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Federal Circuit Finds Product-by-Process Limitations Limited To Recited Process

In En Banc Ruling, Federal Circuit changes course on product-by-process claims, asserts rights are limited by the process terms in the claim when determining infringement.

In *Abbott Labs v. Sandoz*, 90 USPQ2d 1769 (Fed. Cir. 2009) (en banc as to product by process issue), Abbott Labs was the exclusive licensee of U.S. Patent 4,935,507 (the "507 patent"), which occasioned litigation in two separate district courts. The Federal Circuit combined the appeals from the judgments of each of those courts and heard the cases together. In one of the cases, the district court had found that the process limitations were substantive such that the literal scope of the claim required showing that the process was followed in order to infringe the product.

While hearing appeals based on summary judgment issues of non-infringement, the Federal Circuit, *sua sponte*, took en banc the issue of how to construe product-by-process claims for infringement. The Federal Circuit affirmed the lower court's ruling that product-by-process claims are to be construed under the rule in *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992). The Court refused to rely on *Scripps Clinic & Research Foundation*, which taught that the "correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims." *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991). In *Atlantic Thermoplastics*, the patentee asserted that competing, indistinguishable innersoles made by a different process than that outlined in his claim still infringed his patent. The Federal Circuit disagreed and

held that product-by-process claims would be limited by the process included in the claim.

To support its decision to rely on *Atlantic Thermoplastics*, the Federal Circuit relied on numerous Supreme Court cases that noted that "process terms that define the product in a product-by-process claim serve as enforceable limitations." The Federal Circuit also announced that the U.S. Court of Customs and Patent Appeals and the U.S. Court of Claims agreed with the rule. The Federal Circuit also relied on its sister circuits (the 1st Circuit and 3rd Circuit, as well as a precedential ruling from its predecessor court), to provide support for its decision to utilize *Atlantic Thermoplastics*. However, the Court merely recited cases, sometimes with parentheticals, without going into the detailed reasoning of the cases to provide a more persuasive argument for its decision.

The Court did provide analysis from *Cochrane v. Badische Anilin & Soda Fabrik*, (hereinafter "BASF"). *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884). In *BASF*, the patentee claimed a product artificial alizarine that was produced by a specific process. The artificial alizarine was already known in its natural form, and varied from that natural form depending upon the proportion of alizarine and anthrapurpine in the product. Thus, both alizarine and artificial alizarine were products known in the art. The Supreme Court held that the claim for artificial alizarine was limited to the products made by the process steps in the claim. The Supreme Court asserted that "[E]very patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held

to infringe the patent which is not made by that process." 111 U.S. at 310.

The Federal Circuit also cited parentheticals to two other Supreme Court cases that showed support for their position and asserted that the PTO followed a similar line of thinking with regard to product-by-process claims. The Federal Circuit also relied on *Warner-Jenkinson*, which dealt with the doctrine of equivalency, to shore up its reasoning. Specifically, the Federal Circuit noted that the Supreme Court in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997) held that "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention." 520 U.S. at 19. The Federal Circuit applied that logic to product-by-process claims to assert that each element (including process terms) was material to defining the scope of the patented invention. Thus, the Federal Circuit held that, to the extent it is inconsistent with *Warner-Jenkinson* as applied to product-by-process claims, the previous rule of *Scripps Clinic & Research Foundation* was overturned.

The Federal Circuit then dismissed the concerns of the dissent by declaring that the right the dissent "laments" was one that never existed ("the right to assert a product-by-process claim against a defendant who does not practice the express limitations of the claim.") The Court then upheld the legitimacy of product-by-process claims, stating that its decision only clarified that such claims are not infringed by products made by processes other than the ones claimed.

The Federal Circuit also dismissed the jurisprudence of the Court of Customs and Patent Appeals by citing to a passage from *In re Bridgeford*, 357 F.2d 679 (CCPA 1966). Specifically, the Federal Circuit referred to a passage from *Bridgeford* which noted that product-by-process claims were permitted by the PTO to define a patentable product and have developed with the cognizance that courts differ in the interpretation of the claim, with some courts construing such claims to cover only a product made by the particular process set forth in the claim. In its dismissal of this case and the CCPA's jurisprudence, the Federal Circuit noted that the Supreme Court and every circuit court to consider the issue, had construed product-by-process claims to cover only the product made by the particular process set forth in the claim.

The Federal Circuit noted the import of retaining the product-by-process claim structure, but cautioned that the scope of an invention would be held to how it was explicitly defined in the claims. Specifically, the Court noted that since the inventor chose to claim the product in terms of its process, the courts cannot simply ignore

as verbiage the only definition of the invention supplied by the inventor. The Federal Circuit further expounded that, with a product-by-process claim, the only logical way to determine if that claim has been infringed is to compare both products and both processes. The Court explicitly asserts that "[I]f the basis of infringement is not the similarity of process, it can only be similarity of structure or characteristics, which the inventor has not disclosed." Thus, according to the Federal Circuit, suggesting a different rule for product-by-process claims with known and unknown structures would be unnecessary and logically unsound.

After ruling *en banc* on the issue of whether processes provided substantive limitations to product claims during litigation, the Federal Circuit analyzed the claims in the 507 patent. However, the remainder of the Court did not participate in this portion of the opinion. In the instant case, the Federal Circuit also rejected the argument that the language "obtainable by" in the product-by-process claims introduced an optional process, such that the claim is not limited to the explicit process terms included in the claim. In support, the Federal Circuit cited again to *BASF*. The patentee in *BASF* included similar broad language in its patent claim, only to have it rejected by the Supreme Court. There, the Supreme Court refused to attach import to those words, instead holding that the only identification of the claimed invention was through the processes described in the claim.

The Federal Circuit likened the instant case to *BASF*, and ruled that Abbott's claims "do not furnish any test by which to identify the cefdinir crystals except that they are the result of their respectively claimed processes." The Court noted that, without the process steps, there would be no differentiation between the product-by-process claims and the product claims of the 507 patent. Further, the Court pointed to the specification of the 507 patent, which explicitly used specific language to describe the two processes utilized in the product-by-process claims. The Federal Circuit noted that the language was not open-ended, nor a mere description of the process. The Court asserted that it could not ignore the choice to include that language as part of the claims because it must enforce the ways and terms by which a party chooses to define its invention.

The Federal Circuit observed that the prosecution history of the 507 patent also does not support the patentee's contention that "obtainable by" offers an optional set of definitional process conditions. First, the Court pointed to the fact that Abbott Labs cancelled a set of process claims that corresponded to the

product-by-process claims, because the PTO held that the process claims were obvious in view of the product-by-process claims. The Court states that the cancellation of the process claims is proof of the acceptance of the PTO's view that the process elements were critical parts of the product-by-process claims. Second, the Federal Circuit notes that, during prosecution, the product-by-process claims were differentiated from a cited reference because of specific process terms in the claims. The Court asserts that terms considered of import during the patentability analysis cannot be jettisoned for an infringement analysis.

Thus, the Federal Circuit held that the mere use of the word "obtainable by" instead of "obtained by" was not sufficient to broaden the scope of the product-by-process claims or evade the limitations of the process terms in those claims. In summary, the Federal Circuit affirmed the District Court's rulings that the interpretation of product-by-process claims is governed by *Atlantic Thermoplastics*, and noted that merely using phrases such as "obtainable by" will not broaden the scope of a product-by-process claim or allow it to evade the limitations of its process terms.

Newman's dissent to the en banc decision limiting the scope of product-by-process claims

In her dissent, Judge Newman objected to both the procedure and the substance of the majority's en banc decision. With regards to procedure, Judge Newman cited the Federal Circuit's unexplained disregard for Federal Rules of Appellate Procedure 34 and 35 and the Federal Circuit's Internal Operating Procedure 14, because the en banc court failed to give proper notice of the impending en banc action, received no briefing, and held no argument. Judge Newman noted that when "the impact of a sua sponte change of law transcends the interests of the parties to the specific case, notice to the interested public, as well as to the parties, is fundamental to due and fair process." Judge Newman further disdained the en banc court's choice to deprive itself "of input concerning the experience of precedent, of advice as to how this change of law may affect future innovation, and of guidance as to the effect on existing property rights."

With regard to her substantive disagreement with the en banc opinion, Judge Newman advocated a clear distinction between the treatment of product-by-process claims where the products were novel as opposed to such claims where the products were known. Judge Newman began by explaining the reasoning behind product-by-process claims. The "rule of necessity" arose when the courts and the U.S. Patent

Office recognized that not all new products could be fully described by their structure because of the state of scientific knowledge or available analytical techniques. It was also recognized that such products could be distinguished from prior art products by reference to how the product was made. Thus, Judge Newman noted that courts and patent administrators established a product-by-process claim, which had taken various forms. The form at issue in the instant case is one in which the product is new and its structure is not fully or readily known, such that it is defined as a product by referring to the process by which it was made.

Judge Newman observed that the product-by-process claim form has been an accepted way to claim products as products, recognized as an exception to the general rule that new products are claimed without reference to the process by which they were made. This exception was specifically recognized in *Ex parte Painter* in 1891, which noted that the limitations of the English language should not inhibit the rights of an inventor to a patent. Rather, *Ex parte Painter* held that for a product that cannot be properly defined and discriminated from prior art other than by reference to the process by which it is produced, a product-by-process claim may be utilized. 1891 C.D. 200, 200-01 (Comm'r Pat. 1891). Judge Newman continued by expounding upon the importance of recognizing products in this manner especially as technologies continue to become more complex and cited numerous court decisions from District Courts and the CCPA that recognized that product-by-process claims were properly viewed as product claims. See, e.g. *In re Brown*, 29 F.2d 873, 874 (D.C. Cir. 1928); *In re Butler*, 37 F.2d 623, 626 (CCPA 1930); *In re Lifton*, 189 F.2d 261 (CCPA 1951); *Ex parte Pfenning*, 65 U.S.P.Q. 577 (Pat. Off. Bd. App. 1945); *Ex parte Lessig*, 57 U.S.P.Q. 129 (Pat. Off. Bd. App. 1943).

Judge Newman noted that the CCPA confirmed that a product-by-process claim for a novel product was properly construed as a product claim in *In re Bridgeford*, which was also cited by the en banc opinion. Judge Newman disagreed with the en banc court's interpretation of *In re Bridgeford* and offered a more detailed view of the opinion. Specifically, Judge Newman quoted the *Bridgeford* court to demonstrate that the CCPA held that the product-by-process claims where the product could only be defined by the process by which it was made were defined as a product, not a process. Further, Judge Newman pointed out that the opinion explicitly overruled a prior decision (*In re Freeman*) that product-by-process claims were coextensive with process claims. Judge Newman observed that the en banc court erred in its interpretation by failing to distinguish product-by-

process claims for which the full product scope for invention was justified by the necessity rule.

Judge Newman noted that the CCPA continually affirmed this view in *In re Brown*, 429 F.2d 531 (CCPA 1972), *In re Pilkington*, 411 F.2d 1345 (CCPA 1969) and *In re Fessman*, 489 F.2d 742 (CCPA 1974). Judge Newman also pointed to a well-known treatise, Walker on Patents, published in 2008, which re-affirmed the treatment of product-by-process claims that were justified by the necessity rule as product claims and advocated the necessity of such a treatment.

Judge Newman went on to observe that the en banc court seemingly misunderstood this precedent as it asserted, by citing *Hughes*, that the CCPA and Court of Claims mandated a rule similar to theirs regardless of whether the product of the product-by-process claim was known or novel. Judge Newman then expanded upon her interpretation of the holding of *Hughes*, asserting that the *Hughes* court found the product-by-process claim to be improper because the product could have been described without process steps. However, Judge Newman noted that the *Hughes* court still reaffirmed that although product-by-process claims may only recite process steps, it is the product which is covered by the claim and not the process steps. Thus, Judge Newman asserted that the en banc court misinterpreted this holding.

Judge Newman also disparaged the en banc court's misstated precedent of the Court of Claims. Judge Newman distinguished the case which the en banc court cited for support, asserting that the product-by-process claim was directed to a known product. Judge Newman also asserted that the en banc court unfairly disdained the CCPA's experience with regards to infringement litigation and claimed that the Federal Circuit followed in the footsteps of its predecessor court (the CCPA) in distinguishing product-by-process claims justified from the necessity rule. Specifically, Judge Newman pointed to *In re Thorpe*, which was also utilized by the en banc court to support the proposition that all product-by-process claims were to be construed as process claims. Judge Newman distinguished *In re Thorpe* by asserting that the product of the product-by-process claim was not new while stating that the Thorpe court recognized that product-by-process claims are anticipated when the product existed in the prior art even if the product was made by a different process than that claimed.

Judge Newman then cited more recent cases in the biotechnology arena that dealt with a product-by-process claim justified by the necessity rule, with a product that is novel and find that such a claim should be interpreted as a product: *Amgen, Inc. v. Chugai*

Pharmaceuticals Co, 706 F. Supp. 94 (D. Mass 1989); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991). Specifically, Judge Newman noted that the *Scripps* court held that since claims were to be construed the same way for infringement as for validity, infringement could only occur if the two products were the same, regardless of the process by which they had been made.

Judge Newman also discussed the decision from *Atlantic Thermoplastics*, which was decided by the Federal Circuit a year after the *Scripps* decision. In that case, the Federal Circuit refused to distinguish between product-by-process claims where the product was either novel or known. The Atlantic court held that the rule of necessity as applied in *Scripps* was contrary to Supreme Court rulings, but declined to resolve the conflict en banc. Citing *Trustees of Columbia University v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000), Judge Newman noted that courts have still continued to recognize the rule of necessity after the *Atlantic Thermoplastics* ruling.

Judge Newman also expressed surprise at the en banc court's casual misstatement of the PTO's treatment of product-by-process claims. Judge Newman clarified that the PTO's operating manual explicitly endorsed the view that product-by-process claims should be considered by the structure implied by the process claims, but not limited to the process itself. MPEP 2113 (8th ed., July 2008 rev.).

Next, Judge Newman considered the Supreme Court cases cited in the en banc opinion, noting that most are directed towards cases where the product in the product-by-process claim was known and thus interpretation of the process claims was appropriate to distinguish over the known product using the novel process. First, Judge Newman discussed the *BASF* opinion upon which the en banc court relied heavily. Judge Newman disparaged the opinion as providing no support to the position that every product claim that mentions a process step is always restricted to that process, because the product in the *BASF* claim was known and thus such a ruling relying on the process was consistent with known law.

Judge Newman also detailed the Goodyear Dental cases upon which the en banc court relied. *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. (3 Otto) 486 (1876); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. (12 Otto) 222 (1880). The claims in the Goodyear Dental case were not product-by-process claims but rather were written in the then-standard format of incorporating the description in the specification through the phrase "substantially as described." The

Supreme Court held that these claims were for products or manufacture made in a defined manner, and thus could not be separated from the process by which they were created. Further, the Supreme Court held that the products alone would not have been patentable, unless limited to this process. Judge Newman asserted that the en banc court incorrectly took this holding, which was not even explicitly applied to product-by-process claims, to mean that the Supreme Court requires all claims for products whose method of product is set forth in the specification to be infringed only if the method detailed in the specification is utilized.

Judge Newman also distinguished *Merrill v. Yeomans*, 94 U.S. (4 Otto) 569 (1877), upon which the en banc majority relied for support. Judge Newman detailed that the *Merrill* case also did not deal with product-by-process claims. The Supreme Court had explicitly found that the invention as a whole was solely directed towards a process, not towards a product. Thus, the claim at suit was necessarily a process claim, not a product claim. Judge Newman held that the en banc court's assertion that regardless of what the patentee described as his invention, a process step in a product claim would be considered, was inimical on the basis of the *Merrill* case. The Supreme Court in that case thoroughly considered the specification to determine what was invented, and failed to hold that every product invention must be limited by the process that produced that product.

The en banc majority also relied substantially on *Wood Paper Patent*, 90 U.S. 566 (1874) as invalidating the *Scripps* holding. Judge Newman detailed the holdings of the court regarding the two reissued patents at issue in *Wood Paper*. The Supreme Court held that the claim at issue in the first reissue patent was for a product and not the process by which it was obtained. The Court invalidated the claim on the basis that the product obtained by the new process was not a new product. The Court invalidated the second reissue patent on the basis that it claimed a different invention than that in the original patent. Judge Newman explicitly stated that she had been unable to discern, from either the opinion of the case or the opinion of the en banc court, how the en banc majority could have utilized the *Wood Paper Patent* case to invalidate the *Scripps* opinion.

Judge Newman also provided her own analysis of *Plummer v. Sargent*, 120 U.S. 442 (1887) that the en banc court cited. The claim in the *Plummer* case was for a new manufacture, substantially as described. Previously, the trial court had found non-infringement of the claim because the defendant had used a different process for achieving the product. The Supreme Court

affirmed that the claims were limited to the process described in the specification on the basis that the claims would otherwise be void by reason of anticipation of the prior art cited in the trial court. Judge Newman asserted that the reasoning of the Supreme Court in this case was not based on claim construction but rather based on sustaining the validity of the *Plummer* patent.

Judge Newman also commented on apparent lack of relevance in the en banc's use of *General Electric Co. v. Wabash Appliance Corp.*, 304 U.S. 364 (1938). Judge Newman observed that the typical claim at issue was directed towards a product, and had no process steps in the claim. Thus, those process steps could not have been construed by the Supreme Court as limiting the scope of the product claim. The Supreme Court held the claim invalid for indefiniteness and noted that the court doubted whether one would ever not be able to describe some aspect of a product's novelty. However, Judge Newman stated that the Supreme Court's dictum in this case was insufficient to overturn years of judicial recognition of the rule of necessity.

Judge Newman also noted with surprise the en banc court's reliance on the decisions of regional circuits that preceded the formation of the Federal Circuit given that court's disdain for the precedent of the CCPA and Court of Claims. She summarized the cases which the en banc court had noted and expanded the summary to include other pertinent regional court cases. Judge Newman first mentioned *Hide-It Leather Co. v. Fiber Products Co.*, 226 F. 34 (1st Cir. 1915), which the en banc court also discussed. In *Hide-It Leather*, the invention was directed towards a product claim with process terms along with a reference to the specification "substantially as described." The court held that the claim was for a process, not a product.

Judge Newman also analyzed *Paeco, Inc. v. Applied Moldings, Inc.*, 562 F.2d 870 (3rd Cir. 1977). In determining a question of anticipation, the *Paeco* court stated that the manufacturing process for the product was of utmost importance, and construed the claim in light of that process to preserve the claim's validity. Judge Newman asserted that the construction of that product claim in light of the process by which it was made was taken out of its proper context by the en banc court.

Judge Newman also cited *Dunn Wire-Cut Lug Brick Co. v. Toronto Fire Clay Co.*, 259 F. 258 (6th Cir. 1919), which emphasized that product claims cover the product regardless of the variations in the method of making the product.

Finally, Judge Newman mentioned *Buono v. Yankee Maid Dress Corp.*, 77 F.2d 274 (2d. Cir. 1935), where the 2nd Circuit held that a claim for a known product made by a novel process would be limited to products produced by that novel process.

In the final section of the dissent, Judge Newman took issue with implications of the en banc court's change of law. First, she disagreed with the difference in claim construction that the majority allowed with regards to interpretation for validity and for infringement. Second, Judge Newman opposed the en banc majority's conclusion that the best way to compare compounds for infringement was through analysis of the processes by which the compounds were made. Next, Judge Newman dissented from the application of the en banc court's opinion to the term "obtainable by." Finally, she asserted with the majority's view of the implications of this ruling were misjudged.

Judge Newman took issue with the fact that a patent applicant would have to demonstrate patentability of the product of a product-by-process claim to obtain the patent while infringement of the product-by-process claims would be limited to the infringer's use of the process steps. Judge Newman provided a barrage of citations that stress that the scope of claims for validity and infringement must be the same. Further, Judge Newman failed to recognize the distinction between the scope of claims for patentability, validity, and infringement. Judge Newman herself cited a Supreme Court case (*Plummer*) and a 3rd Circuit case (*Paeco*) in which the courts construed the product-by-process claims to include process terms only the sake of upholding their validity. More research is necessary to clarify this issue and determine if the treatment of claim scope for product-by-process claims differs from that of other claims.

Judge Newman also disagreed with the en banc court's conclusion that the best way to compare compounds for infringement was through analysis of the processes by which the compounds were made. Judge Newman provided examples, using the subject matter of the invention at issue, of how to determine if two products with unknown structures were identical. Thus, Judge Newman opposed the en banc majority's simplistic take on novel products whose structures were unknown.

Further, Judge Newman asserted that the application of en banc court's decision to the interpretation of the term "obtainable by" was incorrect. The majority opinion held that a claim cannot capture a product obtained by or obtainable by processes other than those explicitly recited in the claims. Judge Newman noted that the majority reached this conclusion through the

continued misapplication of *BASF* (the product-by-process claim in *BASF* was directed towards a known product). Further, Judge Newman disagreed with the majority's glib dismissal of the applicant's statement in the file wrapper regarding the heart of his invention. In response, Judge Newman cited Supreme Court and Federal Circuit decisions extolling the importance of utilizing the specification to interpret a claim.

Finally, Judge Newman commented on the misjudgment of the majority opinion's implications for its ruling. Judge Newman quoted the majority opinions remarks that its ruling enables others to practice a different process than that described in the product-by-process claim to make a product in a better way. Judge Newman countered with the argument that a better product would not be the same product as that claimed in the product-by-process claim. The ruling wasn't directed towards fostering different processes than those claimed in a product-by-process claim to make better or different products. Rather, the implication of the ruling is directed towards the right to make the same product by making a process change that does not change the product. Judge Newman asserted that majority ensured that right, to the exclusion of the right to patent a novel product that could not be explained except without reference to the process by which it was made.

Significance for Patent Owners

As discussed extensively in Judge Newman's dissent and set forth in the FEATURE COMMENT: THE BROADENING CHASM BETWEEN CLAIM INTERPRETATION DURING LITIGATION AND EXAMINATION FOR PRODUCT BY PROCESS CLAIMS, the implications of *Abbot Labs v. Sandoz* are many. On one level, the establishment of such a bright line rule will simplify the analysis for purposes of infringement since patent owners will have a single potential claim scope for apparatus claims recited in terms of its manufacturing process. On another level, the implications for existing patent owners and patent applicants are that what was previously thought to be a broad apparatus claim is now greatly narrowed to recite both the product and the process. Additionally, there is now a substantial conflict between how claims are interpreted during examination as compared to how claims are interpreted for purposes of infringement, as well as how claims are interpreted during Markman hearings for purposes of validity and infringement. Therefore, while purportedly simplifying the issue, it remains to be seen if the Federal Circuit will extend this rule in order to ensure that claims have consistent scope for purposes of validity and examination, or whether the

Federal Circuit will maintain that such analysis must be distinct for infringement as compared to all other forms

of claims analysis.

Federal Circuit Affirms Obviousness of Gene Sequencing Claim As “Obvious To Try.”

In *In re Kubin*, 561 F.3d 1351 (Fed. Circ. 2009), the applicants filed Patent Application Serial No. 09/667,859 drawn to gene sequencing claims. The applicants applied for a patent claiming DNA molecules (“polynucleotides”) that encoded a protein (“polypeptide”) known as the Natural Killer Cell Activation Inducing Ligand (“NAIL”). Natural Killer (“NK”) cells play a major role in fighting tumors and viruses, and express surface molecules that can activate cytotoxic mechanisms when activated. NAIL is a specific receptor protein on the cell surface that is involved in activating NK cells. Applicants claimed the DNA that encodes the CD48-binding region of NAIL proteins. Applicants’ claim 73 described a genus of isolated polynucleotides that encode a protein that binds CD48 and is at least 80% identical to the amino acid sequence that Applicants have disclosed in their specification. In their specification, Applicants disclosed generic examples of variants of the amino acid sequence that could be contemplated under their claimed invention as at least 80% identical to the disclosed sequence. However, the applicants did not set forth any specific examples of sequences of any such variants.

The Board upheld a rejection of applicants’ claimed invention under 35 U.S.C. § 112, 1st paragraph for lack of written description and a rejection under 35 U.S.C. § 103(a) for obviousness. With respect to the lack of written description, the Board asserted that applicants had not described what domains of their described amino acid sequences were associated with the required binding to CD48, and thus did not describe which of NAIL’s amino acids could be varied and still bind. The Board held that, without correlating the structure of the sequence with function, the specification did not provide adequate written description for claim 73.

The Board also affirmed that claim 73 was obvious under 35 U.S.C. § 103(a), under the combined teachings of U.S. Patent No. 5,688,690 (“Valiante”) and 2 Joseph Sambrook et al., *Molecular Cloning: A Laboratory Manual* 43-84 (2d ed. 1989) (“Sambrook”). The Board found (and Applicants did not dispute) the receptor protein p38 of Valiante to be the same protein as NAIL, existing on the surface of the NK cell and able to activate cytotoxicity. Valiante taught that the DNA and protein sequences for p38 could be obtained by conventional methods (such as those set forth in Sambrook). The

Board held that the disclosure of p38, along with a detailed method of isolating its DNA, including disclosure of a specific probe to do so, established Valiante’s possession of p38’s amino acid sequence and provided a reasonable expectation of success in obtaining a polynucleotide encoding p38, within the scope of applicants’ claim 73. Further, the Board asserted that, given the importance of NAIL’s role in human immune response, motivation existed to apply conventional methodologies (like those of Sambrook) to isolate the NAIL cDNA.

On appeal, the Federal Circuit sustained the Board’s factual inquiries underlying the 35 U.S.C. § 103(a) rejection. Specifically, the Applicants argued that there is insubstantial evidence to find that their methodology of isolating NAIL is equivalent to the teachings and methodologies of Valiante and Sambrook. However, the Federal Circuit asserted that the claimed invention is not to the processes used, but rather to the results of those processes. The Court held that the record was sufficient to show that Valiante’s examples would produce the claimed nucleotide.

Further, the Federal Circuit found that substantial evidence existed that the Applicants used conventional techniques as taught by Valiante and Sambrook to isolate the gene sequence for NAIL. The Court rejected the Applicants’ argument that Valiante and Sambrook fail to provide guidance for preparing the cell culture to serve as a useful source of mRNA for the preparation of a cDNA library due to Applicants’ own admissions. Specifically, the argument was rejected because Applicants asserted that the nucleic acid molecule had been derived from DNA or RNA isolated in pure form and in a quantity or concentration that enabled identification, manipulation and recovery of its component nucleotide sequences using standard biochemical methods (such as those provided by Sambrook).

The Federal Circuit further held that prior art showing NAIL’s binding to the CD48 protein was not necessary to assert a finding of obviousness because CD48 binding is a property necessarily present in NAIL. The Federal Circuit noted that discovering new qualities in a product that others had discovered or new functionality in a structure suggested by prior art is not an invention. *In re Wiseman*, 596 F.2d 1019, 1023 (CCPA 1979); *Gen.*

Elec. Co. v. Jewel Incandescent Lamp Co., 326 US 242, 249 (1945). Since the Board found that Valiante's p38 was the same protein as applicants' NAIL protein, Valiante's teaching to obtain the cDNA encoding of p38 necessarily teaches one to obtain the cDNA of NAIL. P38's cDNA would necessarily exhibit the CD48 binding property and would fall under the scope of claim 73.

The Federal Circuit next rejected the idea that the "obvious to try" test should only be applied to predictable arts (as opposed to a more unpredictable arena like biotechnology). The Federal Circuit held that patent law does not customize its tests for specific scientific fields. In so doing, the Federal Circuit noted that its prior decision in *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), which held that obvious to try was inappropriate as an obviousness rationale in the biotechnological arts, was suspect and greatly limited or overruled after the Supreme Court's decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). Rather, the Supreme Court held in *KSR* that where there is an identified need or pressure, and a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue known options within his or her technical grasp. Solutions of this kind would not be the product of innovation, but rather one of ordinary skill and common sense. Thus, the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. § 103.

After rejecting the analysis in *In re Deuel*, the Federal Circuit noted that the Supreme Court "actually resurrects this court's own wisdom in *In re O'Farrell* [853 F.2d 894, 903 (Fed. Cir. 1988)]." *In re O'Farrell*, which predated *In re Deuel*, noted that obvious to try was a rationale supporting an obviousness rejection. However, the Federal Circuit also noted that the court in *In re O'Farrell* "cautioned that 'obvious to try' is an incantation whose meaning is often misunderstood." In order to differentiate between obviousness resulting from obvious to try and impermissible hindsight, the court in *In re O'Farrell* outlined situations (paralleled in *KSR*) in which passing the "obvious to try" test would be erroneously equated with obviousness.

The first class of cases to which "obvious to try" should not be applied were those where the prior art gave no indication which parameters to vary or which choices were likely to be successful. The second class of cases consisted of those exploring new technologies or a general approach where only general guidance existed as to the particular form of the invention or how to achieve it. However, in contrast to these two cases, an obviousness finding under an "obvious to try" test would be appropriate when the prior art "contained detailed

enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful." 853 F.2d at 902 (emphasis added). The prior art did not have to require absolute predictability of success, but merely a reasonable expectation of such.

The Federal Circuit held that the Applicants' case was dissimilar to either of the erroneous "obvious to try" classes. With regards to claim 73, Valiante and Sambrook, which together teach a protein identical to NAIL, a commercially available monoclonal antibody specifically for NAIL, and explicit instructions for obtaining the DNA sequence for NAIL, gave more than general guidance as to how to achieve the specific form of the invention and provide clear direction as to which methods are likely to be successful. Further, the prior art provided a reasonable expectation of successfully obtaining a polynucleotide of claim 73. Thus, the Federal Circuit held that the "obvious to try" test should be applicable in this case. Further, the Court asserted that use of the test shows that claim 73 was obvious and thus not patentable.

The Federal Circuit affirmed the Board's ruling that applicants' claims were obvious as a matter of law under the "obvious to try" test. The prior art provided an identical protein to that claimed by applicants, a commercially available monoclonal antibody for that protein, and explicit instructions for obtaining the DNA for that protein. Thus, the "obvious to try" test was appropriate because the prior art provided clear direction as to which methods were likely to be successful to achieve the invention, and a reasonable expectation of successfully obtaining a polynucleotide under claim 73.

Significance to Patent Applicants

In re Kubin removed a bright line distinction in how to apply obviousness analysis in predictable arts as opposed to those deemed unpredictable. As such, merely by labeling a technology such as biotechnology unpredictable will no longer immunize applicants from the full scope of analysis authorized by the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) and *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966).

That being said, *In re Kubin* also reinforces the requirement that rejections based upon a conclusion that something is "obvious to try" must still be substantiated by evidence. The Federal Circuit in *In re Kubin* heavily relied upon the existence of a manual as

evidence of routine processing, and that the claimed result was merely the routine processing of a known protein. Without such evidence, “obvious to try” is merely a conclusory statement. Therefore, even after

KSR, applicants should require that examiners provide evidence as to why a particular result would have been obvious to try.

Federal Circuit Rejects Ensnarement Defense and Finds that the Ensnarement Defense is an Issue of Law

In *DePuy Spine, Inc. v. Medtronic, Inc.*, Civ. Case Nos. 90 USPQ2d 1865 (Fed. Cir. 2009), DePuy owns U.S. Pat. No. 5,207, 678 (the ‘678 patent). The ‘678 patent is directed to a medical device that is a pedicle screw used in spinal surgeries. DePuy sued Medtronic, accusing Medtronic of infringing the ‘678 patent with Medtronic’s Vertex pedicle screws. The U.S. District Court for the District of Massachusetts denied Medtronic’s ensnarement defense, found that Medtronic engaged in litigation misconduct, with both decisions being appealed before the Federal Circuit Court. Additionally, DePuy cross-appeals from the District Court’s granting of Medtronic’s motion for judgment as a matter of law (JMOL) of no willful infringement and from the denial of DePuy’s motion for a new trial for reasonable royalty damages.

In a prior appeal, the Federal Circuit Court upheld the District Court’s granting of summary judgment as per Medtronic not literally infringing the ‘678 patent with Medtronic’s Vertex pedicle screws. However, the Federal Circuit Court reversed the District Court’s granting of summary judgment of noninfringement under the doctrine of equivalents. In the prior appeal, the Federal Circuit Court remanded the case because it found a question of fact existed on whether the Vertex screw’s conical shape was insubstantially different from the ‘678 patent’s screw having a limitation in claim 1 of the patent reciting a “spherically-shaped portion. In the remanded case, Medtronic asserted an “ensnarement” defense against the doctrine of equivalents issue, wherein the Medtronic asserted that the scope of equivalency of the ‘678 patent would “ensnare” the prior art.

The District Court, in holding that ensnarement is a legal limitation of the doctrine of equivalents, decided the ensnarement would be decided by the District Court at the end of the infringement proceeding and would not be decided by the jury. Further, the District Court found that the prior art was not ensnared by a hypothetical claim meant to cover the allegedly infringing device.

On appeal, the Federal Circuit stated that ensnarement bars a patentee from asserting a scope of equivalency for the present invention that would encompass or

“ensnare” the prior art, *citing Wilson Sporting Goods Co. v. David Geoffrey & Assoc.*, 904 F.2d 677, 683 (Fed. Cir. 1990). In appealing the District Court’s denial of Medtronic’s ensnarement defense, Medtronic asserts that the ensnarement issue should have gone to the jury, rather than being decided by the District Court because the underlying factual issues are to be resolved by the jury, if such is requested.

The Federal Circuit Court stated that ensnarement should be treated, for procedural purposes, the same as prosecution history estoppel, and found that “[u]ltimately, however, ensnarement is a question of law for the court, not the jury, to decide.” The Federal Circuit Court stated that the Supreme Court, in *Warner-Jenkinson Co., v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997), recognized “various legal limitations on the application of the doctrine of equivalents...,” which “are to be determined by the court either on a pretrial motion for partial summary judgment or on a motion for judgment as a matter of law at the close of the evidence and after the jury verdict.” The Federal Circuit Court goes on to note that, although the Supreme Court did not explicitly recognize ensnarement as one of the various legal limitations on the application of the doctrine of equivalents, the Federal Circuit Court has consistently treated ensnarement as one of the various legal limitations.

In *citing Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 870 (Fed. Cir. 1985), the Federal Circuit Court stated that “[w]e have called ensnarement and prosecution history estoppel, collectively, “two policy oriented limitations” on the doctrine of equivalents, both of which are “applied as questions of law.”” Furthermore, the Federal Circuit Court went on to say that “[e]nsnarement, like prosecution history estoppel, limits the scope of equivalency that a patentee is allowed to assert. This limitation is imposed even if a jury has found equivalence as to each claim element,” *citing Wilson Sporting Goods*, 904 F.2d at 683, 687. Consequently, the Federal Circuit Court views ensnarement as a question of law, and reviewed the ensnarement defense asserted by Medtronic de novo.

For ensnarement, the Federal Circuit Court states that “the burden of persuasion is on the patentee to

establish...that the asserted scope of equivalency would not ensnare the prior art, *Wilson Sporting Goods*, 904 F.2d at 685.” However, in resolving ensnarement’s factual issues, the Federal Circuit Court states that “a district court may hear expert testimony and consider other extrinsic evidence regarding: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art; and (4) any relevant secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).” As such, the Federal Circuit Court goes on to say that “[i]f a district court believes that an advisory verdict would be helpful, and that a “hypothetical claim” construct would not unduly confuse the jury as to the equivalence and validity, then one may be obtained under Federal Rule of Civil Procedure 39(c). See, e.g., *Interactive Pictures Corp. v Infinite Pictures, Inc.* 274 F.3d 1371, 1375 (Fed. Cir. 2001).” The Federal Circuit Court relied upon a hypothetical claim that both parties in the suit agreed as literally covering Medtronic’s Vertex pedicle screw.

In analyzing whether the patentee has carried the burden of persuading the court that the hypothetical claim is patentable over the prior art, the Federal Circuit Court looked at Puno and Anderson, two references introduced by the accused infringer, Medtronic. Both parties agreed that Puno contains all elements of the hypothetical claim except for a “compression member” that presses a screw head against a receiver member. Medtronic asserts that Anderson teaches the compression member missing from Puno, and thus teaches a rigid pedicle screw. However, because Puno “teaches away” from a rigid screw that increases the likelihood that the screw would fail in the human body, DePuy argues, and the District Court found that Puno’s teachings counter the reason for which Medtronic argues would make the combination of Puno and Anderson obvious, i.e. the creation of a rigid pedicle screw.

Medtronic’s argument as per a reason to combine Puno and Anderson relies upon other teachings in the prior art, which Medtronic asserts would have motivated a person of ordinary skill to look past Puno’s warnings regarding a rigid pedicle screw. Medtronic points to a decision of the Federal Circuit Court, wherein the term “operatively” of claim 5 of Puno was interpreted to mean “posterior stabilization of the spine” rather than “micro-motion.” In the present appeal, Medtronic asserted that because of the previous claim construction of Puno claim 5, the pedicle screws of Puno are not limited to “micro” or “limited” motion, and thus, can be rigid. However, the District Court stated that it was not clear that “posterior stabilization” and “micro-

motion” were mutually exclusive, and thus rejected Medtronic’s argument, which the Federal Circuit Court affirmed.

Additionally, Medtronic proffered two additional prior art references, Harms (U.S. Patent No. 4,946,458) and Puno (U.S. Patent No. 4,805,602). Harms, which has the same inventors as the ‘678 patent, and discloses a tightening and loosening of fasteners allowing for a stiff connection or dampening movement. However, the Federal Circuit Court notes that the Harms patent does not disclose “why a person of ordinary skill would have “desired” either of these rigidity levels, much less why a rigid connection would have been selected in the face of Puno’s warning against such rigidity.” Puno ‘602, which lists Dr. Rolando Puno as a co-inventor, discloses a screw-and-rod system having an intermediate amount of rigidity as a resolution between the decreasing rigidity of wired systems and the rigidity of plate systems. However, the Federal Circuit Court notes that “Puno ‘602 consistently views low rigidity as an advantage and high rigidity as a disadvantage...[and] thus bolsters, rather than undermines the district court’s finding that the prior art teaches away from rigid pedicle screws.” Thus, with the Federal Circuit Court consistently noting that Puno, in light of the teachings of the considered prior art, teaches away from rigid pedicle screws, the Court found that the District Court was correct to find that a person of ordinary skill would have been discouraged in combining Puno and Anderson for the purpose that Medtronic asserts.

The Federal Circuit Court also looked to secondary considerations, and specifically “failure by others” and “copying” to support the conclusion that Medtronic’s asserted combination of Puno and Anderson would not be obvious to one of ordinary skill in the art at the time of the invention. The Federal Circuit Court notes that the ‘678 patent, which was published in May 1993, had a priority date of ‘1989, and while Medtronic’s engineers were attempting to solve the same problem for which the ‘678 patent is directed towards, namely making the device more rigid, Dr. Kevin Foley of Medtronic viewed a device design with no compression member to be the best solution through April 1993. However, when the ‘678 patent was issued in May 1993, Medtronic’s engineers changed their device design by inserting a compression member into the pedicle screw device, similar to what was disclosed in the ‘678 patent. In the appeal, Medtronic asserted that it attempted avoid infringement by designing around the ‘678 patent’s “spherically-shaped” limitation, however, Medtronic was unsuccessful.

The Federal Circuit Court agreed with the District Court's finding that secondary considerations indicate nonobviousness. Particularly, Medtronic's quick adoption of the compression member after the '678 patent was issued and because Medtronic argues that such addition of the compression member was obvious despite their initial attempts at making a rigid pedicle screw without the compression member indicate nonobviousness. Thus, the Federal Circuit Court found that the secondary considerations further support the District Court's holding that the hypothetical claim would not have been obvious in light of the prior art, and that Medtronic's ensnarement defense was properly denied.

The Federal Circuit Court also addressed whether the Jury's awarding of lost profits to DePuy, for the amount of \$149.1 million as per the pedicle screws and \$77.2 million as per "pull-through" products, was proper. In order to establish lost profits, DePuy relied upon the four-factor *Panduit* test requiring a showing of (1) demand for the patented product, (2) lack of acceptable non-infringing substitutes, (3) manufacturing and marketing capability to meet the demand for the patented product, and (4) the amount of profit that would have been made by sales of the patented product. *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978).

Medtronic contested the sufficiency of DePuy's showing of the first two factors. As per showing a demand for the patented product, Medtronic argues that DePuy failed to show that demand for DePuy's '678 patent product was due to the "top-loading" feature of the screw. However, the Federal Circuit Court stated that Medtronic's argument "unnecessarily conflates the first and second Panduit factors," and that the first factor "does not require any allocation of consumer demand among the various limitations recited in a patent claim." The Court went on to state that the first factor merely requires a showing of demand for the patented product, which is a product "covered by the patent in suit" or that "directly competes with the infringing device," and cited *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1548-49 (Fed. Cir. 1995) (en banc) for support. The Federal Circuit Court went on to hold that "the focus on particular features corresponding to individual claim limitations is unnecessary when considering whether demand exists for a patented product under the first Panduit factor."

As per the second Panduit factor, Medtronic asserted that non-infringing bottom loading screws were available on the market during the time at issue. However, the Federal Circuit Court stated that "because Medtronic did not actually have a noninfringing

substitute "on the market" during the relevant accounting period, it was Medtronic that bore the burden of overcoming the inference of unavailability," citing *Grain Processing Corp. v. Am. Maize-Products Co.*, 185 F.3d 1341, 1353. Medtronic asserted that bottom-loading screws could have been made during 2000-2003, and that it did provide such screws in 2007. However, DePuy introduced evidence showing Medtronic was unsuccessful in designing a bottom-loading screw until 2007. Thus, the Federal Circuit Court held that "a reasonable jury could have concluded...that...the bottom loading design would not have been available or acceptable to consumers before the end of 2003."

Furthermore, Medtronic asserts that being precluded from introducing the District Court's 2004 summary judgment ruling that Medtronic's Vertex screws did not infringe the '678 patent was unfair, because the ruling would help the jury to understand why Medtronic did not switch to bottom-loading screws until 2007. The Federal Circuit Court noted that the District Court's summary judgment didn't address Medtronic's failure to design a bottom loading screw until 2007 and overcome technical and regulatory hurdles in introducing a non-infringing design to the market. Additionally, with the likelihood of jury confusion resulting from the District Court having to explain how the summary judgment was overruled in part as per equivalence, but not direct infringement, the Federal Circuit Court held that excluding the summary judgment was not an abuse of the District Court's discretion. Thus, the Federal Circuit Court affirmed the jury's award of lost-profits as per DePuy's pedicle screws.

In addition to the lost-profits of \$149.1 million as per the pedicle screws, the jury also awarded DePuy \$77.2 million as per "pull-through" products, which included such products as head braces and vests that are not related to the '678 patent or spinal surgery. The Federal Circuit Court noted that "these products are related only by virtue of the business relationship that is created when a customer first buys a patented Summit and Mountaineer device." The Federal Circuit Court went on to note that lost profits are recoverable for unpatented items when they are assembled with or function with the patented item. *American Seating Co. v. USSC Group*, 514 F.3d 1262, 1268 (Fed. Cir. 2008). However, because the "pull-through" products were only sold due to DePuy's business relationships with the surgeons buying DePuy's patented pedicle screws, the Federal Circuit Court reversed the award of lost-profit damages arising from the pull-through products.

On cross-appeal to the Federal Circuit Court, DePuy challenged the District Court's denial of a motion for a

new trial on reasonable royalty damages. In the original trial, DePuy argued for a royalty rate of 15%, whereas Medtronic argued for a rate of 6%. However, the jury awarded a rate of 0%. Although DePuy indicated to the District Court that the jury may have misunderstood the application of the royalty rate shortly after the jury was dismissed, DePuy did not file a motion for a new trial until several weeks later. In denying DePuy's motion, the District Court stated that any inconsistency in the jury's verdict should have been addressed before the jury was discharged, citing *Wennik v. Polygram Group Distrib., Inc.*, 304 F.3d 123, 130 (1st Cir. 2002). In addition to the timeliness of DePuy's motion, the Federal Circuit Court noted that the lost-profits award of \$149.1 million exceeded DePuy's alternate request of \$59.2 million in damages arising from royalties. Thus, the Federal Circuit Court affirmed the District Court's denial of DePuy's motion for a new trial.

DePuy also cross-appealed the District Court's granting of Medtronic's motion for Judgment as a Matter of Law (JMOL) of no willfulness in the infringement of the '678 patent. Applying the willfulness standard of *In re Seagate Technology, LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc) requires showing "by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." The Federal Circuit Court stated that "[w]e agree with Medtronic and the district court that there was no legally sufficient evidentiary basis to find an objectively high likelihood under Seagate's first prong that the Vertex model...infringed the '678 patent." Accordingly, DePuy's argument that "knowingly copying a competitor's patented invention is objectively risky behavior of the highest order," bears upon the state of mind of the infringer, which corresponds to Seagate's second prong and is not relevant to the objective inquiry of the first prong of Seagate. *Seagate*, 497 F.3d at 1371. In the first appeal, the Federal Circuit Court affirmed the District Court's grant of summary judgment of no literal infringement and overturned the District Court's granting of summary judgment of noninfringement under the doctrine of equivalents, and stated that a jury was needed to resolve the remanded question. Even though an accused infringer is not immunized from a finding of willful infringement when the issue of infringement is submitted to a jury, the Federal Circuit Court stated that "the record developed in the infringement proceeding in this case, viewed objectively, indisputably shows that the question of equivalence was a close one, particularly insofar as equivalence "requires an intensely factual inquiry." *Vehicular Tech. Corp. v. Titan Wheel Int'l, Inc.*, 212

F.3d 1377, 1381 (Fed Cir. 2000)." Thus, Federal Circuit Court held that DePuy failed to meet the requirements of Seagate's first prong, and thus did not need to address Seagate's second prong in affirming the District Court's granting of JMOL of no willfulness.

Lastly, Medtronic appealed the District Court's granting of \$425,375 in attorney's fees to DePuy and the \$10 million sanction levied upon Medtronic based upon the District Court's finding of litigation misconduct on the part of Medtronic. According to the District Court, Medtronic "fail[ed] to accept the claim construction governing this case," and in arguing the reverse doctrine of equivalents as a defense to infringement, "served only to confuse the jury." However, the Federal Circuit Court stated that the District Court incorrectly understood the reverse doctrine of equivalents, which can be applied to individual limitations of a claim. Thus, the Federal Circuit Court held that Medtronic should not be sanctioned for asserting the defense against the infringement of a literal scope of a limitation that did not fall under the District Court's doctrine of equivalents claim construction. The Federal Circuit Court reversed the District Court's finding as per the attorney's fees and the sanction for litigation misconduct because the District Court's ruling was merely based upon Medtronic's assertion of the reverse doctrine of equivalents in its infringement defense, rather than the way Medtronic litigated the defense.

In summary, the Federal Circuit affirmed the District Court's rulings in denying Medtronic's ensnarement defense. The Federal Circuit Court affirmed the jury's award of lost-profits as per DePuy's pedicle screws but reversed the jury's award of lost-profit damages arising from the pull-through products. Additionally, the Federal Circuit Court affirmed the District Court's denial of DePuy's motion for a new trial based on reasonable royalty fees. Lastly, the Federal Circuit Court reversed the District Court's imposition of \$425,375 in attorney's fees and the \$10 million sanction levied upon Medtronic.

Significance to Accused Infringers

While often defenses to doctrine of equivalents are evaluated in terms of prosecution history estoppel and whether differences are insubstantial, *DePuy Spine, Inc. v. Medtronic* is a reminder that even newly-discovered prior art can be useful in ensuring that a claim is not unduly broadened during litigation to cover the prior art. In addition, since the ensnarement defense is a legal issue, it can be resolved without submitting the issues to a jury. Thus, the defense can be useful in reducing issues at trial by removing doctrine of equivalents using a motion for summary judgment.

Therefore, while rarely discussed, the ensnarement defense remains a potentially powerful mechanism for

simplifying issues for trial.

Federal Circuit Holds Standard for Claim Interpretation for Purpose of Interference Is Distinct For Claim Interpretation for Purposes of 35 U.S.C. §§102 & 112

In *Agilent Tech., Inc. v. Affymetrix, Inc.*, Civ. Case No. 2008-1466 (Fed. Cir. June 4, 2009), Agilent owns Schembri patent 6,513,968 (“Schembri”) issued on February 4, 2003 and claimed priority to an application filed August 21, 1998. Affymetrix believed it had earlier invented the claimed methods of the Schembri patent and copied the claims of the Schembri patent into its Besemer patent application 10/619,244 (“Besemer”) to provoke an interference. The Besemer application claimed priority through a string of continuations to a patent application filed June 7, 1995, which made Affymetrix the senior party to the interference under 37 C.F.R 2.96.

The disputed claims in the Besemer application and the Schembri patent deal with “microarray hybridization,” which is a technique for performing multiple genetic analyses on a small fluid sample. Specifically, claim 20 of the Schembri patent and claim 66 of the Besemer application relate to a method for mixing a fluid sample during hybridization, by providing and moving a bubble in a fluid in a closed chamber. (Schembri Patent col. 10 ll. 33-45, Besemer application at 39).

Agilent filed a motion before the Board challenging the validity of the copied claims in the Besemer application, asserting that the written description was inadequate under 35 U.S.C. §112, ¶ 1, to show actual possession of the bubble-mixing invention. The Board found that the Besemer application showed support for the claimed invention, awarded priority to Affymetrix, and cancelled the contested claims of Agilent’s Schembri patent.

Agilent appealed to the U.S. District Court for the Northern District of California under 35 U.S.C. § 146. The parties submitted new expert reports and testimony from their respective expert witnesses, as well as cross motions for summary judgment on the written description issue. The District Court affirmed the Board and granted Affymetrix’s motion for summary judgment that the Besemer application satisfied the written description requirement. Agilent appealed the District Court’s judgment regarding claim construction and the written description requirement.

First, Agilent took issue with the District Court’s use of the Affymetrix application to construe the claim

language. To determine which specification to utilize to construe the claims, the Federal Circuit looked to its prior decisions in *In re Spina*, 975 F.2d 854 (Fed. Cir. 1992), and *Rowe v. Dror*, 112 F.3d 473 (Fed. Cir. 1997).

In *Spina*, the applicant copied a claim from the “Barron” patent to provoke an interference, similar to Affymetrix’s actions. The Board viewed the claim in light of the Barron disclosure, from which the claim had been copied. The Court held that this interpretation was correct. “When an interpretation is required of a claim that is copied for interference purposes, the copied claim is viewed in the context of the patent from which it was copied.” *In re Spina*, 975 F.2d 854, 856 (Fed. Cir. 1992).

In *Rowe v. Dror*, Rowe copied several claims from the Dror patent to provoke an interference. Dror filed a motion seeking judgment against Rowe on the ground that a third party anticipated some of Rowe’s claims corresponding to the interference count. On appeal, the Federal Circuit held that Rowe’s specification should be used to interpret Rowe’s claims because the question was one of novelty or non-obviousness. The Court held that the PTO should interpret the claim in light of its host disclosure, just as it would during *ex parte* prosecution. *Rowe v. Dror*, 112 F.3d 473, 479 (Fed. Cir. 1987). The Federal Circuit also explicitly distinguished *Rowe* from *Spina* due to the different question each case answered. The Court held that the *Spina* rule was applicable when the question turned on whether the copying party’s specification provided an adequate written description for the copied claims. The *Rowe* rule would apply when the question of the claim’s validity under 35 U.S.C. 102 or 35 U.S.C. 103 was at issue.

In reviewing these cases, the Federal Circuit held that the *Spina* rule applied, and reversed the decision of the District Court which used the Affymetrix application to construe the copied claims. The Federal Circuit also rejected Affymetrix’s argument calling for the application of 37 C.F.R. 41.200(b), which calls for the broadest reasonable construction of claim language in light of the specification in which it appears. For support, the Court pointed to its decision in *Rowe*, which asserted that judicial precedent is as binding on

administrative agencies as are statutes. Thus, the Federal Circuit held that *Spina* would be the applicable rule for this issue, and the Agilent specification would be utilized to construe the contested claims.

The Federal Circuit then concluded that the District Court erroneously interpreted the claim term “a closed chamber” to mean “a system of enclosures.” The District Court based its interpretation on Figure 28 of the Besemer application, to include the cavity 310, containers 2810 and 2820, and associated tubes. The Federal Circuit agreed with Agilent’s interpretation that the term was defined by the claim itself. The claim recites a closed chamber defined by “a first substrate and a second substrate having inner surfaces.” The Court interprets the claim to require that the chamber be bound by a first substrate and second substrate, and thus incapable of ambiguously spanning a “system of enclosures.” Rather, the Court looks to the claim language to construe the closed chamber as being explicitly defined by two surfaces. Further, the Federal Circuit asserts that the Schembri specification is replete with references and support for its interpretation of “closed chamber.” Finally, the Federal Circuit rejected the District Court’s interpretation as frustrating or even completely ignoring claim language requiring that “at least one of said inner surfaces is functionalized...” Under a system definition, the Federal Circuit asserted that the Schembri specification provided no guidance as to which surface would be functionalized. Thus, the Court rejected the District Court’s expansive definition of “closed chamber” and relied instead on the language of the claim and the Schembri specification to define the term.

The Federal Circuit also agreed with Agilent’s contention that the District Court erred in construing a “closed chamber... adapted to retain a quantity of fluid” as a chamber that is “capable of being sealed or set apart from its surroundings to retain a quantity of fluid.” Citing *Merck*, the Federal Circuit held that “closed” should be given further meaning because a claim construction that gives meanings to all the terms of the claim is preferred to one that does not do so. *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005). The Court also looked to *Mangosoft* to reject the District Court’s construction that gave no meaning to a term (“closed”) that was not already implicit in the rest of the claim. *Mangosoft, Inc. v. Oracle Corp.*, 525 F.3d 1327, 1330-31 (Fed. Cir. 2008). According to the Federal Circuit, closed was not the same thing as closable because equating the two terms was contrary to the plain language of the claim.

The District Court explicitly recognized that the ordinary meaning of the term “closed” in the context of a fluid retention chamber is “not open” or “sealed,” meaning that the chamber does not allow the fluid to escape. However, the District Court compromised this ordinary meaning to fit its erroneous assumptions that the claims should be construed in light of the Besemer application and that a “closed chamber” can mean a “system of enclosures.” The Schembri disclosure enables the ordinary meaning of the term to be utilized, and provides unambiguous and repeated support for such an interpretation. Specifically, the Schembri disclosure defines both a chamber and a closed chamber, explaining that the chamber becomes a closed chamber with a substrate placed on top of its seal to close it.

Thus, the Federal Circuit reversed the District Court’s construction because it was not grounded in the proper disclosure, and did not honor the customary meaning of the claim language to one of skill in the art. The Federal Circuit averred that the proper meaning of a “closed chamber... adapted to retain a quantity of fluid” is “an enclosed cavity defined by the inner surfaces of the first and second substrates, from which there is no egress of fluid.”

Next, the Federal Circuit examined whether the grant of summary judgment that the Besemer application had adequate possession of the claimed invention at the time of invention was proper. First, the Court cited *In re Wright* to note that the written description doctrine prohibits new matter from entering into claim amendments, especially during the continuation process. *In re Wright*, 866 F.2d 422, 424 (Fed. Cir. 1989). The court further observed that the written description requirement is a question of fact that requires that the specification must “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the [claimed] invention.” *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 110 (Fed. Cir. 1994); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Finally, the court declared that patent applications do not enjoy a statutory presumption of validity. Rather, Agilent’s burden of proving a lack of written description in the Besemer application is merely a preponderance of the evidence. *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1365 (Fed. Cir. 2004).

Before addressing the substantive merits of the grant of summary judgment, the Federal Circuit agreed with Agilent’s contention that the District Court erred by adopting an incorrect standard of review for new evidence that had not been before the Board. Under 35 U.S.C. 146, a party dissatisfied with the Board’s decision

may initiate a civil action in a U.S. District Court to bring forth "further testimony." Under this section, if the parties present new evidence to the District Court that is in conflict with the record before the Board, the District Court must make de novo factual findings regarding the new evidence.

Agilent initiated an action under Section 146 in response to the Board's finding that it had not advanced any "meaningful evidence" to show that one of ordinary skill in the art would not have understood Besemer's application to inherently disclose using bubbles to mix fluid in a closed chamber, as required by the contested claims. The Board specifically told Agilent that, for example, an expert declaration that one of ordinary skill in the art would not have had the requisite knowledge or skills to conclude from the Besemer application that the inventor was in possession of the invention would have been useful. Agilent submitted deposition testimony from Affymetrix's expert to remedy the evidentiary deficiency. Specifically, Affymetrix's expert explained that bubbles were not inherently present in the "vortexer" embodiment of Figure 29 of Besemer's disclosure. Further, in the embodiments of Figures 28 and 30, the chamber was not closed. The parties had already agreed that Figures 28-30 of Besemer's application were the only embodiments relating to the bubble mixing of the contested claims.

The District court dismissed this evidence, concluding that Agilent had not presented any new evidence concerning the written description issue, and deferentially reviewed the Board's decision for substantial evidence. The Federal Circuit asserted that this deferential review was legal error because Agilent had submitted new evidence that specifically pertained to filling evidentiary gaps observed by the Board. The Court emphasized that Section 146 allowed a litigant to shore up evidentiary gaps that may have been evident by the end of the inter partes interference procedure. Here, the Court recognized that Agilent was notified of such evidentiary gaps and took measures to fill them. The Federal Circuit asserted that evidence submitted by Agilent in the Section 146 action should have been considered by the District Court. Thus, the Federal Circuit examined Agilent's evidence without deference to the Board's finding.

As mentioned above, the record showed, and the parties seemed to agree, that the only embodiments depicting bubble mixing in the Besemer application were those illustrated by Figures 28-30, i.e. the "circulator" and "vortexer" embodiments. Agilent contended that these embodiments of the Besemer application failed to provide written description support for the claims at

issue. First, the "circulator" embodiments (as illustrated in Figures 28 and 30 of the Besemer application) failed to describe a method that takes place in a closed chamber. Second, the "vortexer" embodiment (as illustrated in Figure 29 of the Besemer application) failed to describe bubble mixing at all.

Given the Federal Circuit's interpretation of a "closed chamber... adapted to retain a quantity of fluid," the Court initially looked to the Besemer specification to disclose such an enclosed cavity from which there is no egress of fluid. Upon close examination of the Besemer disclosure, the Court found that the "circulator" embodiments of Figures 28 and 30 did not disclose a closed chamber that would prevent the escape of fluid. Rather, those embodiments required the circulation of fluid in and out of the cavity to facilitate mixing. Affymetrix's own expert affirmed that requirement in his deposition to the District Court. Thus, the "circulator" embodiment of Figures 28 and 30 provided no written description support for the bubble mixing of the contested claims.

The Federal Circuit then turned to the "vortexer" embodiment of Figure 29, in which it found a closed chamber. The Court observed that the "vortexer" embodiment allowed the introduction of fluid into a closed reaction chamber from which the fluid did not egress. To fully satisfy the written description requirement, this embodiment must then also describe "providing a bubble in the fluid" and "moving a bubble within the fluid to result in mixing," as required by the contested claims. However, both mentions of bubbles in the Besemer disclosure relied on by Affymetrix were tied to the "circulator" embodiments, where the bubbles are created by forcing fluid in and out of the chamber. The Court found that this creation of bubbles was inconsistent with the requirement of a "closed chamber."

The Court further asserted that Affymetrix's argument that the "vortexer" embodiment inherently produces bubbles was contradicted by Affymetrix's own expert testimony that bubbles were not necessarily generated in the fluid in the system as depicted by Figure 29 (the "vortexer" embodiment). The Federal Circuit cited *In re Oelrich* to note that inherency requires that one of ordinary skill in the art would recognize that a reference unavoidably teaches the property in question. *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981). The mere fact that a certain thing may result from a given set of circumstances would not establish inherency. *Hitzeman v. Rutter*, 243 F.3d 1345, 1355 (Fed. Cir. 2001). Given Affymetrix's expert testimony, the Court declared that Affymetrix's argument that the "vortexer" chamber

might include an unmentioned void that might result in bubble creation was insufficient to establish inherency.

Thus, the Federal Circuit failed to find any embodiments in the Besemer application that disclosed bubble mixing in a closed chamber and concluded that the District Court erred in its grant of summary judgment in Affymetrix's favor. The Federal Circuit stated that Affymetrix copied Agilent's claims into its continuation application despite having failed to disclose the claimed invention. Therefore, the Court reversed the District Court and granted Agilent's motion for summary judgment regarding the written description issue.

The Federal Circuit reversed the District Court's claim construction because it was not grounded in the proper disclosure, and did not honor the customary meaning of the claim language to one of skill in the art. The Federal Circuit stated that the originating disclosure

should be controlling for claim construction when determining if the host application has adequately supported the subject matter claimed by both parties. Further, the ordinary meaning of the claim language should be recognized, if supported by the originating disclosure. The Federal Circuit also reversed the grant of summary judgment regarding Affymetrix's possession of the claimed invention at the time of invention. Here, the Federal Circuit reversed the District Court and considered new evidence submitted by Agilent to the District Court. The Federal Circuit stressed that litigants are given the opportunity through 35 U.S.C. 146 to satisfy evidentiary gaps brought to light at the Board and stated that evidence submitted through a 146 action should be taken into account. In light of that new evidence, and upon close examination of the Besemer disclosure, the Federal Circuit found no evidence that the disclosure supported the invention as claimed.

2nd Circuit Finds Selling Key Words Used for Advertisements on a Search Engine a "Use in Commerce" under the Lanham Act.

In *Rescuecom Corp. v. Google, Inc.*, 562 F.3d 123; 90 USPQ2D 1287 (2nd Circ. 2009), Rescuecom is a national computer service franchising company that offers on-site computer services and sales. Rescuecom receives 17,000 to 30,000 visitors to its website each month and advertises over the Internet, using many web-based services, including those of Google. Since 1998, Rescuecom has been a registered federal trademark. The validity of Rescuecom's trademark is not in dispute in this case.

Google operates a popular search engine, and earns 97% of its revenue through advertising on that search engine. In response to a user search, Google provides a list of links to websites, ordered by descending relevance to the user's search terms, according to Google's proprietary algorithms. If a user enters a trademark as a search term, the Google search engine is able to provide a link to the website maintained by the trademark owner (if such exists). Google also responds to a user search by providing context-based advertising in the form of links to the advertiser's website. Google uses at least two programs to offer context-based advertising links: AdWords and Keyword Suggestion Tool (KST).

Through AdWords, advertisers purchase terms or keywords that will trigger the appearance of the advertiser's content and website link. Thus, whenever a user enters a purchased term or keyword in their search

query, advertisers who have purchased that term or keyword will have their ads and websites links displayed in response to the user search. Google recommends keywords to advertisers to be purchased through KST. KST improves the effectiveness of advertising by helping advertisers identify keywords related to their area of commerce. These keywords can include trademarks of other companies, such as Rescuecom's mark. Those keywords purchased by advertisers through KST would operate in a similar fashion to the terms or keywords purchased through AdWords.

On Google's search results page, advertising results (content and link to the advertiser's website) appear on the right margin and/or in a horizontal band immediately above the column of relevance-based search results. Rescuecom asserts that these advertisements (which appear in response to a user-entered trademark) could cause trademark confusion as to affiliation, origin, sponsorship or approval of service because Google fails to clearly label the ad results as purchased advertisements instead of relevant search results.

Through KST, Google has recommended Rescuecom's trademark to its competitors who purchase advertising through Google. Because the entry of Rescuecom's trademark results in the display of advertisements of Rescuecom's competitors, Rescuecom argues that the user who entered the trademark as a search term will

mistakenly believe that a competitor's advertisement and website link is sponsored by, endorsed by, approved by, or affiliated with Rescuecom's mark.

The plaintiff brought suit for trademark infringement, alleging that Google's recommendation and sale of plaintiff's mark to Google's advertisers, to trigger the appearance of advertisements and links in a manner likely to cause consumer confusion when a Google user launches a search of plaintiff's trademark, properly alleges a claim under the Lanham Act. The District Court granted Google's motion to dismiss under Federal Rules of Civil Procedure 12(b)(6) for failure to state a claim. Specifically, the District Court dismissed Rescuecom's complaint because it held that Rescuecom failed to allege that Google's use of its trademark was a "use in commerce" within the meaning of § 45 the Lanham Act. The 2nd Circuit reversed and remanded the case.

The District Court based its ruling on a 2nd Circuit decision, *1-800-Contacts, Inc. v. WhenU.com, Inc.*, 414 F.3d 400 (2nd Cir. 2005) ("*1-800*"), asserting that Google's use of Rescuecom's trademark was an internal use and thus not a "use in commerce."

The 2nd Circuit ruled in *1-800* that a complaint fails to state a claim under the Lanham Act unless it alleges that the defendant had made "use in commerce" of the plaintiff's trademark, with the term "use in commerce" defined in 15 U.S.C. § 1127. In contrasting this decision, the 2nd Circuit asserted that Rescuecom's complaint adequately plead a "use in commerce," rejecting the District Court's belief that this case and *1-800* were factually similar, and instead asserting that this case is materially different. Specifically, the 2nd Circuit noted that the Lanham act provides for liability, under Sections 32 and 43 (15 U.S.C. §§ 1114 and 1125), for unpermitted "use in commerce" of another's mark which is "likely to cause confusion, or to cause mistake, or to deceive" "as to the affiliation... or as to the origin, sponsorship or approval of his or her goods [or] services... by another person." 15 U.S.C. §§ 1114, 1125(a)(1)(A).

The term "use in commerce" was defined in Section 45 (15 U.S.C. § 1127) of the Lanham Act, providing in part that "a mark shall be deemed to be in use in commerce... (2) on services when is it used or displayed in the sale or advertising of services and the services are rendered in commerce." 15 U.S.C. § 1127.

In *1-800*, the defendant freely distributed software to users who would download and install the software on their computer. This software provided contextually relevant advertising to a user by generating pop-up ads to that user, depending on the website or search term

the user entered in the browser. The advertisement appeared in a new browser, making it clear the pop-up was an advertisement and not a direct response to the user's entry. First, the defendant did not use, reproduce or display the plaintiff's mark. The search term that triggered the pop-up ad was the plaintiff's website address. Thus, the infringing transactions did not involve use of the plaintiff's trademark. Second, plaintiff's mark was never "used or displayed in the sale or advertising of services," because advertisers could not request or purchase triggering keywords. Defendant's program did not offer the plaintiff's trademark as a search term by which advertisements could be triggered.

According to the 2nd Circuit, the present case is in stark contrast to *1-800*. Google not only explicitly sells trademarks to advertisers to trigger their ads, but also recommends trademarks to advertisers who would not have otherwise opted to utilize the trademark as a search term. Thus, Google displays, offers and sells trademarks, including Rescuecom's trademark, to its advertising customers when selling its advertising services. Further, it encourages the purchase of trademarks, including Rescuecom's trademark, through KST. Thus, Google's utilization of Rescuecom's trademark fits clearly within the definition of a "use in commerce" as specified by 15 U.S.C. § 1127.

Google argued that the inclusion of a trademark in an internal computer directory cannot constitute trademark use. However, the 2nd Circuit rejected this argument on several bases. First, it held that such a contention over-reads the *1-800* decision. *1-800* did not imply that the use of a trademark by software in an internal directory precluded a finding of trademark use. Rather, the fact that defendant did not use plaintiff's trademark at all influenced the Court to decide that defendant's use did not constitute a "use in commerce." Second, it noted that Google's recommendation and sale of Rescuecom's mark to advertising customers would not qualify as an internal use by Google's own definition.

Google argued that its use of the Rescuecom mark is no different from a retail vendor who uses product placement to allow a lesser known vendor to benefit from a competitor's name recognition. The 2nd Circuit noted that labeling a practice "product placement" does not shield it against liability under the Lanham Act. Rescuecom has alleged in its complaint that Google's practices are significantly different from benign product placement, because its practices cause confusion as to which result of a user search on a trademark is an advertisement and which result is actually associated

with the trademark. Thus, Google's use of Rescuecom's mark would be a "use in commerce."

In conclusion, the 2nd Circuit found that Google's use of Rescuecom's trademark was a "use in commerce" because its recommendation and sale of Rescuecom's mark to advertising customers as keywords triggered the appearance of the ads and website links in a manner that was likely to cause consumer confusion as to Rescuecom's trademark. Thus, the grant of Google's motion to dismiss under 12(b)(6) was reversed, and the case was remanded.

Significance for trademark owners

Rescuecom Corp. is significant in resolving what has been a problem for trademark owners: Google's sale of keywords matching marks to competitors to allow competitors to advertise whenever the keyword is

searched. In finding that there is a possibility that such sale of keywords can cause confusion as to the source of an advertisement, the ruling provides hope for trademark owners that a remedy may be available due to this sale. That being said, the impact of the ruling may not be sweeping since *Rescuecom Corp.* is currently limited only to the 2nd Circuit, and importantly, the ruling will likely only apply where the displayed advertising is of a type which confuses the consumer as to whether it is from the mark owner or a competitor. It is also unclear as to whether Google will change its advertisement policies to prevent such confusion. Thus, while at least allowing while the suits to proceed, the holding in *Rescuecom Corp.* will still require all the normal evidence required for a showing of trademark infringement based upon confusion as to the source or sponsorship.

Federal Circuit Affirms that the Right to "Make, Use, And Sell" a Licensed Product Inherently Includes Right to have that Licensed Product Made by a Third Party.

In *CoreBrace v. Star Seismic*, 566 F.3d 1069 (Fed. Cir. 2009), CoreBrace owned U.S. Patent 7,188,452 ("452") which claims a brace for use in the fabrication of earthquake-resistant steel-framed buildings. The inventor of the 452 patent and Star entered into a "Non-exclusive License Agreement" ("license") through which Star received a license under the 452 patent. The inventor later transferred his interest to CoreBrace. The license to Star grants it a non-exclusive right to "make, use, and sell" licensed products. Star did not explicitly have the right to have the licensed product made by a third party. Further, the license explicitly stated that Star may not "assign, sublicense, or otherwise transfer" its rights to any party other than an affiliated, parent or subsidiary company. The license also reserved to CoreBrace "all rights not expressly granted to" Star. The license further provided that if a breach occurred, the license could be terminated after written notice of the breach and a thirty-day opportunity to cure.

Star used third party contractors to manufacture products under the license for its own use. On January 4, 2008, CoreBrace sent Star a letter terminating the license without any prior notice. That same day, CoreBrace also filed suit for breach of the license due to Star's use of third party contractors and for patent infringement based on Star's use of patented products under a terminated license. The U.S. District Court for the District of Utah granted Star's motion to dismiss

under Fed. R. Civ. P. 12(b)(6), holding that Star did not breach the license by having third party contractors make the licensed products and that CoreBrace did not properly terminate the license, making patent infringement impossible.

The District Court asserted that the right to "make" an article includes the right to engage others to do work connected with its production. *Carey v. United States*, 326 F.2d 975 (Ct. Cl. 1964). Further, "have made" rights, or rights to have a licensed product made by a third party contractor, are granted in a license unless expressly prohibited. *Advanced Micro Devices v. Intel Corp.*, 885 P.2d 994 (Cal. 1994). The District Court distinguished this case from situations regarding the licensee's rights to make a product and sell it under a third party's name. *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821 (Fed. Cir. 1991). Thus, the Court stated that based upon the license, Star had the right to have a third party manufacture the licensed product for it. The District Court also found that CoreBrace failed to follow the license's termination procedures, and rejected CoreBrace's arguments that the breach was incurable. The District Court noted that the breach did not frustrate the purpose of the license. Thus, CoreBrace should have followed the termination procedures under the license. Because the license was not terminated, the District Court held Star could not have infringed the patent under which it was licensed. CoreBrace appealed the District Court's dismissal.

The Federal Circuit first looked at the issue of breach of license. CoreBrace argued that “have made” rights are not inherent in the right to make, use and sell in a license. Further, CoreBrace asserted that the District Court improperly relied on *Carey* and *Advanced Micro* and improperly distinguished the *Intel* case. Finally, CoreBrace contends that the reservation of rights clause in the license precludes an interpretation that the license includes “have made” rights.

As contract law is a matter of state law as opposed to Federal Law. The Federal Circuit looked to the Utah law to determine whether the “have made” right is included in a license to make or use an invention. With regards to the “have made” rights, the Federal Circuit noted that the Utah Supreme Court had not yet addressed whether the scope of the right to “make, use, and sell” a product inherently include the right to have it made by a third party. The Federal Circuit looked to decisions affirming inherency from its predecessor court and the California Supreme Court to conclude that the Utah Supreme Court would likely rule the same way. Specifically, the Federal Circuit looked to *Carey* and *Advanced Micro*, which were also discussed by the District Court. The Court of Claims held in *Carey* that a license to “produce, use, and sell” a product inherently included the right to have it made by a third party. The Court of Claims stated that the license “is not restricted to production by the licensee personally...” but “permits him to employ others to assist him in the production... of the invention.” *Carey*, 326 F.2d at 979. Further, the California Supreme Court held in *Advanced Micro* that, unless expressly precluded, have-made rights were included in the contractual right to make and sell a licensed product. *Advanced Micro*, 885 P.2d 994 (Cal. 1994).

CoreBrace argued that *Carey* was distinguishable from its case, because the license in *Carey* was exclusive and included a right to sublicense. The Federal Circuit rejected CoreBrace’s argument, stating that the Court in *Carey* had based its decision on the right to “produce, use, and sell,” not on exclusivity or the right to sublicense. Although the licenses were not identical, the logic used by the *Carey* Court was dependent upon rights (to produce, use and sell) included in both the *Carey* license and the instant license. The Federal Circuit held that “have made” rights are included in the right to make, sell and use the product, regardless of whether the license is exclusive or sublicenses are allowed.

To bolster their argument, the Federal Circuit also pointed to *Cyrix Corp.*, which held that expressly granted “have made” rights were not a sublicense.

Cyrix Corp. v. Intel Corp., 77 F.3d 1381, 1387-88 (Fed. Cir. 1996). Thus, a third party contractor used by a licensee could not make or use the licensed product for anyone but the licensee or sell it to third parties.

CoreBrace also argued that the District Court improperly distinguished *Intel*, which CoreBrace interpreted as holding that “have made” rights were restricted by the reservation of rights clause in the license. *Intel Corp. v. U.S. Int’l Trade Comm’n*, 946 F.2d 821 (Fed. Cir. 1991). The Federal Circuit distinguished *Intel* because, in *Intel*, both parties agreed that Sanyo’s license did not provide “have made” rights, and only argued as to the source of the denial of that right. Further, the case was distinguished due to its subject matter (foundry rights, or rights for the licensee to manufacture the licensed product for a third party to sell under the third party’s name). The administrative law judge of the International Trade Commission held that the denial of “have made” rights was due to the reservation of rights clause. The Federal Circuit asserted that their holding of denial of “have made” rights was due to the entire contract, including the limitation to make, use and sell only “Sanyo” products in the contract. Due to their holding based upon a unique clause in the contract and the difference is subject matter, the Federal Circuit refused to find *Intel* persuasive or controlling in this case.

CoreBrace also claimed that the reservation of rights clause in the license precludes an interpretation that the license includes “have made” rights. The Federal Circuit rejected this argument based on its conclusion that “have made” rights were inherent in a license providing rights to “make, use, and sell” a product. The Federal Circuit held that there was no express language or intent shown in the contract to exclude the “have made” rights. Further, the Court found other provisions of the license that would reinforce the inclusion of “have made” rights. Specifically, the Federal Circuit pointed to a clause providing that Star would own any improvements to the technology “by a third party whose services have been contracted by” Star. Further, the license requires Star to allow an “audit of its books and records relating to manufacturing... [And] supply contracts.” Thus, the Court held that the parties must have contemplated that third parties might manufacture and supply the licensed products to Star.

Given its conclusion that Star did not breach the license by contracting with third parties for manufacture, the Federal Circuit held that the issue of CoreBrace failing to adequately terminate the license was moot. CoreBrace was not entitled to terminate the license,

and thus Star could not have infringed CoreBrace's patent under which it was licensed.

The Federal Circuit affirmed the District Court of Utah's ruling that the right to "make, use and sell" includes inherently the right to have licensed products made by a third party, unless expressly precluded by the license.

Significance to Patent Licensors

CoreBrace confirms that licensees of patented products are allowed to use third parties and OEM contracts to

build the patented product. Such a ruling is likely within the expectation of the parties given the prevalence of outsourcing manufacturing work. However, for patent owners who are concerned about such work, this ruling confirms what has always been a best practice for licensing: make clear any exceptions. Therefore, patent licensors who are concerned about particular third parties being allowed to use a patented product (even when used on behalf of a licensee) need to clarify that the power to make or use does not extend to specified parties.

Federal Circuit finds Lack of a Confidentiality Obligation When Distributing Documents is Insufficient to Make Documents Prior Art "Printed Publications."

In *Cordis Corp. v. Boston Scientific Corp. and Scimed Life Sys., Inc.*, 561 F3d 1319; 90 USPQ2d 1401 (Fed. Cir. 2009), the Appellant and Appellee both appealed from a final judgment rendering them liable for infringement of the other's patent. The judgment was based on two separate jury verdicts of infringement: (1) infringement by Boston Scientific of claims 1 and 23 of U.S. Patent No. 4,739,762 ("the 762 patent") and claim 2 of U.S. Patent No. 5,895,406 ("the 406 patent"), and (2) infringement by Cordis of claim 36 of U.S. Patent No. 5,922,021 ("the 021 patent"). The judgment also determined that those claims were not invalid. The Federal Circuit affirmed the lower court's rulings in all respects except one.

Cordis and Boston Scientific both own patents relating to intravascular stents, which are cylindrical lattice-like scaffolds that are inserted into a blood vessel and expanded in order to hold the vessel open. Cordis owns the 762 and 406 patents, while Boston Scientific owns the 021 patent. The jury returned a verdict that Cordis' stents did not literally infringe claim 36 of the 021 patent, but that certain stents infringed under the doctrine of equivalents by having an equivalent to the "corners" limitation of claim 36. The jury further found that Boston Scientific did literally infringe claim 23 of the 762 patent, induced literal infringement of claim 1 of the 762 patent, and literally infringed claim 2 of the 406 patent. Both Cordis and Boston Scientific appealed to the Federal Circuit, which affirmed the verdicts of infringement.

The jury found Cordis did not literally infringe claim 36. Further, there was no instruction of whether Cordis's stents infringed claim 36 under the doctrine of equivalents. Rather, the jury determined whether Cordis's stents infringed the "corners" limitation of

claim 36. The Federal Circuit noted that the judgment must have rested on an agreement between the parties that Cordis's stent literally infringed all other limitations of claim 36, and that the question of infringement turned solely on the "corners" limitation.

Same Wherein Clause in Different Claims Did Not Have the Same Meaning

The Federal Circuit first noted that the District Court properly construed the "wherein" clause of claim 36. The "wherein" clause of claim 36 describes how the struts within one expansion column or ring of a stent are connected to the struts of another column or ring. The Federal Circuit held that the District Court properly construed this clause to mean "the first expansion strut in the first column does not share a longitudinal axis with the second expansion strut in the second column," and properly did not exclude "180 degrees out of phase" stent designs. Cordis asserted that the 180 degrees out of phase designs should have been excluded, meaning that Cordis' stent would no longer be infringing. Specifically, Cordis argued that the wherein clause appears in both claim 1 and claim 23, that the clauses must have the same meaning, and that the prosecution history shows that the wherein clause excludes 180-degree out of phase designs. Since claim 36 depended from claim 23, such a finding would preclude a finding of infringement.

However, the Federal Circuit noted that claims 1 and 23 use different numbering systems for their expansion struts and expansion columns, making the meaning of the wherein clause distinct for each claim. Thus, the language of claim 1 could exclude 180-degree out of phase designs, while the language of claim 23 could include them. Further, the Federal Circuit stated that the prosecution history did not preclude such an

interpretation. The Examiner allowed claims 1 and 23 after the wherein clause was included. However, the Examiner made no reference to 180 degree out of phase designs, and only utilized the numbering system of claim 1 when allowing both claims. The Federal Circuit refused to assume, without some further basis, that the Examiner's utilization of claim 1's numbering system when allowing both claims was based on an assumed identity of numbering systems.

The Federal Circuit also refuted Cordis' attempts to show disclaimer by lack of a figure in the patent that uses 180 degree out of phase design and unclear language in the provisional application, asserting that unclear prosecution history may not be used to limit claims; rather, a disclaimer must be clear and unmistakable. Thus, there was no disclaimer as to the interpretation given claim 23 forcing an interpretation consistent with claim 1.

Application of the Doctrine of Equivalents did not Vitate Claim Term

On the issue of doctrine of equivalents, the Federal Circuit first affirmed that the jury's determination of infringement based on doctrine of equivalents analysis was supported by substantial evidence. The Court held that sufficient expert testimony existed that Cordis's stent met the "corners" limitation of claim 36 under the function-way-result test. The Federal Circuit found that the function-way-result analysis under *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 339 U.S. 605, 608 (1950), "is still useful under *Warner-Jenkinson Co. v. Hilton-Davis Chemical Co.*, 520 U.S. 17, 39-40 (1997), particularly for mechanical inventions." Further, Boston Scientific's expert testified that the "corners" of claim 36 and the circular arcs or rounded corners of Cordis' stent "both function as actual and potential reference points for joining adjacent stent rings, fulfill this function through their similar locations, and can or do result in offset connections between stent rings." Thus, the finding was sufficiently supported by evidence and satisfied the function-way-results test for finding equivalency.

Cordis argues that the doctrine of equivalents should not be applied because the jury's finding of infringement vitiated the "corners" limitation. Cordis noted that such an equivalency meant that the "circular arcs of the BX Velocity stent cannot 'form an angle' as required by the district court's claim construction." The Federal Circuit affirmed the District Court's holding that the circular arcs of Cordis' stent were not antithetical to the "corners" limitation of claim 36, and thus could be held as equivalent. Specifically, the Federal Circuit, without supplying additional analysis, found that the

"corners" limitation did not vitiate the angle limitation "because it does not 'render[] the pertinent limitation meaningless,' *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1359 (Fed. Cir. 2005), or 'effectively eliminate that element in its entirety,' *Warner-Jenkinson*, 520 U.S. at 29." Thus, the Federal Circuit affirmed that claim 36 was found infringed under the doctrine of equivalents.

'021 patent is valid and supported by provisional application

Cordis asserted that the '021 patent was invalid in light of a number of prior art patents. On review, the Federal Circuit quoted *Johns Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342, 1345 (Fed. Cir. 2008) as to the standard of review for obviousness determinations: "We review '[the] jury's conclusions on obviousness, a question of law, without deference, and the underlying findings of fact . . . for substantial evidence.'" (quoting *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1353 (Fed. Cir. 2001)).

The Federal Circuit noted that the District Court cited uncontradicted testimony from Boston Scientific's expert that the prior art patents cited by Cordis would be unlikely to be combined to create the connectors of claim 36 of the '021 patent. This uncontradicted testimony further established that these patents taught away from the bottom-to-top connectors of claim 36 by describing them as potentially harmful. Thus, the Federal Court asserted that the District Court properly concluded that substantial evidence existed to show these prior art patents did not render claim 36 obvious.

Cordis further argued that claim 36 of the '021 patent was not fully supported by the provisional application to which the '021 patent claimed priority. The Federal Circuit noted that the question of compliance with the written description requirement under 35 U.S.C. § 112 is a question of fact, and thus the review of the jury's finding is whether the jury's finding is supported by substantial evidence. *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1243 (Fed. Cir. 2002). The Federal Circuit affirmed the jury's findings that the written description requirement was met, noting the District Court's cite to uncontradicted testimony from Boston Scientific's expert that the provisional application provided a sufficient written description of the limitations of claim 36.

Documents were Not Printed Publications Since Not Published

The Federal Circuit affirmed the District Court's grant of summary judgment that the claims of the '762 patent were not invalidated by the 1980 and 1983 monographs

of Dr. Palmaz, because the monographs were not prior art printed publications under 35 U.S.C. § 102(b). Dr. Palmaz created the monographs and distributed them to his colleagues. Under agreements that did not require confidentiality (one expressly disclaiming liability for confidentiality), Dr. Palmaz also distributed the monographs to two companies while attempting to commercialize the stent technology. Boston Scientific urged that, even if the distribution to colleagues did not make the monographs prior art printed publications, distributions to companies with no legal obligation of confidentiality certain would confer such status on the monographs.

Citing to *In re Wyer*, 655 F.2d 221, 226 (CCPA 1981) and *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988), the Federal Circuit held that a document is publicly accessible for purposes of 35 U.S.C. § 102(b) if it has been made available to the extent that persons interested and ordinarily skilled in the subject matter could locate it and recognize and comprehend therefrom the essentials of the claimed invention. Also, while the widespread distribution of a document may be sufficient to make the document a publication for purposes of 35 U.S.C. §102(b), the Federal Circuit held that a limited distribution does not necessarily do so. Citing to *In re Klopfenstein*, 380 F.3d 1345, 1347 (Fed. Cir. 2004), the Federal Circuit held that courts have been reluctant to assert that dissemination of work to colleagues is public use, because professional and behavioral norms entitle the author to a reasonable expectation that the information will not be copied or further distributed. Moreover, there is no requirement that there be a confidentiality agreement to prevent distribution, although such an agreement is often in place. Thus, Dr. Palmaz's distribution of the monographs to his colleagues with the expectation of limited distribution would be protected from the status of public use.

The Federal Circuit found the issue of distribution to interested companies to be murkier, given that confidentiality agreements were not in place and one company expressly disclaimed an obligation to keep the material confidential. However, because evidence existed to support a conclusion that an expectation of confidentiality existed between Dr. Palmaz and the two companies, the Federal Circuit held that the monographs were not prior art "printed publications" within the meaning of 35 U.S.C. § 102(b). Specifically, no evidence existed that the documents became

available to the public as a result of disclosure by the companies. The Federal Circuit asserted that the lack of a legal obligation of confidentiality regarding documents did not make place them in the domain of "public use."

Functional language can operate as a claim limitation to distinguish prior art.

Boston Scientific argued that the 762 patent anticipates claim 2 of the 406 patent. The parties agree that the 762 patent anticipates claim 2, except for the functional language in claim 1 of the 406 patent (upon which claim 2 depends). The functional language recites "such that the links and bands define an expandable structure having axial flexibility in an unexpanded configuration." Boston Scientific asserted that the "such that" claim language is not a claim limitation that can distinguish the 406 patent over the 762 patent. The Federal Circuit disagreed, citing *Microprocessor Enhancement Corp. v. Tex. Instruments Inc.*, 520 F.3d 1267, 1375, and held that sufficient evidence was presented to the jury to find that the 762 patent did not anticipate claim 2 of the 406 patent.

The Federal Circuit affirmed all of the District Court's judgments regarding infringement, reversing only a dismissal of claims without prejudice. The Federal Circuit held, among other findings, that the use of the doctrine of equivalents was appropriate as long as it did not render the pertinent claim limitation meaningless, that the mere lack of a legal obligation of confidentiality, without more, when distributing documents is insufficient to place in the domain of "public use," and functional language can operate as a claim limitation to distinguish prior art.

Significance to Patent Owners and Applicants

While it is always a best practice to ensure that an application is filed prior to any distribution of a product description, *Cordis Corp.* does confirm that certain distributions may be acceptable. While the descriptions in *Cordis Corp.* related to commercialization attempts with implied confidentiality, it is likely that this holding could be extended to other situations, such as distributions to potential publishers for articles or as proposals for conference presentations. Therefore, *Cordis Corp.* is a reminder that, while filing of an application prior to any distribution of a monograph is always preferable, such distributions will not always be invalidating events for purposes of 35 U.S.C. §102.

Federal Circuit Finds Obviousness Despite Evidence of Commercial Success

In *Ritchie v. Vast Resources, Inc.*, 563 F.3d 1334 (Fed Cir. 2009), Steven D. Ritchie and H. David Reynard own a medical device patent, U.S. Patent No. Re 38,924, which is a reissue of U.S. Patent No. 6,132,366 (hereinafter the '924 patent). They also own a device manufacturer, Know Mind Enterprises, that manufactures medical devices for sexual purposes. The defendant, Vast Resources, Inc., owns Topco Sales, a manufacturer producing the same category of medical devices. The devices manufactured by the two parties are generally shaped into a rod made of rubber, plastic, glass or other similar materials or a combination of such materials. Prior to the plaintiff manufacturing the device of the '924 patent, such glass devices were typically manufactured from soda-lime glass. However, the plaintiff manufactures such devices using an "oxide of boron" or borosilicate glass as the '924 patent claims a device "fabricated of generally lubricious glass-based material containing an appreciable amount of an oxide of boron to render it lubricious and resistant to heat, chemicals, electricity and bacterial absorptions."

The plaintiffs sued Vast Resources for patent infringement. Plaintiff offered evidence of commercial success as evidence of nonobviousness, but did not otherwise offer evidence of nonobviousness. The U.S. District Court, Middle District of Florida, found the patent valid and ruled in favor of the plaintiffs. The defendants appealed the decision, challenging the patent's validity and the plaintiffs cross-appealed on the matter of the amount of relief the District Court granted. The Federal Circuit Court, hearing the appeal, reversed the District Court judgment with instructions to dismiss the suit.

The Federal Circuit Court only considered whether the invention of the '924 patent would have been obvious to a person of ordinary skill in the art, as per 35 U.S.C. §103(a). In analyzing the claimed invention of the '924 patent, the Federal Circuit looked at the use of and features attributed to borosilicate glass, which in the device of the '924 patent is substituted for soda-lime glass as compared to the conventional art. Specifically, since it was not contested as to the well known nature of each component in the claimed invention, the Federal Circuit focused on the use and features of the substituted element, the borosilicate glass, and the effect of evidence of commercial success as evidence of nonobviousness when using well known components.

As an initial point, the Federal Circuit interpreted "lubricious" to include borosilicate glass, which is smoother than soda-lime glass, and thus, the borosilicate glass becomes slippery with less lubricant when compared to soda-lime glass. The Federal Circuit noted that the term "appreciable amount," as recited in the '924 patent, while vague, can be interpreted and defined to mean an amount of boron oxide usually found in borosilicate glass. As such, the amount of boron oxide would be known to those of ordinary skill in the art.

Since no other evidence was contested related to obviousness, the Federal Circuit focused on the extent to which commercial success, which was not contested, is useful for showing nonobviousness. In discussing the commercial success of the invention of the '924 patent, the Federal Circuit noted that borosilicate glass has been used in glassware for nearly 100 years as Pyrex glassware, manufactured by Corning, Inc. (previously Corning Glass Works). Although Corning now also manufactures Pyrex using tempered soda-lime glass, borosilicate glass has been used in the glassware market since in 1893, when borosilicate glass was invented. The Federal Circuit acknowledged that borosilicate glass has the properties recited in the '924 patent, and this fact was not contested on appeal. The Federal Circuit also stated that even if the device is useful due to the recited properties, the invention would not be patentable as it was obvious "to a person having relevant technical skills."

The Federal Circuit noted that because the device of the '924 patent has commercial value, to call the device obvious "may seem the triumph of hindsight over insight." However, because borosilicate glass has been commercially available and used since 1893 and was otherwise very well known, the Federal Circuit proceeded to weigh whether commercial success was an indicator of nonobviousness as per the '924 patent.

The Federal Circuit acknowledged that commercial value is an indicator of nonobviousness (citing *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); *Simmons Fastener Corp. v. Illinois Tool Works, Inc.* 739 F.2d 1573, 1575-76 (Fed. Cir. 1984)). However, this evidence can work both ways. Where an invention with commercial value appears on the market soon after the idea or impetus behind the invention appears, this is evidence of obviousness. In contrast, the delayed appearance of the invention on the market, despite the

commercial value, is evidence that an invention was not obvious. Nonetheless, commercial success is considered as a “secondary” indicator of nonobviousness. The Federal Circuit cited *Graham v. John Deere Co.*, supra, 383 U.S. at 18; *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483-84 (Fed. Cir. 1997)), as per commercial success being a secondary indicator and noted that commercial success is reliant upon many factors unrelated to patentable inventiveness, such as the marketing of a product or invention. Thus, commercial success is not sufficient in and of itself to show nonobviousness.

Also, the Federal Circuit stated that inventions deemed obvious are those that are “modest, routine, everyday, incremental improvements of an existing product or process that confer commercial value...but do not involve sufficient inventiveness to merit patent protection.” The Court went on to state that “[t]his class of inventions is well illustrated by efforts at routine experimentation with different standard grades of a material used in a product—standard in the sense that their properties, composition, and method of creation are well known...This is such a case.” As per the recitation of “an appreciable amount of an oxide of boron,” the Federal Circuit Court noted that the ‘924 patent “does not claim any variant of off-the-shelf borosilicate glass.” Furthermore, the Court stated that because borosilicate glass is a standard product with well known properties, substituting borosilicate glass for ordinary glass, in the device category of the ‘924 patent, “was not a venture into the unknown.”

The Federal Circuit Court went on to state that the present case exemplifies the Supreme Court’s analysis in *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), wherein the Supreme Court stated:

“[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, 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 417.

The Federal Circuit stated that the final sentence of the above quotation describes the present case, and further quoted the Supreme Court, which stated that a court need not “seek out precise teaching directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative

steps that a person of ordinary skill in the art would employ.” *Id.* at 418.

With respect to supporting the Federal Circuit’s statement as per inventions that are “incremental improvements of an existing product or process that confer commercial value...but do not involve sufficient inventiveness to merit patent protection,” the Federal Circuit cited cases involving substitution of one feature or element for another. The cases the Federal Circuit cited include *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1851), *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1535-38 (Fed. Cir. 1983) and *Brunswick Corp. v. Champion Spark Plug Co.*, 689 F.2d 740, 749-750 (7th Cir. 1982). Thus, in the case where well known materials are substituted from one another, there needs to be some evidence that the substitution is more than routine in the art.

In summary, the Federal Circuit Court said that commercial value of an invention is an indicator of nonobviousness. However, while an indicator, it is only one secondary consideration and commercial success can be attributed to a variety of factors unrelated to patentable inventiveness, such as successful marketing. Furthermore, the Court stated that the present case exemplifies the Supreme Court’s analysis in *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), which states 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.” Thus, as no other evidence of nonobviousness was on appeal, the Federal Circuit reversed the District Court’s judgment with instructions to dismiss the suit.

Significance for Patent Applicants

On one level, *Ritchie* stands for the proposition that, under *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), substitutions of well known components is obvious. However, what is more problematic in *Ritchie* is that the Federal Circuit gives scant weight to evidence of commercial success, which *Graham v. John Deere*, 383 U.S. 1 (1966) cites as evidence of non-obviousness. While the Federal Circuit noted that there were many potential reasons for commercial success, the Federal Circuit in *Ritchie* chose not to give this evidence much weight in comparison with the evidence that the materials were all well known. Little explanation was given as to why the commercial success evidence was of little evidentiary value, or why the evidence of being well known was of such greater value to eclipse the evidence of commercial success in the context of an

analysis under *Graham v. John Deere*, 383 U.S. 1 (1966). In light of the ruling in *Ritchie*, it is therefore doubtful that evidence of commercial success will be deemed a

deciding factor in finding nonobviousness even where the evidence of obviousness itself is scant.

4th Circuit Holds Archiving Of Students' Submitted, Copyrighted Materials For Future Use In Detection Of Plagiarism Is A Fair Use Under 17 U.S.C. §107

In *A.V. v. iParadigms, LLC*, 562 F.3d 630 (4th Cir., 2009), the plaintiffs' alleged that iParadigms' use of the plaintiffs' copyrighted materials infringed the plaintiffs' rights in the copyrighted materials. iParadigms counterclaimed that plaintiff A.V.'s unauthorized access to iParadigms' computer system violated the Computer Fraud and Abuse Act (CFAA), 18 U.S.C. §1030, and the Virginia Computer Crimes Act (VCCA), Va. Code Ann. §18.2-152.3. On summary judgment, the district court found in favor of iParadigms on the copyright infringement claims and found in favor of the plaintiff A.V. on the CFAA and VCCA claims. The 4th Circuit affirmed the district court's decision with respect to the copyright infringement claims and reversed and remanded for further consideration iParadigms' CFAA and VCCA claims.

Plaintiffs A.V., K.W., E.N., and M.N., each of which are minors and represented by respective next friends, brought this action against iParadigms for copyright infringement of essays and papers submitted thereto. iParadigms owns and operates "Turnitin Plagiarism Detection Service," which is an online technology system, operated via www.turnitin.com, through which students submit assigned writings to their teachers. In order for a student to submit a paper through the website, the student "must be enrolled in an active class," "enter the class ID number and class enrollment password," and create a user profile on the website. In creating a user profile, the student must click on "I Agree" under the "terms of agreement" or "Click-wrap Agreement," which provides that the offered services are conditioned upon the student's unmodified acceptance of the terms of the agreement and that iParadigms is not liable for any damages arising out of use of the website. Upon submission of a paper or assignment, the service provides a digital comparison of the student's work with content on the internet, commercial databases of journal articles and periodicals, and "student papers previously submitted to Turnitin[.]" The Turnitin system then generates an "Originality Report," which indicates possible plagiarism, and forwards the student's work along the Originality Report to the student's teacher. Participating schools are given the option of "archiving"

student works in a database for future use to be compared with future submitted works. Such "archived" student works are stored as digital code and not read or reviewed by employees of iParadigms.

Upon filing of this suit, plaintiffs A.V., K.W., E.N., and M.N. were students at high schools that subscribed to the Turnitin program and elected to have students' works archived for future use. Such schools required students to submit works via www.turnitin.com to receive credit such that failure to do so would result in a grade of "zero" for that assignment. K.W., E.N., and M.N. each submitted papers to their teachers via www.turnitin.com with a disclaimer objecting to the archiving of their works; however, their works were archived because of their schools' enrollment in the archival program. A.V. submitted works using a password designated for students of the University of California, San Diego (UCSD), which was obtained via an internet search and provided to A.V. by plaintiffs' counsel. Before each of the assignments at issue was submitted, plaintiffs' counsel applied for and was granted a copyright registration.

The plaintiffs alleged that iParadigms archiving of their works in the Turnitin database without their permission infringed their copyright interests. As a result of A.V.'s submissions, iParadigms counterclaimed under the Computer Fraud and Abuse Act (CFAA), 18 U.S.C. §1030, and the Virginia Computer Crimes Act (VCCA), Va. Code Ann. §18.2-152.3. The district court granted summary judgment and found that the students and iParadigms entered into a binding agreement upon the students' clicking on "I Agree," that the agreements shielded iParadigms from liability arising from the plaintiffs' use of the Turnitin.com website, and that the plaintiffs' written disclaimers did not modify the Agreement or render it unenforceable. The district court further held that iParadigms' use of the plaintiffs' written submission qualified as "fair use" under 17 U.S.C. § 107, and therefore, did not constitute infringement specifically because the use was transformative as its purpose was to prevent plagiarism by comparative use and that the use did not impair the market value for the students' works. With regard to iParadigms' counterclaims, the

district court rejected such on summary judgment stating that iParadigms failed to provide evidence of actual or economic damages as a result of the alleged CFAA and VCCA violations.

The ownership rights created by the Copyright Act are not absolute such that, while exclusive, such rights are "limited in that a copyright does not secure an exclusive right to the use of fact, ideas, or other knowledge." Slip at pages 7-8, *quoting Bond v. Blum*, 317 F.3d 385, 394 (4th Cir. 2003). Further, copyright protections are subject to enumerated exceptions explicit in the Copyright Act. One such exception at 17 U.S.C. §107 codifies the common-law doctrine of "fair use," which "allows the public to use not only facts and ideas contained in a copyrighted work, but also the expression itself in certain circumstances." *quoting Eldred v. Ashcroft*, 537 U.S. 186, 219 (2003). "Courts have traditionally regarded 'fair use' of a copyrighted work as a privilege in others than the owner of the copyright to use the copyrighted material in a reasonable manner without his consent." Slip at pages 8-9, *quoting Harper & Row, Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 549 (1985) (internal quotes omitted).

17 U.S.C. § 107 states that "the fair use of a copyrighted work, including such use by reproduction in copies or phonorecords or by any other means specified by that section, for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research, is not an infringement of copyright. In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include-

- (1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
- (2) the nature of the copyrighted work;
- (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
- (4) the effect of the use upon the potential market for or value of the copyrighted work."

The 4th Circuit analyzed each of the four nonexclusive factors in turn.

The Purpose and Character of the Use

Courts have stated that a use of a copyrighted work for commercial purposes tends to weigh against a finding of fair use, but that the profit/nonprofit distinction is not whether the sole motivation was monetary gain but whether the use exploits the copyrighted material

without paying the customary price. *Harper & Row*, 471 U.S. at 562. Courts have further looked to whether the use at issue "merely supersedes the objects of original creation, or instead adds something new, with a further purpose or different character," which indicates that courts should analyze "whether and to what extent the new work is transformative." *Campbell v. Acuff-Rose Music*, 510 U.S. 569, 578-79 (1994). The more transformative a use is, the less important other factors, such as commercialism, become. *Id.* "A transformative use is one that employs the quoted matter in a different manner or for a different purpose from the original, thus transforming it." Slip at 10, *quoting Pierre N. Leval, Commentary, Toward a Fair Use Standard*, 103 Harv. L. Rev. 1105, 1111 (1990) (internal quotes omitted).

The plaintiffs argued that the district court ignored the commercial nature of iParadigms' use of their copyrighted material noting that iParadigms is a for-profit company receiving millions of dollars in revenue based on the database of student works, that iParadigms' use of their copyrighted material could not be transformative because the archiving process did not add anything to their works, and that, even if iParadigms' use has a transformative purpose, the use itself is not transformative if it fails to effect such purpose, i.e., fails to prevent plagiarism. The 4th Circuit rejected such arguments. First, the 4th Circuit noted that since most secondary users seek at least some commercial gain, an emphasis on commercial exploitation would overly restrict the fair use doctrine; instead, commercial use should be weighed along with the other factors in fair use analysis. Next, the 4th Circuit noted that a transformative use need not alter or augment the work to be transformative in nature, but that a transformative use may be transformative in function or purpose without altering or actually adding anything to the original work. Finally, the 4th Circuit noted that, although the Turnitin system may be capable of only detecting the most ignorant or lazy attempts at plagiarism, whether a better detection system could be designed is of no import to the analysis of whether the disputed use serves a different purpose or function. Therefore, the district court's finding that the first factor weighed in favor of fair use was correct.

The Nature of the Copyrighted Work

The Supreme Court has stated that "fair use is more likely to be found in factual works than in fictional works" whereas "a use is less likely to be deemed fair when the copyrighted work is a creative product." Slip at page 14, *quoting Stewart v. Abend*, 495 U.S. 207, 237 (1990). The district court noted that iParadigms' use fostered the development of original and creative works

by deterring efforts at plagiarism by the students enrolled in the program.

The plaintiffs argued that the district court ignored the fact that the students' works were unpublished and that the district court ignored the fact that the students' works were fiction and poetry, which are considered highly creative. However, the 4th Circuit noted that although the district court may have omitted mentioning that the works were unpublished, the district court clearly did not ignore the unpublished nature of the works. As evidence, the 4th Circuit noted that the district court quoted *Bond v. Blum* discussing fair use of unpublished works of fiction in concluding that iParadigms' use was unconnected to any creative element in plaintiffs' works. Further, the 4th Circuit stated that it is clear that iParadigms' use did not have the "intended purpose" or "incidental effect" of supplanting the plaintiffs' rights to first publication because iParadigms did not publicly disseminate or display plaintiffs' works, plaintiffs' works were not seen by any third party other than the instructor to whom the work was submitted, and no employee of iParadigms read or reviewed the plaintiffs' works. Next, the 4th Circuit noted that the district court did take into consideration that the plaintiffs' works were highly creative in nature but stated that iParadigms use was not related to the creative core of the plaintiffs' works. The 4th Circuit found no fault in the analysis of the district court with respect to the second factor and agreed that this factor weighed in support of neither the plaintiffs nor iParadigms.

The Amount and Substantiality of the Work Used

Generally, the 4th Circuit noted, "as the amount of copyrighted material used increase, the likelihood that the use will constitute a fair use decreases." Slip at page 17, quoting *Bond*, 317 F.3d at 396. But, such analysis additionally requires consideration of the "quality and importance" of the portion of the copyrighted material used, i.e., whether the portion used included "the heart of the copyrighted work." *Id.*, quoting *Cambell*, 510 U.S. at 587, and *Sundeman v. The Seajay Soc'y, Inc.*, 142 F.3d 194, 205 (4th Cir. 1998), respectively.

The plaintiffs argued that the district court erred by referring to the transformative nature of iParadigms' use in the amount and substantiality analysis of the third factor, i.e., that the district court improperly blended the third factor into the first factor. The district court did indeed find that because the iParadigms' use of the works was transformative in nature, iParadigms' use of the entirety of the plaintiffs' works did not preclude a finding of fair use such that

this third factor weighed in support of neither the plaintiffs nor iParadigms. The 4th Circuit noted that, in their view, the district court's analysis did not merge the first and third factors and that the plaintiffs' arguments failed to recognize the overlap that exists between the fair use factors. As such, the 4th Circuit found no error in the district court's analysis.

The Effect of the Use

"The Supreme Court described this factor as the single most important element of fair use, *Harper & Row*, 471 U.S. at 566, considering that a primary goal of copyright is to ensure that authors [have] the opportunity to realize rewards in order to encourage them to create." Slip at page 18, quoting Leval, *Toward a Fair Use Standard*, 103 Harv. L. Rev. at 1124, (internal quotes omitted). Such analysis under the fourth factor seeks to determine whether the iParadigms' use of the plaintiffs' works "would materially impair the marketability of the work[s] and whether it would act as a market substitute" for them. *Id.* quoting *Bond*, 317 F.3d at 396. The focus of such analysis is upon whether the secondary use "usurps the market of the original work." *Id.*, quoting *NXIVM Corp. v. The Ross Institute*, 364 F.3d 471, 482 (2nd Cir. 2004). An adverse effect on the market of the original work does not preclude the finding of a fair use. *Id.* The 4th Circuit specifically noted that this fourth factor overlaps to some extent with the question of whether the use was transformative in nature because the more transformative the use, the less likely the secondary use would supplant or supersede the original work. The district court concluded that iParadigms' use did not serve as a market substitute or harm the market value of the works as such were admitted in depositions by the plaintiffs.

The plaintiffs argued that they could be harmed in the future by the Turnitin system upon submission to third parties of works previously submitted to the Turnitin system if such third parties, for example, college admissions and periodicals, use the Turnitin system to verify originality. Further, the plaintiffs argued that the district court erred by focusing on lack of evidence of actual damages instead of considering the effect of iParadigms' use on the "potential market" for plaintiffs' works. The 4th Circuit first noted that, based on how the Turnitin system works, the likelihood of harm to plaintiffs' was speculative at best and dismissed the plaintiffs' first argument. In response to the plaintiffs' second argument, the 4th Circuit found that the district court did consider the potential market effects and concluded that the plaintiffs' arguments were theoretical and speculative. iParadigms' use would

impair the sale of the students' works to other high school students who wish to purchase such papers and submit them as their own, but the plaintiffs testified that they would not sell the works because such a transaction would be dishonest and make them a party to cheating. As such, iParadigms' use does not create a market substitute as iParadigms' use does not supplant the plaintiffs' works in the "paper mill" market, but merely suppresses demand for them by keeping a record that such works were previously submitted.

The 4th Circuit concluded that, in viewing the evidence in the light most favorable to the plaintiffs', iParadigms' use was a fair use under the Copyright Act such that iParadigms was entitled to summary judgment on the copyright infringement claim.

iParadigms' Cross Appeal of CFAA and VCCA Counterclaims

iParadigm counterclaimed against plaintiff A.V. because of A.V.'s accessing the Turnitin system via a password assigned to USCD students and alleged that A.V.'s unauthorized access to Turnitin violated 18 U.S.C. §1030(a)(5)(iii), which prohibits any person from "intentionally access[ing] a protected computer without authorization, and as a result of such conduct, caus[ing] damage," and, by such conduct, cause, in violation of 18 U.S.C. §1030(a)(5)(B)(i), "loss to 1 or more persons during any 1-year period ... aggregating at least \$5,000 in value." Slip at page 23. The CFAA further imposes that such damages are limited to economic damages. iParadigms offered evidence that, upon learning of the unauthorized access to the Turnitin system, iParadigms was fearful of a technical glitch and assigned several employees to determine what had happened. The district court concluded that iParadigms failed to produce evidence of any actual or economic damages and, instead, only presented evidence of consequential damages, i.e., economic damages does not encompass consequential damages.

iParadigms argued that "economic damages" should be given its ordinary meaning, which includes

consequential damages to the exclusion of recovery for pain and suffering or emotional distress. The 4th Circuit agreed that the district court's interpretation was too narrow and concluded that the wording of 18 U.S.C. §1030 plainly included consequential damages of the type sought by iParadigms. As such, the 4th Circuit reversed the district court's decision and remanded this issue for further consideration of iParadigms' CFAA claims.

iParadigms further alleged that A.V.'s unauthorized access to Turnitin violated the VCCA, which provides that "[a]ny person who uses a computer or computer network, without authority and ... [o]btains property or services by false pretenses ... is guilty of the crime of computer fraud." Slip at page 25, quoting Va. Code Ann. §18.2-152.3. Further, the VCCA states that "any person whose property or person is injured by reason of a violation of [the VCCA] ... may sue thereof and recover any damages sustained and the costs of the suit." Va. Code Ann. §18.2-152.12. The district court granted A.V. summary judgment on the basis that iParadigms had failed to provide evidence of actual or economic damages.

iParadigms argued that the district court narrowly construed "any damages" to exclude consequential damages. The 4th Circuit found nothing in the statute to suggest that consequential damages were unavailable under the VCCA, and thus, reversed the district court's decision and remanded this issue for further consideration of iParadigms' VCCA claims.

The 4th Circuit found that iParadigms' secondary use of archiving for future use of the students' submitted, copyrighted materials did not constitute copyright infringement because iParadigms' use was a "fair use," mainly because iParadigms' use was transformative in nature and did not usurp the plaintiffs' potential market for the plaintiffs' works. Further, the 4th Circuit remanded for further consideration iParadigms' counterclaims against plaintiff A.V. under the CFAA and the VCCA.

Northern District of Illinois Finds That Declaratory Judgment Action Available Against Private Sector Owner of Patent Owned in Common with Government

In *Sourceone Global Partners LLC. V. KGK Synergize, Inc.*, Civ. Case No. 08 C 7403 (N.D. Ill. May 13, 2009), KGK Synergize ("KGK") is an assignee of U.S. Patent No. 6,987,125 (the '125 patent), which generally relates to a nutritional supplement for lowering cholesterol. The

'125 patent was invented by Najla Guthrie, Elzbieta Kurowska, John Manthey, and Robert Horowitz pursuant to a partnership between the Department of Agriculture and KGK. Pursuant to the partnership agreement, Mr. Mathaney and Mr. Horowitz assigned their rights to the

Federal Government, and Ms. Guthrie and Ms. Kurowska assigned their rights to the KGK. KGK later exclusively licensed their interest in the '125 patent to Sourceone Global Partners (Sourceone) for the purpose of making and selling Sytrinol. The Government is not a signatory to this license.

Subsequently, Sourceone developed on its own Cholesstrinol, which Sourceone believed did not infringe the '125 patent and therefore was not subject to the royalty provisions of the license. KGK sent threatening letters to Sourceone's partners, suppliers, and customers indicating that Cholesstrinol infringed a number of patents, including the '125 patent. In response, Sourceone filed a Declaratory Judgment Action alleging, among other issues related to tortious interference with contracts, that Cholesstrinol does not infringe the '125 patent and that the '125 patent was invalid.

KGK moved for dismissal of the Declaratory Judgment Action as to those claims related to the '125 patent since the '125 patent is co-owned by the Federal Government. As any judgment resulting from the Declaratory Judgment Action affecting the validity of the '125 patent will affect a property owned by the Federal Government, the Declaratory Judgment Action violates the Federal Government's sovereign immunity to Declaratory Judgment Actions. In essence, KGK's position was that any patent commonly owned by a private party and the Federal Government could not be the subject of a Declaratory Judgment Action to the same extent that a Declaratory Judgment Action cannot lie against a patent wholly owned by the Federal Government since Rule 19 requires joinder of the Federal Government in such situations.

In disagreeing with KGK, Magistrate Judge Schenkier found that the court retained subject matter jurisdiction over the Declaratory Judgment Action since the mere fact that one owner enjoys sovereign immunity does not affect the liability of the remaining owners. In reaching this decision, the court first acknowledged that Rule 19 does not require joinder since KGK is a co-owner of the patent. In this manner, the court distinguished the situation from the situation in *Enzo APA & Son, Inv. V. Geapag A.G.*, 134 F.3d 1090 (Fed. Cir. 1998) where the failure of a join the patent owner prevented a Declaratory Judgment Action since the non-exclusive licensee who was actually sued lacked standing to bring suit. Since KGK was a co-owner, KGK was not in the same situation as a non-exclusive licensee and therefore could be the subject of a Declaratory Judgment Action without the remaining co-owners.

The Court further noted that the failure to join a party is not a matter of subject matter jurisdiction, but instead falls within the joinder requirements of Rule 19. While Rule 19 requires joinder of indispensable parties and the parties agreed that the Government is an indispensable party, Rule 19(b) provides an exception where the court determines, according to a set of four factors, whether "in equity and good conscience, the action should proceed among the existing parties or should be dismissed." Quoting Rule 19(b).

In applying the exception, the court noted that it needed to balance the harm against the missing party should the action proceed as compared to the harm against the party opposing dismissal. According to this balance, the court found that there was greater harm in dismissing the action to Sourceone than there was harm to the Federal Government in forcing dismissal under Rule 19 for failure to join an indispensable party.

In applying the first factor, the Court cited to the Federal Circuit's decision in *Dainippon Screen Mfg. Co. v. CFMT, Inc.* 142 F.2d 1266 (Fed. Cir. 1998) for the proposition that, in the case of a licensee who is sued under a Declaratory Judgment Action, Rule 19(b) should allow the suit to proceed where the interest of the licensee is aligned with the interest of the patent owner. In *Dainippon*, CFMT was the licensee of a patent, and patent was owned by the parent of CFMT. In the same way, while the Government had argued that its interest in the '125 patent would be prejudiced should the Declaratory Judgment Action proceed and the '125 patent be found invalid, the Court found that there was no action of adverse interests between the coowners of the '125 patent. As such, this alignment of interest indicated that the first factor weighed heavily in favor of maintaining the suit.

After finding the second and third factors were also in favor of Sourceone, the court applied the fourth factor, which considers whether Sourceone would have an adequate remedy outside of the Declaratory Judgment Action. The court found that there was no alternative remedy available should the action be dismissed. Specifically, while KGK noted that the Government can be sued under 28 U.S.C. §1498 for patent infringement, there was no allegation of Government infringement. Moreover, since the Court of Federal Claims can only grant money damages under 28 U.S.C. §1498, there would be no available remedy for Sourceone should a Declaratory Judgment Action be filed under 28 U.S.C. §1498. Therefore, 28 U.S.C. §1498 failed to provide a remedy. Thus, the court held that, while KGK and the Government "see no unfairness in requiring Sourceone to wait until they together decide to sue Sourceone

before Sourceone can raise its invalidity and noninfringement defenses” as KGK continues threatening infringement against Sourceone and its partners, when viewed from the perspective of equity, the court “failed to see how the public interest is advanced by allowing a private patentee such as KGK that kind of unreviewable sway in exercising its patent rights.” Thus, the fourth factor also weighed heavily in favor of maintaining the suit.

Therefore, the court found that merely because the Federal Government could not be joined under Rule 19, Rule 19(b) provided an exception which allowed the Declaratory Judgment Action to continue.

Significance for Government Licensed Patents

Sourceone demonstrates that co-ownership of a patent does not always require joinder of all owners for purposes of declaratory judgment actions, and that even where joinder is otherwise necessary, an exception is available. Thus, merely because one owner enjoys sovereign immunity does not mean that the remaining owners enjoy the same immunity. However, the situation in *Sourceone* is relatively unique. Unanswered is the question of what would have happened if the patent is not commonly owned with the Government. In

the more typical situation, the Government will license the patent and it is the licensee who, with authority to bring suit in its own name, sends such letters which can result in a declaratory judgment action. In this situation, the result may well not be the same. For instance, unless the license is fully paid up, the interests of a licensee is not exactly the same as that of the patent owner since the licensee may want to reduce royalties it owes. An example of this situation was recently demonstrated in *MedImmune, Inc. v. Genentech Inc.*, 549 U.S. 118 (2007). Further, since all licenses for Government patents, even exclusive ones, allow the Government to re-license the patent to others under limited circumstances as set forth in 37 CFR 404.5, the Government may be in a position to terminate a suit by negotiating a deal directly with the accused infringer in limited circumstances. Therefore, unlike the situation in *Sourceone*, the parties’ interests are not wholly aligned and the Government may well be required for maintaining a declaratory judgment action in order to ensure that public assets are adequately protected. Therefore, while declaratory judgment actions appear more viable against private parties who own patents commonly with the Government, the same may not be possible for exclusive licensees of Government owned patents.

Practice Tip: Pitfalls of Priority Document Exchange

By James G. McEwen¹

Background

The Paris Convention for the Protection of Industrial Property allows foreign applicants to claim priority in a United States patent application to a foreign patent application. The Paris Convention is implemented at 35 U.S.C. §119. In order to claim this benefit, 35 U.S.C. §119 requires applicants to complete at least two tasks: 1) making a claim for priority, and 2) filing a certified copy of the foreign priority application. Ideally, this claim is made during the pendency of the U.S. application. It is the applicant’s responsibility to ensure that these requirements are met.

If either the claim or the priority document is not filed while the application is pending, it is still possible to rescue the priority claim by filing a reissue application. MPEP 201.16 (noting reissue applications can be used to perfect priority claims, whereas certificates of correction cannot). However, this is not a preferred method since reissue applications can be complex to

prepare and are expensive to file. Therefore, it is important for applicants to ensure that both the claim for priority and the certified copy of the foreign priority document are timely filed while the U.S. application is pending.

Traditionally, an applicant complied with these requirements by obtaining a certified copy of the foreign priority document, shipping the certified copy to a U.S. patent attorney, and the U.S. patent attorney would file the certified copy. This process therefore incurred fees for both obtaining the certified copy, and shipping the certified copy. Moreover, the United States Patent and Trademark Office (USPTO) was forced to store such documents in their files and repositories. Also, where the application is stored in the image file wrapper, USPTO was forced to disassemble the certified copy and scan the certified copy. Therefore, the process incurred a number of costs on both the applicant and the USPTO.

Overview of the PDX Program

In order to reduce these costs, the USPTO implemented the Priority Document Exchange (PDX) program. Under this program, the USPTO entered into Memoranda of

¹ The opinions in this article do not represent the official positions of Stein McEwen, LLP.

Understanding with select countries which allow the USPTO to directly retrieve electronic copies of the foreign priority documents. Therefore, the applicant is not required to separately submit certified copies of foreign priority documents, and the USPTO no longer has to store and scan filed certified copies of foreign priority documents. Additional information on the program can be found on the United States Patent and Trademark Office website at: <http://www.uspto.gov/web/patents/pdx/pdx.html>

Currently, only the Japanese, Korean, and European patent offices participate in the PDX Program. Additionally, priority documents can also be obtained from those already filed with the World Intellectual Property Office for PCT applications. As such, the PDX program only applies to select foreign patent offices.

Drawbacks of the PDX Program

Assuming that the foreign priority application is on file with a participating foreign patent office, in order to electronically retrieve the foreign priority application, an applicant is required to submit a request for retrieval. The request can be included in the Declaration or on the Application Data Sheet. The request can be also separately made by filing a separate form: Request to Retrieve Electronic Priority Application (form PTO/SB/38). Thus, there are multiple mechanisms allowing the applicant to submit the request.

However, merely filing the form PTO/SB/38 or including the request in Declaration or Application Data Sheet does not guarantee that the foreign priority application will be retrieved. For instance, the Declaration might be a scanned or facsimile copy, and the application number may not be clear. The application number might be in a format that is not recognized by the foreign patent office. If the requested foreign priority document is too large (1000 pages), the request will be denied. As such, there are multiple opportunities which may interfere with the retrieval of the priority document.

Moreover, the USPTO will not guarantee that the retrieval will be in a timely fashion, and estimates that the process itself can take months after the request is made.

Best Practices to Resolve Problems with the PDX Program

Since the applicant is ultimately responsible for ensuring that the correct priority application is retrieved during

the U.S. application's pendency, the USPTO indicates that the requests needs to be made early. This is because the USPTO estimates that each electronic retrieval can take months to complete. Therefore, it is important that the first attempt at a retrieval be done early.

Ideally, the request is contained in the Declaration or Application Data Sheet at the time of filing. However, where the Declaration is not readable or has the application number in the wrong format, there is a likelihood that the request will fail. Therefore, at the time of filing, if the Declaration appears not to be readable or has the foreign priority application number in the wrong format, the applicant should file the form PTO/SB/38 with the application number in the correct and readable format. In this way, any defects in the Declaration's format can be cured early.

Even where the Declaration or Application Data Sheet has the correct and readable information, the request may be denied. If the first retrieval attempt is unsuccessful, a second attempt is made. However, when either attempt fails, the applicant is not guaranteed a notification (although the examiner should notify the applicant in any subsequent office action or Notice of Allowance). Therefore, it is incumbent on the applicant to review the Patent Application Information Retrieval (PAIR) system to ensure that the foreign priority application is actually received. As such, periodic checks are a necessity since the mere filing of a request does not guarantee compliance with 35 U.S.C. §119 until the image file wrapper actually receives the correct foreign priority application. Where the priority document has not been retrieved, the applicant needs to again file the request using the form PTO/SB/38.

Assuming the PAIR system indicates that a foreign priority document is retrieved, the applicant needs to ensure that the correct priority document has been received. Since the process is entirely electronic, it is possible that small system errors could retrieve the incorrect application. Thus, the applicant is well advised to review the electronic copy of the retrieved foreign priority document in order to ensure that what was retrieved is what is claimed.

Lastly, the applicant needs to be sure that the correct foreign priority application is retrieved by the time any Notice of Allowance is received or where foreign priority is required for purposes of showing prior invention. Since the USPTO does not guarantee that the foreign priority application will be received in the image file wrapper in a timely fashion, filing a supplemental request may not cure the defect in time. Therefore, where the foreign priority application is not in the

image file wrapper or only the incorrect foreign priority application has been retrieved, the applicant needs to be ready to obtain and courier to the U.S. patent attorney a certified copy of the foreign priority document to be hand filed at the USPTO.

Conclusion

While there are many potential cost savings to the USPTO and clients utilizing the PDX program, it is important to recognize that the PDX program is purely for the convenience of the USPTO. As such, the applicant is not excused where, despite all efforts to retrieve the foreign priority application, the foreign priority application is not timely received by the USPTO.

Feature Comment: The Broadening Chasm between Claim Interpretation during Litigation and Examination for Product by Process Claims

By Ramya Possett & James G. McEwen²

Background

Traditionally, claim interpretation has differed during a patentability analysis, when the claim is an application being examined, and a validity analysis, when the claim is patented and being analyzed during an infringement action. The reasons for this difference are understood and accepted in the art, and have been espoused by both the courts and the Patent Office as justified and reasonable. However, for purposes of preserving the public notice function of the claim, the validity and infringement analysis have generally been consistent since it makes little sense to narrowly interpret a claim for purposes of infringement while broadly interpret the claim for purposes of validity. Moreover, while the patentability analysis has generally given the examiner more leeway in rejecting claims than might be afforded under the validity analysis, the patentability analysis will generally track the claim interpretation given during subsequent litigation so as to allow the applicants to obtain the broadest coverage for their new and non-obvious inventions while still putting the public on notice of what was invented. Thus, this difference in claim interpretation was not designed to require an applicant to give up substantial amounts of claim scope in order to obtain a patent merely because the claim was analyzed by an examiner as opposed to a judge. As

Therefore, it is possible that the unaware applicant will fail to properly comply with 35 U.S.C. §119 during pendency of the application, and incur the substantial costs and inconvenience of filing a reissue application.

However, where the applicant or their representative employs a regime such as those outlined above, the applicant is in a better position to ensure that the correct foreign priority application is retrieved. In this way, the applicant can realize the cost savings in not having to unnecessarily obtain and ship foreign priority documents while avoiding the inconvenience of filing reissue applications caused by USPTO administrative issues.

will be explained in below, in light of the Federal Circuit's decision in *Abbott Labs v. Sandoz*, 90 USPQ2d 1769 (Fed. Circ. 2009) (en banc as to product by process issue), the Federal Circuit appears to have advocated a much larger difference between interpretation during litigation and examination for one special category of claims: those having product by process limitations.

Examination and the Broadest Reasonable

Interpretation Standard

During the examination process, the broadest reasonable interpretation standard has been established for interpreting patent claims for patentability. Courts and the MPEP have repeatedly endorsed this standard, for example, in *In re American Academy of Science Tech Center*, 70 USPQ2d 1827, 367 F3d 1359 (Fed. Cir. 2004). Here, the Court held that patent claims construed during reexamination should be given their broadest reasonable interpretation consistent with specification, and should be read in light of specification as it would be interpreted by person of skill in art. *Id.* at 1830. Giving claims their broadest reasonable construction serves the public interest by reducing the possibility that the claims, when issued, would be given a broader scope than is justified. *Id.* The Court noted that construing the claims broadly was not unfair to patentee or patent applicant, who has ample opportunity to amend claims to obtain more precise coverage. *Id.* By approaching claim interpretation in this manner, the patent applicant and the Patent Office have the opportunity to enter into a dialogue that enables each

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to come to an agreement of the scope of the invention as portrayed by the claims.

As such, the justification for more broadly construing claims during examination is that applicants can still amend the claims to clarify the meaning in order to ensure that one of ordinary skill in the art, when confronted with two reasonable interpretations, would come to the correct conclusion. In this manner, the examiner is allowed to wordsmith, and force the applicant to clarify the claims where one of ordinary skill in the art might reasonably conclude that the claims are broader than would be justified under 35 U.S.C. §§101, 102, 103 and 112.

Person of Ordinary Skill Analysis

The person of ordinary skill standard has been utilized in claim interpretation for validity analyses. The Federal Circuit set out a widely utilized methodology explaining how to interpret claims in *Phillips v. AWH Corp.* *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-19 (Fed. Cir. 2005) (en banc). As explained by the Federal Circuit in *Felix v. American Honda Motor Co.*, “the ordinary and customary meaning of undefined claim terms as understood by a person of ordinary skill in the art at the time of the invention” is relied upon for claim interpretation. *Felix v. American Honda Motor Co.*, 90 USPQ2d 1524 (Fed. Cir. 2009). Quoting from *Phillips*, the Federal Circuit asserted in *Felix v. American Honda Motor Co.* that “[T]he court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Id.* at 1314 (internal quotation marks and citations omitted). Thus, the claim interpretation turns on the public record of the case as understood by someone of ordinary skill in the art.

By making the claims, specification and prosecution history paramount in determining claim scope and taking into account the state of the art according to one of ordinary skill in that art, courts recognize the importance of understanding what property rights the inventor acquired from the patent office when his or her patent issued. By enabling a dialogue between the inventor and the patent examiner, the patent office acknowledges the importance of establishing an agreement as to the bounds of the invention. Thus, although the scope of claim interpretation differs between the patentability and validity analyses of the

patent claims, the end goal of that interpretation remains the same: to create recognizable property rights whose limits can be ascertained through the negotiations that occurred during their creation and the state of the art that existed during their incipience.

This shared end goal is important for several reasons. First, it enables patent owners to be cognizant of the property rights that they are able to enforce via their patent. The Federal Circuit addressed the import of a clear public record for innovation as well. *Vitronics Corp. v. Conception Inc.*, 90 F.3d 1576, 39 USPQ2d 1573 (Fed. Cir. 1996). The court asserted that the public record of the patentee’s claim (which includes the claims, specifically and file history of the patent) is relied upon by the public. “In other words, competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee’s claimed invention and, thus, design around the claimed invention.” *Id.* By creating a clear record and sharing an end goal of claim interpretation, further development and innovation is fostered.

However, unlike examination where the claims can be revised to further clarify the claims, a patented claim cannot be revised easily. Moreover, the patented claim is presumed valid such that the courts are less likely to take positions to invalidate a claim merely due to differences in wordsmithing. Therefore, courts will generally require additional evidence that one of ordinary skill in the art would actually be confused by the claim scope since the remedy of obtaining the wrong claim scope is to invalidate the claim (and deprive the patent owner of a property right).

Effect of the *Abbott Labs*

The recent en banc decision in *Abbott Labs* threatens to undermine this common goal regarding the scope of claim interpretation and create confusion as to what property rights exist in pending patents with product-by-process claims and what rights are now obtainable by such claims. *Abbott Laboratories v. Sandoz Inc.*, 90 USPQ2d 1769 (Fed. Cir. 2009). The en banc court in *Abbott Labs* held that interpretation of product-by-process claims had to take into account the process terms in the claims, regardless of whether the product produced by the process terms in those claims was novel. *Id.*

Although the patent statute does not explicitly provide for product-by-process claims, the courts have long recognized the appropriateness and necessity of product-by-process claims. *See, e.g., Ex parte Painter*,

1891 C.D. 200, 200-01 (Comm'r Pat. 1891); *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985); *In re Brown*, 459 F.2d 531, 535 (C.C.P.A. 1972); *In re Steppan*, 394 F.2d 1013, 1018 (C.C.P.A. 1967). The USPTO also recognized such claims, for example, in MPEP 2173.05(p). The Federal Circuit reinforced in *SmithKline* that the purpose of product-by-process claims is to allow inventors to claim "an otherwise patentable product that resists definition by other than the process by which it is made." *SmithKline Beecham Corp. v. Apotex Corp.*, 78 USPQ2d 1097 (Fed. Cir. 2006) (quoting *In re Thorpe*, 777 F.2d at 697). The Federal Circuit also recognized that established law prohibits product-by-process claims from validly claiming products already known in the art. *SmithKline Beecham Corp.* at 1101. However, this narrowing of claim scope would have been consistent with the public record and state of the art at the time the invention was filed. Patents can only be issued for novel inventions, and if the product produced by the product-by-process claim is not novel, a narrower interpretation of the claim would be necessary to capture what was novel in the patent.

With their en banc decision in *Abbott Labs*, the Federal Circuit expanded that prohibition on old products to instead encompass all products not explicitly defined by the process terms in the product-by-process claim. This holding undermines the initial rationale for allowing such claims to be issued. More significantly, it produces a dichotomy between claim interpretation during the patentability and validity analyses of product-by-process claims that undermines that shared end goal of such analyses.

With the en banc decision in *Abbott Labs*, product-by-process claims must be construed so as to include the process terms in the claim during litigation. In direct conflict with such an interpretation, the USPTO instructs examiners to consider only the structure implied by the process terms in the claim in MPEP 2113. Thus, the scope of the claims as produced by the two analyses is completely different. The public record created by the examination procedure in the Patent Office is no longer representative of the property rights that are enforceable during the litigation process.

As mentioned above, for patentability, courts and the patent office have agreed that patent claims should be given their broadest reasonable interpretation consistent with the specification, and should be read in light of the specification as it would be interpreted by a person of skill in art. The MPEP quotes *In re Zletz* to expand upon the reasoning behind the broadest reasonable interpretation standard. MPEP 2106, Section II.C. "During patent examination the pending claims

must be interpreted as broadly as their terms reasonably allow.... The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process." MPEP 2106, Section II.C (quoting *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)). The Patent Office also asserts in MPEP 2111 that "[t]he broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. MPEP 2111 (quoting *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999)). For product-by-process claims, this rationale is no longer applicable using the instructions set forth in the MPEP. The broadest reasonable interpretation of claims endorsed by the patent office for product-by-process claims is no longer reasonable in light of *Abbott Labs* since the broadest interpretation available prior to *Abbott Labs* (that the process is not a limitation) is no longer feasible after *Abbott Labs*.

The en banc court in *Abbott Labs* adopted the rule set forth in *Atlantic Thermoplastics Co. Inc.* to determine the scope of product-by-process claims. *Atlantic Thermoplastics Co. Inc. v. Faytex Corp.*, 24 USPQ2d 1138 (Fed. Cir. 2002). In both *Abbott Labs* and *Atlantic Thermoplastics*, the Federal Circuit did not utilize the person of ordinary skill standard. Rather, the Court analyzed previous precedent to reach its decisions. When dealing with patent interpretation, this departure from the widely used standard can prove dangerous due to its implications. In this case, it produced a disparity such that the rights that a patent applicant negotiates during examination are unequivocally not the same rights that he will be able to enforce in litigation.

Further, the benefits of the broadest reasonable interpretation of the claims during examination prove moot by the patent office's current standards for product-by-process claims. The process terms in those claims which will be widely scrutinized during litigation will only be analyzed during examination to the extent that they provide insight into the structure which they imply. The claims will not be fashioned in a way that is "precise, clear, correct, and unambiguous," with the uncertainties of claim scope removed. *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Instead, only litigation of those claims will provide some understanding of the scope of the invention that the patentee will be able to enforce.

Conclusion

The en banc decision in Abbott Labs has introduced a dichotomy into claim interpretation for patentability and validity purposes that undermines the previously shared goal of both distinct interpretations. Previously, although the scope of claim interpretation differed between the two analyses, the end goal of that interpretation remained the same: to create recognizable property rights whose limits can be ascertained through the negotiations that occurred during their creation and the state of the art that existed during their incipience. With the stark contrast in interpretation between the PTO standard and the new

Federal Circuit holding, recognizable property rights whose limits can be ascertained through the public record and the state of art are no longer created when patents with product-by-process claims are issued. Until the Federal Circuit or Supreme Court revisits the interpretation of these claims, the Patent Office should change its operating procedure to again sync its interpretation of product-by-process claims with those of the courts. Otherwise, the property rights created by issued patents with product-by-process will only be ascertained through the litigation of those patents. The implications of continuing to issue such patents with regards to licensing and infringement are alarming.

Intellectual Property and Government Contracts Treatise on Sale

In March 2009, Oxford University Press issued *Intellectual Property In Government Contracts: Protecting And Enforcing IP At The State And Federal Level*, which was coauthored by James G. McEwen in collaboration with two pre-eminent intellectual property practitioners whose combined experience spans the private and government sectors. *Intellectual Property in Government Contracts: Protecting and Enforcing IP at the State and Federal Level* provides a comprehensive survey of U.S. federal and state intellectual property procurement laws and gives valuable advice to government and private-sector attorneys on aspects of intellectual property, government procurement, and litigation from the perspectives of both the government and the contractor communities.

IP attorneys will find an extensive overview of U.S. federal and state procurement systems, strategies for preserving IP rights in the procurement process, and the

practical guidance needed to avoid the pitfalls of government IP contracting while taking advantage of existing contracting flexibility. The treatise will provide a roadmap for high-tech contractors doing business with the government sector in the United States and will include an examination of methods proven to ensure compliance with government provisions. Additionally, the treatise analyzes remedies that actually work, and those that do not. Further, the treatise will offer an honest, nuanced appraisal of areas in which the government is legitimately vulnerable (like trademarks) and areas in which misapprehensions have wrongly scared off private sector companies (like patent march-in rights).

To order *Intellectual Property in Government Contracts: Protecting and Enforcing IP at the State and Federal Level*, please visit amazon.com, contact customer service at 1.866.445.8685, or visit Oxford University Press.

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