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PATENT HAPPENINGS

during July 2007 **(Part II)**

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

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JUDICIAL HAPPENINGS

Declaratory Judgments

Continuing its adjustment to the Supreme Court's criticism in *MedImmune* of the Federal Circuit's "reasonable apprehension" standard,[1] the Federal Circuit reaffirmed in *Benitec Australia Ltd. v. Nucleonics, Inc.*, No. 06-1122, 2007 WL 2069646 (Fed. Cir. July 20, 2007) (Whyte (sitting by designation), Rader, Dyk), two important principles of declaratory judgment jurisdiction. First, the court reaffirmed that under the appropriate circumstances, a patentee may divest a district court of subject matter jurisdiction by taking acts that moot the controversy between the parties. Second, the court held that even under the new "all circumstances" standard, a dispute between a declaratory judgment plaintiff and the patentee must have a certain degree of immediacy; generally shown by the accused infringer having actually performed potential infringing activity or having taken concrete steps to begin such activity.

In *Benitec*, the patentee sued the accused infringer for infringing a patent directed to a RNA-based disease therapy. The accused infringer filed counterclaims seeking a declaratory judgment of invalidity. After acknowledging that the accused infringer's limited activity regarding testing for possible human use most likely fell with the safe harbor provision of 35 U.S.C. § 271(e)(1), the patentee obtained a voluntary dismissal with prejudice of its infringement claims. The district court further dismissed the accused infringer's invalidity declaratory judgment counter-claim after ruling that while the accused infringer probably showed a reasonable apprehension of suit, it failed to show that it was making a commercial product that could be the subject of an infringement suit. The district court concluded that "any threat of litigation that may have existed now lacks sufficient immediacy and reality to support declaratory judgment jurisdiction." 2005 WL 2415959, *3 (D. Del. Sept. 29, 2005).

On appeal, the accused infringer argued that, despite the dismissal and the patentee's covenant not to sue given in its opposition brief, a case or controversy remained between the parties because the accused infringer wanted to engage in future activities in areas

[1] *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 774 n.11 (2007).

not protected by the safe harbor provision (specifically commercial sales for human use and animal investigations). The Federal Circuit found that the accused infringer came up short because it failed to show the requisite immediacy in its plans to begin the identified future activities to support jurisdiction.

As an initial matter, the Federal Circuit held that even under *MedImmune*, subsequent events can divest a district court of subject matter jurisdiction for a declaratory judgment claim. 2007 WL 2069646, at *4. It also held that the declaratory judgment plaintiff bears the burden of proving that subject matter jurisdiction continues to exist throughout the entire pendency of the suit. *Id.* at *3. Rather than relying on its prior precedent of *Super Sack*, which originally held that a patentee can divest a court of subject matter jurisdiction over a declaratory judgment if it takes acts to moot the controversy,[2] the Federal Circuit analyzed the issue anew under *MedImmune* since *Super Sack* relied in part on the discredited "reasonable apprehension" standard. *Id.* at *5.

Addressing the accused infringer's arguments that a sufficient controversy remained between the parties, the Federal Circuit noted that the accused infringer did not even anticipate filing a NDA for at least three to five more years, and hence its future plans to market a product for human use were several years away. This failed to show a sufficient immediacy of the dispute to find an actual case or controversy. *Id.* at *5. Regarding the planned animal investigations, the court found that the accused infringer had failed to show that it actually had undertaken any animal investigations or had made any definite offers to sell products to any suppliers in the animal market. The accused infringer had only showed that it had entered into a confidentiality agreement with an unnamed entity and expected "to begin work shortly," but had failed to show concrete steps of having begun actual work that could potentially be accused of infringement. Thus, the Federal Circuit concluded that the accused infringer failed to show that it "engaged in any present activity that could subject it to a claim of infringement," and therefore failed to show that a case or controversy continued to exist. *Id.* at *7-*8. Noting that "to allow such a scant showing to provoke a declaratory judgment suit would be to allow nearly anyone who so desired to challenge a patent," the Federal Circuit affirmed the dismissal of the invalidity counterclaim for lack of subject matter jurisdiction. *Id.* at *8.

Judge Dyk dissented. He agreed that the accused infringer's actions regarding future human use and animal investigations did not show a sufficient degree of immediacy to sustain subject matter jurisdiction if the accused infringer had filed its claim as an original declaratory judgment action. *Id.* at *9. But since the accused infringer filed its declaratory judgment claim as a counterclaim to the patentee's original infringement complaint, Judge Dyk thought a different standard should apply. He construed the Supreme Court's holding regarding the public importance of validity challenges in *Cardinal Chemical Co. v. Morton Int'l, Inc.*, as mandating that a lower standard for showing a sufficient case or controversy should apply to invalidity declaratory judgment counterclaims where a patentee, after asserting infringement allegations, withdraws its infringement allegations in an attempt to defeat the invalidity challenge to its patent. *Id.* at *11-*12. According to Judge Dyk, an accused infringer's declaratory judgment counterclaim for a determination of invalidity "should not be dismissed unless *the patentee* demonstrates that there is no possibility of a future controversy with respect to invalidity." *Id.* at *9. Thus, Judge Dyk would place the burden to moot an accused infringer's declaratory judgment counterclaim on the patentee rather than having the burden on the accused infringer to show that a controversy remains.

§ 271(e)(1) Safe Harbor

Back in June 2005 the Supreme Court in *Merck KgaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), rejected the Federal Circuit's ruling that the safe harbor provision of § 271(e)(1) has a narrow scope and does not apply to experimental activity related to finding an optimal drug candidate where such experimental activity results in data that the infringer never submits to the FDA. In *Merck*, the Supreme Court held that a use of a patented drug can, in appropriate circumstances, qualify for the exemption of § 271(e)(1) even if the accused infringer never ultimately submits data to the FDA. But, basic research on a patented drug without the intent to develop it to the point of seeking FDA approval or without having a reasonable basis for believing the experiments will yield information relevant to the regulatory process would not qualify for the exemption. In view of this statutory construction, the Supreme Court vacated the Federal Circuit's affirmance of a jury verdict finding that the accused

[2] *See generally* see Robert A. Matthews, Jr., ANNOTATED PATENT DIGEST §§ 37:56 – 37:60 [*hereinafter* APD].

infringer's experimental activities seeking to understand the mechanism of action, efficacy, pharmacology, pharmacokinetics, and safety of a certain type of peptide to influence a specific biological process and to find the optimum candidate for further pharmaceutical development was an infringing use that did not qualify for the § 271(e)(1) exemption.

After a two-year pendency on remand, the Federal Circuit ruled, as a matter of law, in *Integra Lifesciences I, Ltd. v. Merck KgaA*, No. 2002-1052, 2007 WL 2142878 (Fed. Cir. July 27, 2007), that the accused experimental activities fell within the scope of the safe harbor provision as construed by the Supreme Court, and therefore reversed the finding of infringement. The Federal Circuit construed the Supreme Court's holdings in *Merck*, as mandating that "studies of compounds that are not ultimately proposed for clinical trials are within the FDA exemption, when there was a reasonable basis for identifying the compounds as working through a particular biological process to produce a particular physiological effect." *Id.* at *5. Because the uncontradicted evidence showed that all of the accused experiments were performed after the discovery that a cyclic RGD peptide inhibited angiogenesis – the biological process under investigation – the accused activities designed to understand the mechanism of action, efficacy, pharmacology, and pharmacokinetics of the RGD peptides fell within the safe harbor of § 271(e)(1) as activities "reasonably related to research that, if successful, would be appropriate to include in a submission to the FDA." *Id.* at *13-*14.

The remand panel also ruled that its opinion did not impact patents covering "research tools" because the asserted patents did not concern "research tools." *Id.* at *13. In partial dissent, Judge Rader objected to the panel's decision as gutting the enforceability of patents directed to "research tools." He viewed two of the four asserted patents as being patents directed to "research tools," and therefore dissented as to the noninfringement finding for these two patents. He characterized the panel's decision as casting a cloud over the practical enforceability of patents covering research tools. He predicted that "[u]niversities and independent researchers will have to understand that their work on research tools is likely to amount only to a charitable (but nondeductible) gift to the pharmaceutical industry." *Id.* at *19. He urged the panel to follow the law of other countries where patented research tools are "protected when used to conduct research as specified by the invention, but fall within an experimental exemption when studied to learn their method of operation or to improve operation." *Id.* Interestingly, Judge Rader's view is strikingly similar to the view Judge Newman stated in her dissent in the original panel opinion. *See* 331 F.3d at 878 (Newman, J.) ("[I]nvestigation into patented things, . . . has always been permitted, and investigation using patented things . . . has never been permitted. . . . Use of an existing tool in one's research is quite different from study of the tool itself.").

Obviousness-type Double Patenting

The Federal Circuit affirmed a summary judgment of invalidity for obviousness-type double patenting in *In re Metoprolol Succinate Patent Litig.*, No. 2006-1254, 2007 WL 2080393 (Fed. Cir. July 23, 2007), where the patentee in its later issuing patent individually claimed an element that it had also recited as being a member of a combination claimed in an earlier issuing patent. More specifically, the court held that a claim in a later issued patent reciting "metoprolol succinate" was invalid for obviousness-type double patenting over an earlier issued parent patent claiming an extended release pharmaceutical composition having an outer core, an inner-layer, and a central core, where the central core had one of eleven possible active ingredients of which "metoprolol succinate" was one of the ingredients. Ruling that it would have been obvious to omit the outer core and inner layer and use just the active ingredient, the Federal Circuit found that the claim to the active ingredient as a chemical composition was obvious in view of the earlier-claimed combination. *Id.* at *5. The court also rejected the patentee's argument that a double-patenting analysis should turn on whether the claims are characterized as genus-species or combination-subcombination claims. It found that such "semantic distinctions" are irrelevant in the double patenting context. *Id.* Finally, although the court affirmed the invalidity summary judgment, it further vacated a summary judgment finding inequitable conduct since it had yet to decide whether a terminal disclaimer filed during litigation will have retroactive effect in overcoming an invalidity finding for obviousness-type double patenting. *Id.* at *8 n.4.

Judge Shall dissented from the finding of invalidity. In his view, because the earlier issued claim, i.e., the claim directed to the outer core, inner-layer and central core combination, was a three-element composition claim and the later issued claim

to just "metoprolol succinate" was a single element claim, the two claims claimed different inventions based on the principle that the court should consider the invention "as a whole." *Id.* at *11.

Infringing Method Claims

Vacating a summary judgment of infringement, the Federal Circuit reiterated in *Cybersettle, Inc. v. Nat'l Arbitration Forum, Inc.*, No. 2007-1092, 2007 WL 2112784 (Fed. Cir. July 24, 2007) (*nonprecedential*), that method claims are only infringed if the accused process performs all the steps of the claimed method. Showing that an accused device has the capability to perform a recited step without more ordinarily does not prove that the method claim is infringed. Hence, the court stated that: "It is not enough that a claimed step be 'capable' of being performed. A party that does not perform a claimed step does not infringe a method claim merely because it is capable of doing so." *Id.* at *3. Applying this principle, the Federal Circuit held that the district court, in construing claims directed to an on-line dispute resolution system, erroneously construed the claimed steps of "receiving a plurality of demands" and "receiving a plurality of settlement offers" as only requiring the capability of receiving at least two demands and two settlement offers. Instead, the correct construction required that the method actually receive at least two demands and two offers. In reaching this conclusion, the Federal Circuit rejected the patentee's argument that requiring the actual receipt of two or more demands and offers, rather than just the capability of receiving two or more demands and offers, would read out one of the preferred embodiments because other claims of the patent covered the allegedly omitted embodiment. The court stated that "our interpretation of claim 1 does not exclude the discussed embodiments from the scope of the claimed *invention*, but only excludes those embodiments from the scope of *that claim*." *Id.* at *5 (emphasis added). Also rejecting the patentee's argument that the narrow claim construction was illogical because it only covered one aspect of use of the claimed method, the Federal Circuit explained that "[p]atents frequently contain claims to devices or methods whose scope includes fewer than all the embodiments that would routinely be used in practice." *Id.* at *4.

Appealing ITC Exclusion Orders

In a highly publicized case between Broadcom Corp. and Qualcomm, Inc. before the United States Int'l. Trade Commission, the Federal Circuit in *LG Elecs. MobileComm U.S.A., Inc. v. U.S. Int'l Trade Comm'n*, No. 2007-1392, 2007 WL 2110799 (Fed. Cir. July 20, 2007) (*nonprecedential*), dismissed the defendants' appeal of an ITC limited exclusion order for lack of subject matter jurisdiction. The exclusion order prohibits the importing of chips made by the defendant, Qualcomm, and prohibits nonparties from importing handheld wireless communications devices, such as cellular telephone handsets and PDAs, that contain the Qualcomm accused chips. The court held that since the sixty-day period for presidential review had not expired when the appeal was filed, the ITC's exclusion order did not constitute a final determination that would permit an appeal under 28 U.S.C. § 1295(a)(6). The court further rejected the defendants' arguments that, as an injunctive order, the exclusion order was appealable under 28 U.S.C. § 1292(c)(1), the provision governing appeals of interlocutory injunction orders. Rather in view of the legislatively imposed mechanism of presidential review and the right given to a defendant to post a bond to allow entry of an excluded product, the court held that Congress did not intend to allow § 1292(c)(1) to apply to an ITC exclusion order under these circumstances. Finally, the court also rejected the defendants' arguments that the ITC's denial of their request to stay the exclusion order during the pendency of the appeal provided a jurisdictional basis to review the exclusion order since the denial of a stay is also a non-final order, and therefore it too is not appealable.

Permanent Injunction Denied

On remand from the Supreme Court vacating its original denial of a permanent injunction, the district court in *MercExchange, L.L.C. v. eBay, Inc.*, 2007 WL 2172587, *9-*12 (E.D. Va. July 27, 2007), denied the patentee's renewed motion for an entry of a permanent injunction. Under the totality of the circumstances, the district court found that the patentee had failed to meet its burden of showing it would suffer irreparable harm absent entry of an injunction. Key to the court's ruling was its finding that the patentee was only trying to use the patent as a sword to extract royalties from participants already in the market and not as a means to exercise the right to exclude in a manner to help further develop the patented technology or increase the patentee's reputation as a technology leader. The court also noted that the patentee's decision not to seek a preliminary injunction, but instead to let damages accumulate during the course of the litigation, further

showed that the patentee only sought to use the patent to obtain money. Further, the district court noted that the patentee had stated to the media that it did not seek to shut the infringer down, but that it only wanted a royalty. These factors, coupled with the fact that even after obtaining a jury verdict in its favor, the patentee continued its practice of licensing its patent to any interested member of the public, demonstrated that money damages would adequately compensate the patentee. The district court also rejected the patentee's argument that due to the willful nature of the infringement, the equities demanded the entry of a permanent injunction. According to the court, an award of enhanced damages would fairly compensate the patentee for the willfulness of the infringement. The court also seemed somewhat influenced by the now questionable validity of the patentee's business method patent in view of *KSR*.

The district court also refused to stay further activity in the case regarding the infringed patent even though the PTO, on a subsequent reexamination, had rejected all of the infringed claims. Since the infringer had not sought reexamination until after the jury returned its infringement verdict, the court stated it was "not inclined to stay the post-trial proceedings as doing so would create the incentive for adjudicated infringers to seek to circumvent an otherwise enforceable jury verdict by utilizing an alternate forum." *Id.* at *6. The court did stay further proceedings as to a second patent during the pendency of a reexamination since the circumstances were different for that patent.

Tacking Delay Periods for Laches

The equitable defense of laches generally applies as a product-specific defense, i.e., a patentee's unreasonable delay in filing suit for infringing activities of a first product normally does not apply to also bar presuit damages for a second product sued on within a reasonable period of time. In certain circumstances, however, the period of delay for a first product may be "tacked" on to a second product, thereby extending the defense of laches to the second product. Addressing when such "tacking on" is proper, the district court in *Heraeus Electro-Nite Co. v. Midwest Instrument Co., Inc.*, No. 06-355, 2007 WL 2071905, *5 (E.D. Pa. July 17, 2007), held that "a delay in bringing an infringement suit for different products will 'tack' if the nature of the alleged infringement remains substantially constant throughout the relevant time periods." The court instructed that the analysis does not depend on when the additional products were first introduced to the market, but whether the products are "essentially identical from the viewpoint of an infringement analysis." Applying this standard to the facts before it, the court held on summary judgment that where the accused infringer's expert offered many of the same reasons to support its noninfringement contentions for each accused product, the accused infringer had shown that the products were sufficiently similar so that the delay periods for each product tacked, i.e., would be considered as one continuous period. Nevertheless, the court denied the accused infringer's motion for summary judgment on laches since it found there were issues of fact as to whether the patentee had actual or constructive notice of the alleged infringement sufficient to trigger laches and whether the patentee's voluntary participation in a reexamination proceeding excused its alleged delay in bringing suit.[3]

In a second district court case addressing laches, the court held in *Crown Packaging Technology, Inc. v. Rexam Beverage Can Co.*, 2007 WL 2118785 (D. Del. July 24, 2007), that an accused infringer could present evidence of the patentee's alleged laches to the jury even though, as an equitable defense, laches would be tried to the court. Following one of its prior decisions, the court ruled that a patentee's laches has relevance in assessing the totality of the circumstances regarding willful infringement, and therefore an accused infringer should have the opportunity to present to the jury evidence of laches. *Id.* at *9-*10. Additionally, the district court ruled that where the patentee contends that the willfulness of the accused infringer's conduct is a factor that negates any laches, the patentee has thereby effectively conceded that the evidence of its laches has direct relevance to its claim of willful infringement. *Id.*

Combining Elements to Show Anticipation

Addressing the issue of whether a prior art reference that discloses elements meeting all of the limitations of a claim, but does not disclose those elements arranged exactly as claimed, provides an anticipatory disclosure the district court in *Therasense, Inc. v. Becton, Dickinson*, No. C04-02123 MJJ, 2007 WL 2028197, *6-*7 (N.D. Cal. July 10, 2007), provided an insightful standard to determine if anticipation should be found. The court held that: "Where a prior art reference contains disparate elements in alternative embodiments that appear

[3] For more cases addressing tacking see APD § 11:92.

inconsistent with each other, . . . the burden is on the party asserting anticipation to prove that the prior art reference discloses how all elements could be used together to one of ordinary skill." Applying this rule, the court denied the accused infringer's motion for summary judgment of anticipation and ruled that while individual figures of the prior art reference may have collectively shown all limitations of the claimed invention, the figures appeared to show disparate elements. Because the accused infringer failed to provide expert testimony showing that one of skill in the art would read the prior art reference as disclosing that the disparate elements could be combined as claimed, the court ruled the accused infringer did not meet its burden to show anticipation.[4]

Opinions of Counsel

Acknowledging that judicial opinions often refer to an accused infringer's reliance on an opinion of counsel as asserting an "affirmative defense," the district court held in *LG. Phillips LCD Co., Inc. v. Tatung Co*., 2007 WL 2027334, *3-*4 (D. Del. July 13, 2007) (Farnan, J.), that because the presence of an opinion of counsel is only one factor for the willfulness inquiry, reliance on an opinion of counsel does not rise to the level of a true "affirmative defense" under Rule 8(c) of the Federal Rules of Civil Procedure. Consequently, an accused infringer does not have to formally plead in its answer reliance on an opinion of counsel, nor must a patentee wait for such a pleading before attempting to seek discovery from the accused infringer on whether it will rely on an opinion of counsel. Judge Farnan further noted that timing constraints will apply as to when an accused infringer must notify the patentee that it intends to rely on an opinion of counsel, but that this timing issue is best addressed on a case-by-case basis.[5]

Discovery Sanctions

Several weeks ago, Judge Davis, from the Eastern District of Texas, when imposing a death-knell sanction against a patentee for not complying with discovery obligations, stated that the ruling "makes clear to attorneys and parties in the Eastern District of Texas that they must understand and comply with this Court's discovery rules and their discovery obligations." *ClearValue v. Pearl River Polymers, Inc.*, 2007 WL 1847640, *21 (E.D. Tex. June 28, 2007). As an example showing that the court meant what it said and that it will not tolerate willful disobedience of its discovery orders, Judge Ward punished an accused infringer's willful discovery violations by imposing severe sanctions in *Juniper Networks, Inc. v. Toshiba Am., Inc.*, No. 2:05-CV-479, 2007 WL 2021776, *4 (E.D. Tex. July 11, 2007). In that case, the accused infringer had to produce certain of its source code to the patentee. Instead of seeking alternative relief from the discovery order requiring production of the source code, the accused infringer chose not to produce its source code and told the court that its code was "unavailable," even though it had the code in its possession. Judge Ward found that this attempt at deception showed willful disobedience of the discovery order. As sanctions for the violation, Judge Ward imposed a variety of sanctions limiting what the accused infringer could do at trial, which included 1) precluding the accused infringer from proffering at trial "*any* expert testimony or opinion from *any* source during trial regarding non-infringement, save and except through cross-examination of the plaintiff's expert witnesses;" 2) instructing the jury as to the deliberate misconduct of the accused infringer and telling the jury that it could draw an adverse inference therefrom when assessing the credibility of any of the accused infringer's witnesses; 3) limiting the accused infringer's time for *voir dire* to half the time given to the patentee and limiting the accused infringer to two juror strikes while the patentee would have four strikes; 4) limiting the duration of the accused infringer's opening statement to one-half the time of the patentee's opening statement and limiting the accused infringer's closing statement to one-third the time used by the patentee; and 5) requiring the accused infringer to pay the patentee's attorneys' fees and costs attributable to the discovery abuses.

ADMINISTRATIVE HAPPENINGS

Obviousness Rejections

The PTO has taken several steps to further address the Supreme Court's decision in *KSR* and how that opinion impacts examination of patent applications. As a first step, the Board of Patent Appeals and Interferences redesignated as "precedential" three opinions it previously issued that affirmed obviousness rejections. Under the PTO's internal operating procedures: "All [PTO administrative] judges, including the Chief Judge, are bound by a published or

[4] For more cases addressing this issue see APD § 17:43.
[5] For additional case law on compelling an accused infringer to identify if it will rely on an opinion of counsel and the timing of production of such opinions see APD §§ 41:125 & 41:126.

otherwise disseminated precedential opinion of the Board unless the decision supported by the opinion is (1) modified by the Court of Appeals for the Federal Circuit, (2) inconsistent with a decision of the Supreme Court or the Court of Appeals for the Federal Circuit, (3) overruled by a subsequent expanded panel, or (4) overturned by statute." Standard Operating Procedure 2 (rev. 6), ¶ IV(D) (Aug. 10, 2005). Accordingly, all examiners will have to follow precedential opinions of the Board. District courts need not follow "precedential" board decisions, but such decisions "may carry some persuasive weight since they 'represent the views of a panel of specialists in the area of patent law.'" APD § 2:26 (quoting *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1163 (Fed. Cir. 2006)).

In the first precedential decision, *Ex parte Kubin*, No. 2007-0819, 2007 WL 2070495, *5 (Bd.Pat.App. & Interf. May 31, 2007) (*precedential*), the PTO expressly held that an obviousness rejection based on an "obvious-to-try" situation could be sustained where there are a limited number of predictable possibilities to try and one of skill in the art would have "had reason to try these methodologies with the reasonable expectation that at least one would be successful." The Board affirmed a § 103 rejection to a claim directed to an "isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22-221 of SEQ ID NO:2, wherein the polypeptide binds CD48." The Board agreed with the Examiner that the claimed invention was obvious in view of a prior art reference showing a prophetic example isolating a protein that through the application of conventional methods could yield the claimed nucleic acid. Key to the Board's affirmance was its finding that there were only a limited number of predictable ways to isolate a nucleic acid molecule from the disclosed protein. The Board noted that "[u]nder *KSR*, it's now apparent 'obvious to try' may be an appropriate test in more situations than we previously contemplated."

In the second case, *Ex parte Smith*, No. 2007-1925, 2007 WL 1813761, *9-*11 (Bd.Pat.App. & Interf. June 25, 2007) (*precedential*), the Board affirmed an obviousness rejection for claims directed to an insert for a book where each limitation of the claim was found in a combination of prior art references, performed the same role in the claimed invention as in the prior art and did so in a predictable manner, and the applicant failed to show in its specification or through arguments that the one of skill in the art would have been "uniquely challenged" in combining the prior art components in the manner claimed. Stating that *KSR* foreclosed the applicant's argument that "a specific teaching [of a motivation to combine] is required for a finding of obviousness," the Board concluded that "[b]ecause this is a case where the improvement is no more than 'the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement,' no further analysis was required by the Examiner."

In the third case, *Ex Parte Catan*, No. 2007-0820, 2007 WL 1934867,*9 (Bd.Pat.App. & Interf. July 3, 2007) (*precedential*), the Board affirmed § 103 rejection of claims directed to a consumer electronic device that used a bioauthentication means as a security feature in accessing a consumer's credit limit. The Board found that one prior art reference showed all the claim elements as combined in the claimed invention but for the presence of the bioauthentication means. A second prior art reference showed the claimed bioauthentication means. Applying the rationale of the Federal Circuit's opinion in *Leapfrog*, the Board held that in the absence of any evidence of unexpected results or that making the combination was beyond the skill of one of ordinary skill in the art, the claimed invention did nothing more than apply updated technology to an old device in a predictable manner, and therefore was obvious.

On July 20, 2007, the PTO announced that it had sent a draft of final guidelines for use by patent examiners in determining if an invention is obvious in view *KSR* to the Office of Management and Budget (OMB) for review. The PTO further stated that it will post the guidelines on the PTO website after the OMB completes its review. In the interim, it will begin training examiners on implementing *KSR*; no doubt in accordance with the trio of precedential cases noted above. While the guidelines may provide some help to applicants and examiners, the guidelines will not bind the courts or the Board. APD § 2:4; *Kubin*, 2007 WL 2070495, at *10 (stating that the PTO guidelines are not a "rigid test" and affirming a written description rejection over applicant's argument that its specification complied with an example in the PTO guidelines showing a sufficient written description).

Continuation Applications and Number of Claims

On July 25, 2007, the PTO announced that late this summer it expects to publish its final rules for limiting

continuation applications and the number of claims that will be examined in an application. It further noted that new "rules will become effective at least 60 days after publication in the Federal Register, and no earlier than October 1, 2007."

Proposed Changes to PTO Appeal Briefs

In a July 19 announcement, published in the July 30 issue of the Federal Register, the PTO proposed a comprehensive and lengthy set of new rules to govern the content and format of briefs submitted to the Board of Patent Appeals and Interferences. 72 Fed. Reg. No. 145, 41472-41490. The PTO will accept comments on the proposed rules through September 28, 2007. Some of the proposed rule changes will substantively impact the prosecution of patent applications and may create far reaching effects for litigation. Hence, practitioners should take heed. For example, for a § 102 or § 103 rejection the new rules require the applicants to not only point out why an examiner's rejection is in error, but also identify each limitation of the claim that allegedly is not found in the prior art, and then explain why the claim is patentable over the prior art. This raises the question, if the applicant fails to identify a limitation as not being present in a reference used to support a rejection, has the applicant effectively admitted that the limitation is present therein for a future litigation? The rules further state that "[a] general argument that all limitations are not described in a single prior art reference would not satisfy the requirements of this paragraph." Some commentators have stated that this rule appears to shift to the applicant the burden of proving patentability where, under the current law, the Examiner is supposed to bear the burden of showing a *prima facie* case of unpatentability before the burden to prove patentability shifts to the applicant. *See* APD § 18:14. Additionally, the proposed rules appear to increase the amount of material an applicant must include in the appeal brief. While that alone may not be overly burdensome, the new rules limit the appeal brief to twenty-five pages of double spaced text presented in 14 point Times New Roman font or the equivalent; footnotes must also be double spaced and incorporation by reference from the appendix is prohibited. Further, all arguments must be presented in the argument section. Any argument not included in the argument section will be deemed waived. There are many other aspects to the proposed rule changes that merit scrutiny, including the requirement to include in the appendices a "drawing analysis section" in which the applicant must identify where limitations are shown in the drawings for each claim separately argued; and a "means-plus-function analysis section" in which the applicant must identify where all corresponding structure can be found in the specification for any means-plus-function limitation contained in any claim separately argued. These requirements appear to apply even if a given limitation is not at issue in the appeal for the claim under consideration. The impact of these appendices in claim-construction analysis in litigation could be dramatic.