notice under § 287 from filing complaint
11	measured from filing date, not service date 6 One month delay in seeking leave to amend failed to show diligence

ADMINISTRATIVE HAPPENINGS

On August 21, 2007, the PTO published its final rules regarding changes to filing continuation applications, identifying commonly-owned applications with patentably indistinct claims, and limiting the number of claims examined in each

application. 72 Fed.Reg. 46716. The new rules take effect on November 1, 2007. But some of the new rules will affect currently pending applications. For example, currently pending applications may need to comply by February 1, 2008, with the new rules pertaining to the identification of applications and patents naming at least one inventor in common, *i.e.* §§ 1.78(f)(1) and (2). Further, applicants will not be able to circumvent the new continuation rules by filing a continuation application before the effective date. But it does appear that applicants can circumvent the petition requirement for second or subsequent RCEs, at least until November 1, 2007. Additional details of some of the new rules are provided below.

Continuation Applications

The new continuation rules, including Rules 1.78(a) and (d), apply to continuing applications filed on or after November 1, 2007. For applications filed before or that entered the national stage before August 21, 2007 and are second or subsequent continuing applications, applicants may file "one more" continuing application without a petition and showing (see below). Two continuation applications (continuations or CIPs) and one RCE are allowed per "application family," i.e., the initial application and its continuations/CIPs. Additional continuing applications or RCEs may be filed upon successful petition/showing and payment of \$400 petition fee. The showing must be sufficient to satisfy the Office that the "amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior filed application." See 37 C.F.R. § 1.78(d).

In response to public comment, the Office has advised that it likely will *not* grant petitions in some circumstances, including where the reasons presented by the applicant include: 1) that the applicant has newly obtained financial resources, 2) when clinical trials now indicate that the subject matter may be useful, 3) that a product recently becomes

commercially viable, 4) when a competing product is newly discovered, 5) to correct inventorship of the application, or 6) that the subject matter to be added was not present at the time of the original filing. With respect to CIPs, the applicant must identify where support can be found in the prior-filed application for the claims of the CIP and may be required by the examiner to particularly point this out.

Divisional Applications

Divisional applications may be filed if the priorfiled application was subject to a restriction requirement, the divisional claims only a non-elected invention that has not been examined, the restriction requirement is not provisional, and the applicant does not traverse the restriction requirement. Contrary to the originally proposed rules, divisional applications are not required to be filed during the pendency of the initial application and may be filed in parallel or series with respect to the initial application, so long as the copendency requirement of 35 U.S.C. § 120 is met.

Divisional applications start a new application family. Thus, two continuations/CIPs and one RCE may be filed within the divisional application family. As described above with respect to continuation applications, additional continuing applications or RCEs may be filed in a divisional application family upon successful petition/showing and payment of \$400 petition fee.

Examination of Claims

New Rules 1.75, 1.142(c), and 1.265 apply to applications filed on or after or entering national stage on or after November 1, 2007, as well as to applications filed before November 1, 2007 where a first Office Action on the merits was not mailed before November 1, 2007. A total of 25 claims, which may include up to 5 independent claims (5/25), are allowed per application without an Examination Support Document (ESD). For each invention, 15/75 claims are allowed. Thus, 15/75 claims may be presented in each application family. For example, an initial application and two continuations/CIPs together may have 15/75 claims and a divisional and two continuations/CIPs together may have 15/75 claims.

If an application contains more than 25 claims total or more than 5 independent claims, then an ESD is required and the ESD must be submitted before the mailing of a first Office Action on the merits. If an ESD is not filed before the first Office Action, then the application must remain at 5/25 or fewer claims. For

inadvertent omissions of an ESD, the Office will notify the applicant that an ESD is required. For applications filed on or after November 1, 2007, the applicant must then, within two months (not extendable) of the notice, file an ESD or amend the application to contain less For applications filed before than 5/25 claims. November 1, 2007 that did not receive a first Office Action on the merits by November 1, 2007, the applicant must then, within two months (extendable to a total of six months) of the notice, file a Suggested Restriction Requirement (SRR) (see below), file an ESD, or amend the application to contain less than 5/25 claims. The ESD requirement does not apply to applications filed before and that received a first Office Action on the merits by November 1, 2007.

A negative Patent Term Adjustment (PTA) will be applied to any patent term adjustment due for failure to comply with the ESD requirements of Rule 1.75(b). This PTA rule, however, only applies to applications filed on or after November 1, 2007.

The ESD is a somewhat relaxed form of the Accelerated Examination Support Document required for purposes of accelerated examination. For example, with respect to the "Detailed Explanation of Patentability," the ESD need only explain how each independent claim is patentable over the cited references, whereas for purposes of accelerated examination the applicant is required to explain the patentability of all claims. Further, small entities (i.e., a small business concern as defined in the Regulatory Flexibility Act) are not required to identify claim limitations disclosed by the cited references. The Preexamination Search requirement for the ESD is similar to that required for accelerated examination in that the search must involve U.S. patents and patent application publications, foreign patent documents, and non-patent literature (unless otherwise justified). Further, among other identification requirements, the applicant must identify the field of search by U.S. class and subclass and the search logic or chemical structure or sequence used as a query.

If an application contains more than one invention, an applicant may file a SRR. The SRR, however, must be filed before the first Office Action on the merits or a Restriction Requirement and be accompanied by an election of an invention to no more than 5/25 claims. The Office may or may not accept the SRR. If the SRR is not accepted and the application contains more than the allowed 5/25 claims, the applicant will be notified of the requirement to file an ESD or amend the

application to reduce the number of claims. The applicant must respond to this notice within two months, which is not extendable.

Patentably Indistinct Claims

Applicants must identify other commonly owned applications or patents that have 1) an inventor in common with the application and 2) a filing date or priority date within two months of the filing date or priority date of the application. Patentably indistinct claims in a co-pending application are included in the 5/25 count, if owned or subject to an obligation of assignment to the same person. Identification of such applications must be presented in a separate paper to the Office. The Office projects it will have a new form, SB/206, in October.

A rebuttable presumption that the application contains at least one patentably indistinct claim will arise where there is 1) substantial overlapping disclosure and 2) the applications have the same filing date or priority date. Substantial overlapping disclosure exists if the other application has 35 U.S.C. § 112, first paragraph, support for at least one claim of the application at issue. The applicant can rebut this presumption by explaining how its application contains claims that are patentably distinct from the claims of another application or by submitting a terminal disclaimer and explaining why there are two or more applications with a common inventor, that are commonly owned, and that contain patentably indistinct claims.

The new rules provide non-extendable time periods for identifying such commonly owned applications and taking responsive actions. Indeed, for applications filed before November 1, 2007 that have not yet been allowed, applicants must comply with the identification and action requirements of §§ 1.78(f)(1) and (2) by the later of February 1, 2008, four months from the filing date of the application, four months from the date national stage commenced, or two months from the mailing date of the initial filing receipt.

JUDICIAL HAPPENINGS

Patentee's Failure Shows Lack of Enablement

Adding to the body of law that an inventor's failed attempts to make the claimed invention may show the specification lacks an enabling disclosure, ¹ the Federal

 $^{\rm 1}$ See generally, Robert A. Matthews, Jr., 2 Annotated Patent Digest \S 20:59 Failed Attempts to Make Invention.

Circuit in Ormco Corp. v. Align Tech., Inc., No. 2006-1240, 2007 WL 2404723, *10 (Fed. Cir. Aug. 24, 2007), affirmed a summary judgment that claims directed to a computer-aided design and manufacturing system of custom orthodontic appliances lacked an enabling disclosure. As construed by the court, the claims of the asserted patent required a fully-automated The patentee had argued that two of its commercial products demonstrated enablement of the But these two products were not fullypatent. automated. The Federal Circuit ruled that since the patentee had argued that its two products showed enabled embodiments of the patented invention, but it could not be disputed that those products did not achieve a fully-automated state, those two products evidences failed attempts by the patentee to build an invention within the scope of the claims. Further, one of the named inventors, who was an employee of the patentee, testified that the patentee had never attempted to create a fully-automated computerized system. He also testified that while it was the patentee's goal to have a fully-automated design system, variations in human anatomy had prevented the attainment of that goal and he was unsure if the problems due to variations in human anatomy could ever be overcome. In view of this uncontradicted evidence, the Federal Circuit affirmed the summary judgment that the claims were not enabled. The court stated "filf an inventor attempts but fails to enable his invention in a commercial product that purports to be an embodiment of the patented invention, that is strong evidence that the patent specification lacks enablement."

While the court referred to the failure to enable a "commercial product" as showing evidence of lack of enablement, one should remember that a patent specification need only enable any one mode of the invention, and not necessarily a commercial embodiment. In *Ormco* the inventor's testimony that he was unsure if the problems due to variations in human anatomy could ever be overcome appeared to show that no embodiment of the invention as claimed, commercial or non-commercial, could be built based on the patent's disclosure.

Points of Novelty

Whether a combination of prior art elements can constitute a point of novelty for purposes of design patent infringement has suffered some confusion in the

² See APD § 20:48 Enabling of any One Mode Suffices.

³ See APD § 20:49 Need Not Enable Commercial Embodiment.

law.⁴ The Federal Circuit sought to remove that confusion in Egyptian Goddess, Inc. v. Swisa, Inc., No. 2006-1562, 2007 WL 2439541 (Fed. Cir. Aug. 29, 2007), by confirming that, under some circumstances, a combination of elements individually present in the prior art may constitute a point of novelty of an ornamental design. Over the dissent of Judge Dyk, the majority held that a combination of individually known design elements can constitute a point of novelty where the combination is a "non-trivial advance over the prior art." Id. at *2. Applying this rule, the court affirmed the district court's rejection of the patentee's proffer of a combination of individually known design elements as a point of novelty because the combination did not show an advancement over the art. Specifically, the asserted four-element combination only differed from the prior art in the use of a square cross-section where the similar four-element combination in the prior art used a triangular cross-section. Since other relevant prior art showed that the use of square cross-sections was common, the court concluded that the asserted combination did not present a non-trivial advance over the prior art sufficient to be a point of novelty. Id. at *3. Because the patentee had alleged only one other point of novelty, and the parties did not dispute that the accused product lacked that point of novelty, the Federal Circuit affirmed the summary judgment of noninfringement.

Judge Dyk dissented. In his view, requiring a patentee to show that a combination of design elements is a non-trivial advance over the prior art effectively requires the patentee to prove the nonobviousness of the claimed design as part of proving its case of infringement. He found this shift in the conventional proof burdens to be untenable. *Id.* at *4.

Collateral Estoppel Did Not Apply Against PTO

The due process concerns that preclude applying collateral estoppel to a non-party in litigation apply to the PTO during *ex parte* prosecution so held the Federal Circuit in *In re Trans Texas Holdings Corp.*, No. 2006-1599, 2007 WL 2377009 (Fed. Cir. Aug. 22,

⁴ See Lawman Armor Corp. v. Winner Int'l, LLC, 437 F.3d 1383, 1385-86 (Fed. Cir. 2006), supplemented, 449 F.3d 1190, 1192 (Fed. Cir. 2006) ("In our decision, we did not intend to cast any doubt upon our prior decisions indicating that in appropriate circumstances a combination of design elements itself may constitute a 'point of novelty.' Such a combination is a different concept than the overall appearance of a design which, as indicated, our cases have recognized cannot be a point of novelty."), order denying en banc reh'g, 449 F.3d 1192 (Fed. Cir. 2006).

2007). There, an applicant in a reexamination proceeding contended that the PTO erred by not applying a narrow construction of a claim limitation rendered by a district court in an earlier litigation. Presumably, under the narrow construction, the applicant's claims would have avoided the prior art. Noting that it has "never applied issue preclusion against a non-party to the first action," the Federal Circuit rejected the applicant's contention that issue preclusion applied to prohibit the PTO from giving the claims their broadest reasonable interpretation, which resulted in a claim scope broader than that found by the district court. Id. at *5. The Federal Circuit rejected the applicant's arguments that the ex parte nature of prosecution justified applying issue preclusion on claim construction rulings against the PTO where the PTO was not a participant in the underlying litigation. Id. The Federal Circuit also distinguished the use of issue preclusion against the PTO from its prior decision in In re Freeman. In Freeman, the Federal Circuit had affirmed the PTO's use of issue preclusion against an applicant on a matter of claim construction since the applicant had been a party in the underlying district court action. According to the Federal Circuit, nothing in Freeman supported applying issue preclusion against the PTO where the PTO did not participate in the underlying litigation. *Id.* at *6.

After rejecting the applicant's arguments for a narrow claim construction, the Federal Circuit affirmed the PTO's obviousness rejections of all the asserted claims. The court found that substantial evidence supported the PTO's findings as to what the main prior art reference disclosed. Regarding claims that required combining the main prior art reference with other art, the Federal Circuit cited *KSR* in affirming the PTO's ruling that one of skill in the art would have combined "well-known" practices of securing loans with mortgaged real estate and using balloon payments with loans to supply the missing limitations not disclosed in the main prior art reference. *Id.* at *8.

Right to Jury Trial on Aspects of § 256 Action

While noting that a litigant generally has no right to a jury trial of an action to correct inventorship under 35 U.S.C. § 256, the Federal Circuit held in *Shum v*. *Intel Corp.*, No. 2006-1249, 2007 WL 2404718, *4-*6 (Fed. Cir. Aug. 24, 2007), that where the correction of inventorship claim has overlapping factual issues with other claims for which a right to a jury trial does attach, the overlapping issues must be decided by the jury. In *Shum*, the plaintiff had asserted a correction of

inventorship claim, for which no right to a jury trial applied, and a state-law fraud claim, for which a right to a jury trial attached. As grounds for the fraud claim, the plaintiff asserted that the defendant misrepresented to the PTO that the defendant was the sole inventor of the claimed invention. The Federal Circuit found that the facts the plaintiff needed to prove relating to the conception of the claimed invention to support his assertion of joint inventorship were common, if not identical, to the facts the plaintiff needed to prove to support his fraud claim. Accordingly, under the Supreme Court's decision in *Beacon Theaters*,⁵ the common facts had to be tried to the jury. Hence, where the district court bifurcated the inventorship claim from the fraud claim, and tried the inventorship claim to the bench before the fraud claim was tried by the jury, the district court erred since it denied the plaintiff the right to have the jury make findings on the common factual questions and to have those findings applied by the district court when it decided the § 256 inventorship claim. The Federal Circuit concluded that "[w]hile [the plaintiff] would not be entitled to a jury trial on the § 256 inventorship claim standing alone, given the copendency of the asserted fraud claim, a jury should determine the facts regarding inventorship. Accordingly, the [district] court's decision to try the inventorship claim before a jury trial on the state law claim ran afoul of the Seventh Amendment, and thus was an abuse of discretion." Id. at *6. Judge Friedman dissented. He viewed Beacon Theaters as applying only where the two legal claims were effectively the same. Analogizing to the Supreme Court's treatment of claim construction in Markman, he opined that a court may first decide an equitable claim even though that decision may effectively determine an essential element of later-decided second claim for which a right to a jury trial applies.

Foreign Priority

Addressing the issue of foreign priority under 35 U.S.C. § 119(a), the Federal Circuit reaffirmed in *Frazer v. Schlegel*, No. 06-1154, 2007 WL 2350266, *4-*6 (Fed. Cir. Aug. 20, 2007), that a foreign patent application may be used to show a constructive reduction to practice, as of the foreign filing date, of an invention claimed in a later-filed U.S. patent application, if the foreign application provides § 112 support for the claims in the U.S. application. *Id.* at *4. Reversing the Board's denial of a foreign priority

⁵ Beacon Theatres, Inc. v. Westover, 359 U.S. 500 (1959).

claim to an Australian patent application made by a party in an interference proceeding, the Federal Circuit found that where an interference count was directed to a virus-like particulate made with a recombinant DNA molecule having a sequence that encoded a papillomarvirus L1 protein, and the applicant's Australian application enabled the making of a viruslike particulate with recombinant DNA that encoded the papillomarvirus L1 protein and L2 protein, the foreign application provided an enabling disclosure of a species within the count. Consequently, the Board erred in denying foreign priority since the Australian application provided § 112 support for a species that met the count. Id. at *5. The Federal Circuit rejected the Board's rationale that since the party did not know that the L1 protein could be used by itself when it filed its Australian patent application, but discovered this fact later, the party could not claim priority to its Australian patent application for purposes of the interference. It held that because the party's later discovery that either the L1 protein or both the L1 and L2 proteins led to capsid formation did "not negate or contradict his disclosure and constructive reduction to practice of the method of the count that produced the papillomavirus-like particle of the count," the Board erred in denying the foreign priority claim. Id. The Federal Circuit further noted that "acknowledgment of the complexities of the science does not negate the disclosure of the production of these virus-like particles. ... The Australian application was not 'merely proposing an unproved hypothesis' or guess; it was an enabling disclosure." Id. at *6.

Rebuttal of a Prima Facie Case of Obviousness

The Federal Circuit vacated a Board affirmance of an obviousness rejection for a pharmaceutical composition useful to treat rattlesnake bites in In re Sullivan, No. 2006-1507, 2007 WL 2433841 (Fed. Cir. Aug. 29, 2007). The invention related to using Fab fragments from antibodies to bind to snake venom and thereby neutralize the lethality of the venom. The Federal Circuit agreed with the PTO that a prima facie case existed to show a motivation to combine the applicant's prior-art work using whole antibodies with other prior art showing that Fab fragments could be used to detect venom of a different snake. Quoting KSR, the court noted that "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or

her skill." Id. at *5. Nonetheless, while assuming for purposes of the appeal that the PTO had established a prima facie case of unpatentability, the Federal Circuit found that the Board erred by not giving meaningful consideration to the applicant's rebuttal evidence. The applicant had submitted three expert declarations to show that one of skill in the art would not have been motivated to combine the prior art and that the invention was not obvious. The declarations provided evidence that i) the claimed invention possessed an unexpected property of being especially suitable for treating rattlesnake bites; ii) one of skill in the art would not have expected the ingredient of the composition to be useful as an anti-venom; and iii) the successful use of the composition as an anti-venom was contrary to what the experts believed, and therefore the prior art taught away from the invention. The Board dismissed these declarations for only addressing a new use for an old composition. The Federal Circuit ruled this was error. It held that "when an applicant puts forth relevant rebuttal evidence, ... the Board must consider such evidence . . . [and] give the declarations meaningful consideration before arriving at its conclusion." Id. at *6. The court also rejected the Board's contention that the declarations were not relevant since they only related to the use of the composition. According to the Federal Circuit, the issue was not whether the composition was being put to a new use, but whether the composition possessed an unexpected use. It explained, "In this case, [the] applicant does not concede that the only distinguishing factor of its composition is the statement of intended use and, in fact, extensively argues that its claimed composition exhibits the unexpected property of neutralizing the lethality of rattlesnake venom while reducing the occurrence of adverse immune reactions in humans. Such a use and unexpected property cannot be ignored." *Id*.

Failing to Disclose to Standard-Setting Body

A district court denied a patentee's attempt to avoid the consequences of its failure to disclose an asserted patent to an industry standard-setting body in *TruePosition Inc. v. Andrew Corp.*, 2007 WL 2429400 (D. Del. Aug. 23, 2007). Initially, the court held that the federal patent laws did not preempt the accused infringer's fraud and state law unfair competition claims because those claims were not based on the patentee's assertion of its patent rights against the accused infringer in the current litigation. The court found that the accused infringer's claims were based

on the patentee's alleged breach of its duty to disclose the patents to a standard setting body and the accused infringer's reliance on the non-disclosure to support its belief that no essential patents covered the standard, and therefore it was safe to launch it product. *Id.* at *8. The patentee also argued that it had no duty to disclose the asserted patent to the standard setting body since the patent allegedly was not an "essential patent." The court rejected this argument by noting that the patentee claimed lost profit damages, which necessarily implied that there were no acceptable noninfringing alternatives to the patented technology. The court stated: "Plaintiff cannot have its cake and eat it too. That is, plaintiff cannot simultaneously assert that no non-infringing alternatives exist in the market and that no question of fact remains as to whether it had a duty to disclose the '144 patent to 3GPP/ETSI as 'essential IPR." Id. at *11. Accordingly, the district court denied the patentee's summary judgment motion seeking to dismiss the accused infringer's fraud claim, and its defense of equitable estoppel and implied license. Id. at *13.

Declaratory Judgment

A patentee's settling infringement controversies with all third-party generic manufacturers that supplied the market mooted the declaratory judgment claims of a re-seller of generic drugs according to the court in Rite Aid Corp. v. Purdue Pharma, L.P., 2007 WL 2388912, *4 (S.D.N.Y. Aug. 21, 2007). The court found that because the settlement agreements between the patentee and the generic manufacturers released all re-sellers from liability, no actual controversy remained between the re-sellers and the patentee. The re-sellers argued that a controversy continued to exist because the settlement agreements contained a "blowup" clause that could nullify the releases if the agreements were struck down by a court in the future. Rejecting this argument, the district court ruled that contingent nullification of the settlement agreement was too remote and speculative to show a continued actual controversy.

Actual Notice Under § 287

In denying an accused infringer's motion for summary judgment to preclude presuit damages for the patentee's alleged failure to comply with the notice provisions of § 287, the district court in *New Medium v. Barco*, 2007 WL 2403208, *4-*5 (N.D. Ill. Aug. 15, 2007), made several rulings of interest regarding "actual notice" under § 287(a). First, the district court

rejected the patentee's argument that actual notice could relate back to an earlier complaint the patentee filed that did not name the specific accused infringer. The court explained that "[f]iling a complaint against unrelated parties, regardless of whether it relates to the same or similar products relevant to the claims of infringement against [a specific accused infringer], does not provide actual notice of infringement to [that specific accused infringer]." Accordingly, actual notice for a specific accused infringer does not arise until the filing of the first complaint that names that specific accused infringer. Second, applying a literal construction of the statute, and in the face of concession by the accused infringer, the district court accepted the patentee's contention that actual notice, based on the filing of a complaint under § 287(a), is effective as of the filing date of the complaint and not the date that the patentee actually serves the accused infringer with the complaint. Third, the district court also accepted the patentee's contention that an executed license agreement which failed to require the licensee to mark its products does not automatically bar presuit damages for failing to comply with the duty to mark. Since the duty to mark does not arise until the licensee actually begins to make and sell products covered by the patent, presuit damages are not barred for infringing acts done after the execution of the license agreement and before the licensee began to make and sell product covered by the patent.

Amending Pleadings

To amend a pleading to assert new claims or defenses after the scheduling order deadline has passed, Rule 16(b) requires parties seeking leave to amend to show "good cause." To meet this standard, a party typically must show that it acted diligently in investigating information related to the new claims or defenses, and that it promptly sought leave to amend from the court after obtaining sufficient information to plead the new claims or defenses. Demonstrating that in some cases a high standard of diligence may apply, the district court in Computer Acceleration Corp. v. Microsoft Corp., 2007 WL 2315223, *2-*4 (E.D. Tex. Aug. 10, 2007), held that a one-month delay in seeking leave was too long to show good cause. Specifically, the court held that by delaying for over a month in seeking leave after the accused infringer had completed the deposition that allegedly gave it the necessary information to assert the new inequitable conduct grounds, the accused infringer failed to act with the requisite diligence. The court noted that much of the documentary evidence supporting the new inequitable conduct grounds had been in the accused infringer's possession for many months before the deposition, and hence, the accused infringer should have acted more quickly in seeking the deposition and investigating the new grounds.

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