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FEDERAL CIRCUIT REFINES LAW OF WILLFUL INFRINGEMENT

EN BANC DECISION CHANGES
EVIDENCE REQUIRED TO SHOW
WILLFULNESS

In *In re Seagate Technology, LLC*, 83 U.S.P.Q.2d 1865 (Fed. Cir. 2007), the Federal Circuit, sitting *sua sponte en banc*, overruled established doctrine to establish that "proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness". 83 U.S.P.Q.2d at 1870.

BACKGROUND

On July 13, 2000, Convole, Inc. and the Massachusetts Institute of Technology (hereinafter "Convole") sued Seagate Technology, LLC ("Seagate") alleging patent infringement of U.S. Patent Nos. 4,916,635 (the '635 patent) and 5,638,267 (the '267 patent). On January 25, 2002, Convole amended its complaint to include U.S. Patent No. 6,314,473 (the '473 patent), which issued on November 6, 2001.

Before litigation began, Seagate retained Gerald Sekimura to provide possible infringement analysis with regard to Convole's patents. On July 24, 2000, Seagate received the first of three opinions. The first opinion analyzed the '635 and '267 patents and an international application containing similar disclosure to the application which resulted in the '473 patent. The first opinion concluded that many of the claims were invalid and that Seagate's products did not infringe. On December 29, 2000, and February 21, 2003, Seagate received updated opinions containing similar conclusions.

Seagate notified Convole that Seagate, in defending against willful infringement, intended to rely on the opinions of Sekimura, disclosed his entire work product, and made him available for deposition.

Convole moved to compel discover of any communications and work product with regard to the formal opinions, including communications between Seagate and any attorneys.

The trial court determined that, in reliance on Sekimura's opinions, Seagate waived attorney-client privilege for all communications between Seagate and any counsel regarding Sekimura's opinions. As such, the trial court ordered production of the requested documents. Also, the trial court determined that protection afforded to work product communicated to Seagate was waived.

Seagate was denied a motion for stay and certification of an interlocutory appeal, and petitioned for a writ of mandamus.

WILLFUL INFRINGEMENT

"Given the impact of the statutory duty of care standard announced in *Underwater Devices, Inc. v. Morrison-Knudson Co.*, 717 F.2d 1380 (Fed. Cir. 1983), on the issue of waiver of attorney-client privilege, should this court reconsider the decision in *Underwater Devices* and the duty of care standard itself?" 83 U.S.P.Q.2d at 1867.

In *Underwater Devices*, the Federal Circuit, in determining a standard for willful infringement, held that a potential infringer having actual notice of another's patent rights has an affirmative duty to exercise due care to determine whether the pursued activities would amount to infringement. Further, such affirmative duty includes seeking and obtaining competent legal advice from counsel before pursuing any potentially infringing activity. Analysis of willfulness and *Underwater Devices's* affirmative duty of due care evolved into a totality of the circumstances analysis including factors to indicate the state of mind of the accused. See *The Read Corp. v.*

Portec Inc., 23 U.S.P.Q.2d 1426 at 1435-1436 (Fed. Cir. 1992) (listing nine factors and stating: "Willfulness is a determination as to a state of mind.").

However, the Federal Circuit determined that the standard for willful infringement of *Underwater Devices* was not in line with established law for enhancing damages in the civil context. For example, under the Copyright Act, trial courts have discretion to enhance damages for willful infringement, which has been consistently defined as including reckless behavior despite there being no statutory basis for such definition. Also, the Supreme Court determined willfulness for punitive damages for civil liability to include reckless behavior. "Significantly, the Court said that this definition comports with the common law usage, which 'treated actions in 'reckless disregard' of the law as 'willful violations.'" 83 U.S.P.Q.2d at 1870 quoting *Safeco Ins. Co. of Am. v. Burr*, 127 S. Ct. 2201;167 L. Ed. 2d 1045 (2007).

Here, the Federal Circuit determined that duty of care standard of *Underwater Devices* provides a lower threshold for willful infringement than the established definition of willfulness requires. "Accordingly, we overrule the standard set out in *Underwater Devices* and hold that proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness." 83 U.S.P.Q.2d at 1870. In order to establish willful infringement, a patentee must now show by clear and convincing evidence that the alleged infringer "acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." *Id.* Upon such a showing, the patentee must also "demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer." *Id.*

ATTORNEY-CLIENT PRIVILEGE

As the trial court held attorney-client privilege waived with respect to all communications regarding the Sekimura opinions between all counsel, the Federal Circuit next addressed the appropriate scope of such waiver resulting from an advice of counsel defense asserted in response to a charge of willful infringement. The Federal Circuit noted the "significantly different functions" of trial counsel and opinion counsel and "advise[s] against extending waiver to trial counsel". 83 U.S.P.Q.2d at 1871. As a general proposition, the Court held that the assertion of the defense of advice of

counsel and disclosure of opinions by opinion counsel does not constitute waiver of the attorney-client privilege with respect to communications with trial counsel regarding such opinions. However, the Court does not "purport to set out an absolute rule" such that waiver may occur in exceptional circumstances as determined at the discretion of the trial court.

WORK PRODUCT PROTECTION

As the trial court also determined that protection of work product communicated to Seagate was waived, the Federal Circuit addressed the extent of waiver with regards to an advice of counsel defense asserted to refute a charge of willful infringement and whether any waiver extends to work product of the trial counsel. The Federal Circuit generally maintained the state of the current law in that in order to discover factual work product, the movant needs show substantial need and undue hardship while "mental process work product is afforded even greater, nearly absolute, protection." Slip op. at 19. Thus, the mere reliance on an opinion does not automatically waive any work product with respect to the trial counsel.

IMPACT ON PATENT OWNERS

It is important to note two changes that this new willfulness test makes to the establishment of willful infringement. First, the standard for enhancing damages with a finding of willful infringement has been raised from a negligence-type reasonable duty of care standard to an objective reckless standard. Second, such objective reckless standard does not take into account the state of mind of the accused. As such, the new test may be summarized as: an alleged patent infringer may be held to enhanced damages as a willful infringer if he knew or should have known that his activities had an objectively high likelihood of constituting infringement of a valid patent.

Moreover, in regard to the effect of relying on an opinion of counsel as a defense to willfulness, the rule that disclosure of opinions by opinion counsel does not constitute waiver of the attorney-client privilege is not absolute. Therefore, while accused infringers may rely on *In re Seagate* to help shield attorney client confidences where trial and opinion counsel are the same, it may be best practice, in an attempt to avoid such issues, to maintain minimal, if any, communications between opinion and trial counsel. In thus manner, if such communications are required to be produced, any damaging effects may be limited.

FEDERAL CIRCUIT *FURTHER DEFINES SCOPE OF FORESEEABLE ALTERNATIVES FOR PURPOSES OF PROSECUTION HISTORY ESTOPPEL*

In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.* 83 U.S.P.Q.2d 1385 (Fed. Cir. 2007) (*Festo XIII*), the Federal Circuit recently clarified some remaining issues surrounding prosecution history estoppel and the doctrine of equivalents in the most recent decision handed down in the on-going case of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.* In this decision, the thirteenth decision in the litigation, the Federal Circuit laid down rules for the "unforeseeability" exception to the bar raised by prosecution history estoppel.

In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2001) (*Festo VIII*), the Supreme Court held that amendments to a claim for the purposes of patentability raised a complete bar to the application of the doctrine of equivalents. The Court laid down three exceptions to this rule: the alleged equivalent was unforeseeable at the time of the application for the patent, the rationale behind the amendment bore only a tangential relation to the alleged equivalent, or for some other reason suggesting that the patentee could not reasonably have been expected to have described the insubstantial substitute.

The origins of the suit stretch back to 1981, when Dr. Kurt Stoll filed an application for a magnetically coupled rodless cylinder, which can be used in automobiles. These cylinders include a piston forced through a cylinder and magnetically coupled to a driven member or driven assembly. The driven member can then be used to drive an automobile or other vehicle. When the piston moves through the cylinder, the magnetic force moves the driven member, and the driven member then drives the vehicle. The '125 patent was directed toward a "small gap" cylinder, which minimizes the distance between the piston and the driven member so as to increase the strength of the magnetic force.

After the examiner rejected the claims, Dr. Stoll responded by amending claim 1 to include "a cylindrical sleeve made of a non-magnetizable material". The amendment also replaced the limitation of "sealing means" with "first sealing rings located axially outside said guide rings". The purpose of the amendments was not explained in the response. After the amendment and a few other changes, the examiner allowed the application, which issued as U.S. Patent No. 4,354,125 (the '125 patent).

Festo sued SMC (Shoketsu Kinzoku Kogyo Kabushiki Co.) for infringement of the '125 patent in August 1988. The accused device was also a magnetically coupled rodless cylinder; however, the device had two key differences. In the accused device, the sleeve is made of aluminum alloy, which is non-magnetizable material. In addition, the device contained two guide rings, but used only one sealing ring. Festo argued that the SMC device infringed under the doctrine of equivalents. SMC replied that the device did not infringe under the doctrine of equivalents, and that, in any event, prosecution history estoppel prevented the application of the doctrine of equivalents in this case.

Eventually, after nearly 15 years of litigation, the Supreme Court in *Festo VIII* remanded the case to determine whether any of the exceptions applied. Upon remand, the Federal Circuit, sitting *en banc*, held that whether a device met one of the named exceptions was a question of law for the judge, and that the only exception applicable to the facts of the case was the "unforeseeable" exception. *Festo X*, 344 F.3d 1359 (Fed. Cir. 2003).

After the remand from the Federal Circuit, the district court held a two-day bench trial. The district court then ruled that both of the differences in the SMC device were foreseeable. The aluminum alloy was foreseeable because containing magnetic leakage fields was not necessary to serve the purpose of the invention, and the sealing ring was foreseeable because, in light of Festo's lack of evidence on the strength of magnets in 1981 (the time of filing) and 1988 (the time of the suit), the court was unwilling to credit Festo's assertion that advances in magnetic technology had made the use of one sealing ring feasible. Festo appealed the decision to the Federal Circuit.

THE FEDERAL CIRCUIT'S NEW TEST

The Federal Circuit affirmed the district court, holding that the aluminum alloy was a foreseeable modification. The Federal Circuit did not reach the issue of whether the sealing ring was also a foreseeable modification. In reaching this conclusion, the Federal Circuit created a new rule to determine whether an alleged equivalent was foreseeable.

According to the Federal Circuit, an alleged equivalent is unforeseeable to one of ordinary skill in the art at the time of the amendment if "it is known in the field of the

invention as reflected in the claim scope before amendment." The rule applies even if "the suitability of the alternative for the particular purposes defined by the amended claim scope were unknown." Festo had argued that the proper test was to determine whether the equivalent was foreseeable through application of the function/way/result test. In other words, the proper test, according to Festo, was whether the equivalent was foreseeable to a person of ordinary skill in the art to perform the same function as the claimed device in substantially the same way, to achieve substantially the same result.

As an initial matter, the Federal Circuit noted that Festo's argument seemed to run counter to the purpose of the doctrine of equivalents. Under Festo's proposed test, a device having novel elements (elements not known at the time of the invention as being substantially similar to elements in the claim) would be captured by the proposed test. However, the doctrine of equivalents is intended to protect the scope of the invention, not to expand the scope of the invention to cover a new invention.

In addition to pointing out the inconsistency of Festo's proposed argument with the purposes of the doctrine of equivalents, the Federal Circuit went on to provide several additional reasons for rejecting Festo's test. First, the function/way/result test is used to determine whether an element of an accused device has only insubstantial differences with an element of the claims, not whether prosecution history estoppel applies to a limiting element. Festo provided, according to the Federal Circuit, no reason to import the function/way/result test from the old context (determining equivalency) to the new context (determining foreseeability and the application of prosecution history estoppel.)

Second, Festo's test would have the result of removing prosecution history estoppel as a serious restriction on the doctrine of equivalents. The Federal Circuit viewed Festo's proposal as applying prosecution history estoppel only where an applicant was aware, or should have been aware, that the alleged equivalent would be an equivalent for the purposes of the invention. Under this scenario, prosecution history estoppel would be applied only rarely.

Third, Festo's proposed test would lead to additional litigation and inconsistent positions taken by parties to a suit. In arguing for application of the doctrine of equivalents, the patentee would assert that the alleged equivalent performed the same function in substantially the same way, to achieve substantially the same result. However, in arguing against application of prosecution

estoppel, the patentee would assert that no one skilled in the art would have foreseen the equivalent because the equivalent, at the time, did *not* perform the same function in substantially the same way, to achieve substantially the same result. The accused infringer would be placed in a similar position. The subtle difference between the two tests, the timing, might easily be lost in the rush of litigation.

Finally, the Federal Circuit faulted Festo's timing. Whether an equivalent is foreseeable is determined as of before the narrowing amendment, not after the narrowing amendment, as argued by Festo. A foreseeable equivalent to the broad limitation does not become unforeseeable as a result of the narrowing amendment. Rather, it is the narrowing amendment that removes the foreseeable equivalent from the range of possible equivalents. An applicant who is aware of an equivalent under the broader claim, but chooses to amend the claim so as to eliminate the proposed equivalent from the scope of the claims, must have done so intentionally.

APPLICATION OF THE TEST

Having set forth the new test and turned aside Festo's arguments, the Federal Circuit applied the test to the facts of the Festo case. In the Festo case, non-magnetizable sleeves were known in the art at the time Dr. Stoll amended the claims. In fact, two German patents, cited by Dr. Stoll in his response, disclosed a sleeve made of a non-magnetic material. In his amendment, Dr. Stoll argued that the amended claims clearly distinguished the invention of the '125 patent from the two German patents. Further, the '125 patent itself indicated that choosing a magnetic (magnetizable) sleeve over a non-magnetizable sleeve was merely "a matter of personal selection". Since non-magnetizable sleeves were known in the art at the time of the amendment, the court held that the non-magnetizable sleeves were a foreseeable alternative to the magnetizable sleeves recited in the claim. Accordingly, prosecution history estoppel served to bar the use of the doctrine of equivalents to this element. Because this ground alone was enough to affirm the district court's holding that the doctrine of equivalents did not apply, the Federal Circuit did not consider whether the one guide ring in SMC's device was an equivalent to the two guide rings in the amended claim.

DISSENT

Judge Newman issued a forceful dissent. The most important distinction lay in whether the alleged equivalent had to be known as an equivalent at the time of the amendment, or whether the alleged equivalent had merely to exist. The majority opinion held that the

alleged equivalent merely needed to exist, and to be known to exist, for the equivalent to be foreseeable. However, Judge Newman believed that the alleged equivalent must also have been known to be an equivalent. To do otherwise would be to apply hindsight reasoning. As Judge Newman pointed out, "hindsight is not foreseeability."

SIGNIFICANCE TO PATENT OWNERS

Festo XIII is yet another nail in the coffin for the doctrine of equivalents. Under the rule in this case, patent applicants will be placed in the difficult position of trying to determine whether a potential equivalent, which is not an equivalent at the time of making the amendment, may later become an equivalent due to

advances in technology. The seemingly inconsistent result arrived at by the Federal Circuit may tempt lower courts to read the ruling narrowly. For example, Dr. Stoll gave no reason for the amendments at issue in *Festo*. Further, the specification itself indicated that non-magnetizable sleeves could be used. Given these facts, the Federal Circuit may have been less inclined to give *Festo* the benefit of the doubt. Avoiding the same fate may be as simple as carefully laying out the reasons for amendments to the claims, so as to limit the presumption of prosecution history estoppel. Any amendment should also be reviewed in light of the specification to see if any equivalents disclosed in the specification, even in passing, are being unnecessarily excluded from the narrower scope.

FEDERAL CIRCUIT FINDS INVENTION NON-OBVIOUS DUE TO LACK OF CONSIDERATION OF NON-OBVIOUSNESS EVIDENCE

In *In Re Sullivan et al.*, Civ. Case 2006-1507 (Fed. Cir. August 29, 2007), the applicants filed U.S. Patent Application No. 08/405,454 (the '454 application), which is drawn to an antivenom composition that comprises a portion of an antibody molecule, a Fab fragment. Fab fragments recognize and bind to specific antigens, such as the toxin in rattlesnake venom. The prior art taught using whole antibody molecules.

The examiner rejected the claims as being obvious over two references (Sullivan and Coulter). The examiner asserted that Sullivan teaches whole antibodies purified from horse serum for use against venom from rattlesnakes, but fails to teach the use of Fab fragments. The Examiner also found that Coulter discloses a method for producing Fab fragments in place of whole antibodies. The Examiner noted that Coulter further teaches using Fab fragments in enzyme immunoassays ("EIAs") to detect textilotoxin, a kind of snake toxin from the venom of the Australian brown snake. Also, Coulter teaches that Fab fragments used in EIAs yielded results similar to those obtained with whole IgG.

Over the course of prosecution, Applicants submitted three declarations to rebut the prima face case of obviousness put forth by the examiner, and amended the rejected claim as follows:

An antivenom pharmaceutical composition for treating a snakebite victim, comprising Fab fragments which bind specifically to a venom of a snake of the *Crotalus* genus and which are essentially free from contaminating Fc as

determined by immunoelectrophoresis using anti-Fc antibodies, and a pharmaceutically acceptable carrier, wherein said antivenom pharmaceutical composition neutralizes the lethality of the venom of a snake of the *Crotalus* genus.

The Board held that the amendments to the claim merely relate to the use of the claimed product and do not render the claim patentable, because a new use of an obvious composition is not patentable. In regards to the declarations, the Board stated in a footnote that the declarations of record relate only to the use of the claimed composition as an antivenom, and thus, the Board expressly declined to give any meaningful consideration to them. Thus, the Board affirmed the Examiner's decision that the claims were obvious.

On appeal, the Federal Circuit reversed. In reversing the Board, the Federal Circuit held that a claimed composition cannot be held to have been obvious if competent evidence rebuts the prima facie case of obviousness. In reviewing the Board's decision, the Federal Circuit held that, by failing to consider the submitted evidence, the Board committed an error since the Board must give the declarations meaningful consideration before arriving at its conclusion.

The Federal Circuit held that the Board was mistaken to assert that the declarations only relate to the use of the claimed composition. The declarations were put forth to show an unexpected result from use of the claimed composition, how the prior art taught away from the composition, and how a long-felt need existed for a new antivenom composition. The Board incorrectly focused

on the intended use of the claimed composition. While a statement of intended use may not render a known composition patentable, the claimed composition was not known, and therefore, whether the subject matter of the claim possesses an unexpected property is relevant. Whether the compound would have been obvious depends upon consideration of the rebuttal evidence. Thus, the unexpected property is relevant, and the declarations describing it should have been considered by the Board prior to finding the invention to be obvious.

SIGNIFICANCE FOR PATENT APPLICANTS

While *KSR v. Teleflex*, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385, (2007) may have signaled that the courts and the USPTO should be more flexible in their approach to obviousness, the requirement for evidence to support

whichever approach is taken is still very much in force. Conclusory statements that are unsupported by evidence (or which are contradictory to evidence) will not be sufficient to support a prima facie obviousness rejection even after *KSR*. As is evident from *In Re Sullivan et al.* as well as the *Takeda Chemical, Ex Parte Catan* and *Ex Parte Smith* discussed below, applicants should stress the evidentiary requirement in contesting obviousness rejections, and should require the Examiner explain any contrary evidence conflicting with any evidence relied upon by the Examiner. However, where such evidence is lacking or where there is only evidence of market pressures to make a combination, applicants and patent owners must provide contrary evidence to explain how a combination would not have been obvious as opposed to merely stating that there is no explicit teaching in the prior art.

FEDERAL CIRCUIT FINDS PATENTS INVALID UNDER OBVIOUSNESS TYPE DOUBLE PATENTING WHERE THE SPECIES ISSUES BEFORE THE GENUS

In *In re Metoprolol Succinate Patent Litigation*, 83 U.S.P.Q.2d 1545 (Fed. Cir. 2007), Lejus Medical AB filed application no. 690,197 (the '197 application) in 1985. The '197 application described "delayed and extended release dosage forms of pharmaceutical compositions, including metoprolol succinate." During prosecution, an inventorship dispute arose between Lejus and Astrazeneca. As a result of a settlement resulting from this inventorship dispute, Lejus agreed to divide the claims in the '197 application into claims to "metoprolol succinate," which was to be owned by Astrazeneca, and claims to "pharmaceutical composition, characterized by the active substance is metoprolol succinate" to be owned by Lejus.

Lejus cancelled the claims to the metoprolol succinate in the '197 application, and subsequently filed a continuation application to the metoprolol succinate, which it assigned to Astrazeneca. Lejus continued prosecution of the '197 application for the remaining claims, which eventually resulted in U.S. Patent 4,780,318 (the '318 patent) in 1988. Claim 8 of the '318 patent claims:

8. Pharmaceutical composition according to claim 7 [A core comprising the therapeutically active compound, a first inner layer coating on the core, and a second outer layer coating on the inner layer] wherein the active compound is quinidine sulphate, quinidine bisulphate, quinidine gluconate, quinidine hydrochloride, metoprolol tartrate, *metoprolol*

succinate, metoprolol fumarate, furosemide, 5-aminosalicylic acid [sic], propranolol or alprenolol or a pharmaceutically acceptable salt thereof, or a mixture thereof with another weak base, weak acid, or salt thereof having a pka of 1 to 8. (emphasis added)

Astrazeneca was issued two patents, both continuations of the '318 patent, of which only one was appealed in this case: U.S. Patent 5,081,154 (the '154 patent). The '154 issued in 1992 and claims simply:

1. Metoprolol succinate.

During the prosecution of its patents, Astrazeneca did not notify the examiners about the previous inventorship dispute.

Astrazeneca brought infringement actions against several defendants. On summary judgment, the District Court ruled Astrazeneca's '154 patent was invalid due to obviousness type double patenting over the '318 patent and additionally ruled the '154 patent unenforceable due to inequitable conduct.

INVALIDITY DUE TO OBVIOUSNESS TYPE

DOUBLE PATENTING

In affirming the District Court's ruling that the '154 patent was invalid due to obviousness type double patenting, the Federal Circuit noted that "[n]on-statutory, or 'obviousness-type,' double patenting is a

judicially created doctrine adopted to prevent claims in separate applications or parents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection." Determining double patenting is completed in two steps: first by construing each of the claims in the patents at issue, then second by determining whether the claims are patentably distinct.

On appeal, the only dispute was the second step: the comparison of the claims. The District Court found that because the '154 patent "broadly claims any pharmaceutical compositions containing metoprolol succinate", the '154 patent was a genus as compared to the '318 patent issued prior, which is a species of the genus and is drawn to the pharmaceutical composition including the metoprolol succinate. Since a genus is obvious in view of a prior disclosed species, the District Court found the '154 patent was patently indistinct and void for obviousness type double patenting.

Astrazeneca specifically contested the characterization that the claims were in a genus species relationship and were instead were in a patentably distinct element-combination relationship. In rejecting AstraZeneca's argument, the Federal Circuit held that "the characterization of the relationship" is irrelevant and "the critical inquiry remains whether the claims in the [latter application] define an obvious variation of the invention claimed in the [former] patent" *In re Emert*, 124 F.3d 1458, 44 U.S.P.Q.2d 1149 (Fed. Cir. 1997). The Federal Circuit specifically analogized the instant claims with the situation in *In re Emert*, where a claim for B1 was found obvious in light of a claim to [A and B]. In *In re Emert*, since the differences between B and B1 were conceded to be not material, the Federal Circuit found that because it would have been an obvious variation to omit the inner and outer layers, the patent in *In re Emert* was invalid for double patenting. Since the Federal Circuit viewed the claims in the '154 and '318 patents as being in the same basic relationship as existed in *In re Emert*, the Federal Circuit found that the claims were patentably indistinct, and that the later filed genus claim was thus invalid under *In re Emert*.

The Federal Circuit also rejected Astrazeneca's reliance on three cases from the Court of Customs and Patent Appeals which stand for the proposition that there is no obviousness type double patenting if a later application sets out an element found in a previously issued combination. *In re Walles*, 366 F.2d 786 (C.C.P.A. 1966); *In re Allen*, 343 F.2d 482 (C.C.P.A. 1965); *In re Heinle*, 342 F.2d 1001 (C.C.P.A. 1965). While acknowledging that these cases do support AstraZeneca's

position, the Federal Circuit held that a later issued opinion from the C.C.P.A., *In re Schneller*, 397 F.2d 350, 158 USPO 210 (C.C.P.A. 1968), limited these cases to their facts.

In *In re Schneller*, the Court of Customs and Patent Appeals affirmed a rejection where the applicant's "first application disclosed ABCXY and other matters. He obtained a patent claiming BCX and ABCX, but so claiming these combinations as to cover them no matter what other feature is incorporated in them, thus covering effectively ABCXY. He now, many years later, seeks more claims directed to ACBY and ABCXY. Thus, protection he already had would be extended, albeit in somewhat different form, for several years beyond the expiration of his patent." As such, the Federal Circuit found that *Schneller* limited *In re Walles*; *In re Allen*; *In re Heinle* to their facts.

The Federal Circuit noted that the same situation occurred in the instant appeal. Specifically, Lejus first obtained a patent claiming (A1, A2, A3, etc.)BC in Claim 6 of the '318 Patent. Astrazeneca later obtained a patent claiming A1 in Claim 1 of the '154 Patent. Therefore, the Federal Circuit found that the later issued genus claim was rendered obvious by the prior issued species claim.

UNENFORCEABILITY FOR FAILURE TO DISCLOSE INVENTORSHIP DISPUTE IN RELATED APPLICATION

The Federal Circuit vacated the District Court's determination of inequitable conduct and remanded on this issue. The Federal Circuit focused on whether Astrazeneca had an intent to deceive when prosecuting its patents with regards to the inventorship dispute. The District Court had inferred an intent to deceive due to the severe negative side effects had the inventorship dispute been related to the office and the inventor determined differently. According to the District Court, this intent to deceive would have been to prevent the loss of the effective filing date, which would have been lost and the patent would have been anticipated by Lejus' patent application published abroad.

However, the Federal Circuit rejected the District Court's "but for" analysis above. Specifically, the Federal Circuit noted that there was no evidence of this concern, and noted that the deposition of AstraZeneca's in-house patent counsel indicated "that he did not know of and was not concerned about the incentives identified by the district court." This lack of evidence raised a substantial issue of fact regarding intent to deceive that was not properly disposed of at summary

judgment. As such, the issue was remanded for further consideration.

SIGNIFICANCE FOR PATENT APPLICANTS

In re Metoprolol Succinate Patent Litigation demonstrates a difficulty which will be faced by applicants in maintaining separate pending applications for components and systems using the components under the new Claims and Continuation rules. As more thoroughly set forth in the *Feature Comment: An Overview Of USPTO Issues New Continuation And Claim*

Limitation Rules And Proposed Strategic Responses below, the new Claims and Continuation rules penalize applicants having copending applications with patentably indistinct claims. Specifically, under *In re Metoprolol Succinate Patent Litigation*, patentably indistinct claims can exist where there is a genus-species relationship as well as a component-system relationship. Thus, in addition to traditional obviousness type double patenting issues, applicants need to be prepared for possible 37 CFR 1.75 and 37 CFR 1.78 issues which will arise after November 1.

FEDERAL CIRCUIT FINDS OBVIOUSNESS WHERE INVENTION MERELY CONFIRMS PRIOR ART, AND OWNERSHIP REQUIRED FOR CONTRIBUTORY INFRINGEMENT

In *PharmaStem Therapeutics, Inc. v. Viacell, Inc., et al*, 491 F.3d 1342; 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007), the Federal Circuit affirmed a Judgment as a Matter of Law (JMOL) finding non-infringement and reversed a JMOL finding there was no invalidity. At the District Court of Delaware, a jury found infringement of PharmaStem's two patents, and found that they were not invalid. After the jury verdict, a JMOL was granted finding non-infringement, and another was rejected upholding the patents' validity. Both parties filed appeals, challenging both rulings.

The infringement analysis provided by the plaintiff regarding a claimed composition of matter was predicated primarily on the defendants' advertising materials, and not on any direct analysis to show infringement of all elements. The defendant's advertising materials did not illustrate all the elements of the invention, and the plaintiff's expert witness who testified regarding infringement of the composition patented based their testimony on these advertising materials, not on additional direct testing of defendant's service. Because the testimony was no more than an interpretation of the advertising materials and was not aided by the expert's expertise, it was not an abuse of discretion for the district court to strike the testimony in its JMOL.

The infringement of the claimed method was alleged under a theory of contributory liability under 35 U.S.C. § 271(c). Because the defendants were holding the property in bailment for the families, and provided only a service, its does not constitute a "sale or offer for sale" as required by 35 U.S.C. § 271(c).

Lastly, statements in the patent specifications regarding prior art bound the plaintiffs, despite expert testimony at trial that a skilled practitioner would expect the proof illustrated by the invention to be successful. Simply engaging in the routine research to confirm what was otherwise inferred by prior art did not raise the invention to the level of novelty.

NATURE OF THE INVENTION

Both patents in this suit, U.S. Patent No. 5,004,681 and continuation-in-part U.S. Patent No. 5,192,553, relate to the medical use of cryogenically frozen cells to rebuild an adult's immune system after it has been compromised. Blood is drawn from an infant or umbilical cord, cryogenically frozen, and may be used for hematopoietic reconstitution.

The claims at issue in this appeal are as follows:

Claim 1 of the '681 patent:

A cryopreserved therapeutic composition comprising viable human neonatal or fetal hematopoietic stem cells derived from the umbilical cord blood or placental blood of a single human collected at the birth of said human, in which said cells are present in an amount sufficient to effect hematopoietic reconstitution of a human adult; and an amount of cryopreservative sufficient for cryopreservation of said cells.

Claim 13, an independent claim, of the '553 patent:

A method for hematopoietic or immune reconstitution of a human comprising:(a) isolating human neonatal or fetal blood components

containing hematopoietic stem cells; (b) cryopreserving the blood components; (c) thawing the blood components; and (d) introducing the blood components into a suitable human host, such that the hematopoietic stem cells are viable and can proliferate with the host.

EXPERT TESTIMONY SUPPORTING INFRINGEMENT OF '681 PATENT

On appeal, infringement of the '681 patent was limited to whether the defendants provided a composition "in an amount sufficient to effect hematopoietic reconstitution in a human adult" from a single unit of cord blood. PharmaStem did not provide direct testing of samples to show that Defendants' cord blood contained enough stem cells, but provided indirect evidence from defendants' advertisements, scientific evidence of stem cells in general, and expert testimony.

On motion for JMOL, the district court, and the Federal Circuit here agreed, that the indirect evidence presented was not enough to constitute substantial evidence to support infringement. Similarly, generalized advertisements about the uses of cord blood were made by the defendants' advertisements, for example: reciting successes of cord blood transplants in children and adults related to the children, transplants by the company itself, and company-specific advertisements of transplants to adults. However, none of the advertisements indicated that single units of cord blood were used or successful at reconstitution post-transplant. The Federal Circuit notes this as particularly relevant because "in most cases, the physicians [performing transplants] regarded a single unit as insufficient for an adult transplantation."

The expert testimony provided by PharmaStem was stricken by the district court because the testimony was primarily an interpretation of the defendants' marketing materials, and the testimony was not aided by the expert's expertise in the field. The Federal Circuit agreed, stating "[we agree that] the defendants' materials did not constitute sufficient proof of infringement of the '681 patent and that those materials did not become proof of infringement when Dr. Hendrix read those materials back to the jury from the witness stand."

CONTRIBUTORY INFRINGEMENT OF '553 PATENT FOR BAILEES

Regarding the '553 patent, none of the accused infringers enacted all four steps (a-d) of the patented method solely. The defendants withdrew the blood (a),

froze the blood (b), thawed the blood (c), and then transferred the blood to transplant physicians who transplanted the blood (d). The only theory of infringement of patent '553 raised in the trial and the appeal is contributory infringement under 35 U.S.C. § 271(c). Section 271(c) states: "Whoever offers to sell or sells . . . a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention . . . shall be liable as a contributory infringer."

The Federal Circuit held that to be held liable according to 35 U.S.C. § 271(c), there must be a sale or offer for sale which requires as a prerequisite that the accused infringer be the owner of the component of the method. The defendants acted as bailees for the blood which was actually owned by the families that requested it drawn because the blood was drawn at the families' request, and the defendants contractually agree to return the same sample upon request. Because there was no actual sale by the owners, merely a transfer by bailees, there is no infringement under § 271(c).

The Federal Circuit rejected the argument that the sale of a service may satisfy contributory infringement under 35 U.S.C. § 271(c). While the court notes that it may satisfy 35 U.S.C. § 271(b) (inducement of infringement), the sale of a service does not satisfy the plain language requirement that indicates the sale of an actual good, and moreover is supported by the legislative history.

In addition, the defendants did not sell the service to the transplanters, but sold services to the families, and merely transferred the cells to the transplanters at the families' direction and therefore was not a sale to the transplanters.

OBVIOUSNESS

To invalidate the patents for obviousness, the defendants had to prove that both one skilled in the art would have reason to attempt to make the composition or practice the method, and there would have been a reasonable expectation of success. On this appeal, the issue was whether there would have been an expectation of success, which for this patent was construed to mean whether cord blood could be successfully used in transplants for hematopoietic reconstitution.

At trial, PharmaStem's expert stated there were problems with previous transplant tissues, including adult blood; it was not believed in the field that blood was suitable; and that researchers were surprised at the successful result. In addition, "[t]he cornerstone of Dr.

Bernstein's testimony at trial was that none of the prior art showed that cord blood contains stem cells" and that it was not conclusively established until the disclosure in the first patent. Several of the prior art references did, however, state that there are stem cells in cord blood, which Dr. Bernstein described as an error in nomenclature. In the patent specification itself, the inventors stated "hematopoietic stem cells have been demonstrated in human umbilical cord blood," which discredits Dr. Bernstein's assertion that there was mistaken nomenclature in the prior art. Because admissions in the specification are binding on the applicant, the jury was not free to disregard this admission and must have accepted the existence of prior art showing that a person of ordinary skill in the art would have believed that cord blood contains stem cells.

The experiments conducted by the inventors which confirmed the existence of stem cells, while advancing the field of art, did not rise to the level of nonobviousness. Citing the Supreme Court's decision in *KSR v. Teleflex*, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385, (2007), the Federal Circuit held that the inventors "used routine research methods to prove what was already believed to be the case," and the conclusions drawn from them were "not inventive in nature." In this case, because the patented invention arose from routine research which only proved what was believed to be true, it does not rise to the level of patentability. It was not a case of "varying all parameters [until success is found] . . . where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988). Each step of the process used to verify the

existence of stem cells in cord blood and the patented method were set out in the specification as present in the prior art.

SIGNIFICANCE FOR PATENT APPLICANTS AND OWNERS

PharmaStem Therapeutics highlights the importance of ownership and control in order to show contributory infringement to infringe. If possible, assemblers, distributors and shippers should include contractual language that establishes similar bailment defenses which are otherwise unavailable where the actual sales are established. For patent owners and applicants, *PharmaStem Therapeutics* confirms the need for adequate claim coverage to obtain direct infringement under 35 U.S.C. §271(a). The bailment defense, while applicable under the wording of 35 U.S.C. §271(b), does not apply to infringement under 35 U.S.C. §271(a).

Moreover, for applicants drafting new applications, *PharmaStem Therapeutics* highlights the need to ensure the specification does not contain unnecessary admissions against interest. Specifically, it was an admission against interest in the specification which undercut the patent owner's evidence of non-obviousness, and thus removed the most powerful evidence of non-obviousness needed to show patentability under *KSR v. Teleflex*, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385, (2007). Moreover, as was also the case in *SafeTCare* discussed below, such statements can be used to construe patent claims and disclaim both literal coverage and coverage under the doctrine of equivalents. Therefore, unnecessary statements characterizing the prior art should be removed from specifications.

FEDERAL CIRCUIT USES BACKGROUND OF THE INVENTION TO DISCLAIM CLAIM SCOPE

In *SafeTCare Manufacturing Inc. v. Tele-Made Inc.*, 83 U.S.P.Q.2d 1618 (Fed. Cir. 2007), SafeTCare owns U.S. Patent No. 6,357,065 (the '065 patent), which is drawn to a variable width bariatric modular bed for use with obese hospital patients. In order to move bed sections, a force is applied to a lift dog, which the court recognized as a term of art relating to a bracket attached to a movable deck assembly or lift assembly. In the Background section of the specification, the '065 patent discusses how the prior art uses "electric motors [that] are known to apply a pulling force on structural members attached to the bed frame." By way of contrast, the '065 patent in the Summary of the Invention describes motors which "apply pushing forces

against the lift dogs" and that the electric motors use "pushing (as opposed to pulling) forces applied by the electric motors to raise the frame and the mattress support deck." The specification also includes statements in the Detailed Description noting that "an important feature of the present invention" utilizes motors which "apply pushing forces against their respective lift dogs." Consistent with this description, claim 12 of the '065 recites "a plurality of electric motors ... for exerting a pushing force on said plurality of deck sections."

Tele-Made sells a bariatric hospital bed named the Tri-flex II, which is manufactured by Burke, Inc. The Tri-

flex II includes moveable bed panels that rotate upward relative to the bed frame similarly to the claimed bariatric bed and uses multiple electric motors. However, only one of the motors exerts a pushing force to achieve this upward motion. The other motor exerts a pulling force, which through various other members of the bed results in the upward motion of the foot section.

SafeTCare filed suit in the Southern District of Texas against Tele-Made asserting that the Tri-flex II infringed claim 12. During the Markman hearing, the District Court found that the recited "pushing force" of claim 12 was a "physical force applied in a direction away from the body exerting it." Based upon this construction, Tele-made filed a motion for summary judgment for non-infringement since the Tri-flex II lacked multiple motors applying a pushing force. The District Court granted the summary judgment.

On appeal, SafeTCare argued that the other motor, which resulted in the upward motion, also exerted a pushing force as defined by the claimed invention. In affirming the District Court's decision, the Federal Circuit quoted *Phillips v. AWH Corp.*, 415 F.3d 1303,

1315-16 (Fed. Cir. 2005)(en banc) for the proposition that the specification "is the single best guide for the meaning of a disputed term" and "may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." In reviewing the specification, the Federal Circuit found that the specification disavowed claim scope to cover motors which exert a pulling force, even where the pulling force otherwise resulted in a same upward motion for the bed panel which the claimed invention obtains through pushing. Specifically, the Federal Circuit found that the multiple disclosures and comparison of pushing versus pulling on the lift dogs made "clear that this attribute of the invention is important in distinguishing the invention over the prior art." As such, the inventors' disavowal of pulling motors in the specification limited the literal scope of the claims such that the Tri-flex II bed was not infringing.

For similar reasons, the Federal Circuit relied on its prior decision in *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 13612 (Fed Cir. 2006) that this disavowal also prevented infringement under the doctrine of equivalents. As such, the Federal Circuit affirmed the District Court's decision of no infringement under the doctrine of equivalents.

FEDERAL CIRCUIT FINDS LACK OF JURISDICTION FOR DECLARATORY JUDGMENT ACT

In *Benitec Australia, LTD. v. Nucleonics, Inc.*, 83 U.S.P.Q.2d 1449 (Fed. Cir. 2007), the United States Court of Federal Appeals for the Federal Circuit affirmed the Delaware District Court's decision dismissing Nucleonics' declaratory judgment counterclaims against Benitec Australia regarding invalidity of U.S. Patent No. 6,573,099 (" '099 patent"), which related to RNA-based disease therapy, for lack of subject matter jurisdiction.

Benitec and Nucleonics are both biotechnology companies that are engaged in gene silencing, where a cell is exposed to foreign DNA specifically engineered to contain portions of the target gene to be silenced. The foreign DNA then produces molecules that shut down the expression of the target gene. This technology is called RNA interference (RNAi) gene silencing. Benitec owns the '099 patent which relates to RNA-based disease therapy, and sued Nucleonics for infringement. Nucleonics moved to dismiss Benitec's complaint for failure to state a claim and lack of jurisdiction. Nucleonics also argued that it would not be ready to file a New Drug Application until 2010-2012, if ever; consequently Benitec's claim is premature for a Court at this time.

On October 4, 2004 and May 18, 2006, Nucleonics filed a request to the USPTO for reexamination of the '099 patent; both requests were granted and merged into one proceeding. Benitec then canceled claims 1, 2, and 8 during reexamination, but in April of 2006, the examiner rejected all other claims of the patent. On June 2006, Benitec attempted to overcome the rejection, but as of December 2006, the examiner has not substantively responded.

Benitec encountered other obstacles. First, Nucleonics received evidence that the inventor of patent '099 may have misappropriated the idea from other inventors who were not named in the patent. Consequently, in February of 2005, Nucleonics sought to amend its answer to add declaratory relief counterclaims of invalidity and unenforceability based on alleged inventorship fraud. On June 2006, Nucleonics obtained testimony from two Australian scientists indicating that they had contributed to the subject matter of patent '099, but neither was named as inventor in the patent. Second, the Supreme Court decided *Merk KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), which expansively read exception §271(e)(1) concluding that the use, sale, or import of a patent that is primarily

manufactured using RNA, amongst others, is non-infringing.

On August of 2005, Benitec moved to dismiss its complaint without prejudice only because of the *Merk* decision, which indicated Benitec had no viable infringement claim against Nucleonics.

The district court granted Nucleonics' motion to amend its answer, but two weeks later the court granted Benitec's motion to dismiss its complaint without prejudice for lack of jurisdiction under the Declaratory Judgment Act, 28 U.S.C. §§2201-02. Between Nucleonics motion to amend and the court's dismissal, Nucleonics allegedly began discussing an expansion of its efforts to animal husbandry and veterinary products. Next, Nucleonics appealed the dismissal of its declaratory judgment counterclaims because Benitec's covenants and promises not to sue Nucleonics for patent infringement were entered in this action. As such, the issue on appeal was whether the court at this time has declaratory judgment jurisdiction over Nucleonics' counterclaims seeking declaration of invalidity and unenforceability of Benitec's '099 patent

As noted by the Federal Circuit, the Supreme Court in *MedImmune Inc. v. Genentech*, 127 S. Ct. 764 (2007) rejected the "reasonable apprehension of imminent suit" test, and held that the standard for determining Declaratory Relief jurisdiction is "whether the facts alleged, under all circumstances, show that there is substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment" *Id.* at 771. Moreover, in *Sandisk Corp v. STMicroelectronics NV*, 480 F.3d 1372 (Fed. Cir. 2007), the Federal Circuit explained that Article III jurisdiction may be satisfied "where a patentee asserts rights under a patent based on certain ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without a license"; however, that party need not risk an infringement suit by engaging in the identified activity prior to seeking declaratory judgment. Also, there must be an underlying legal cause of action that the declaratory defendant could have brought or threatened to bring suit, but for the fact that the declaratory plaintiff has preempted it.

Regarding the burden, the party claiming declaratory judgment jurisdiction must establish that such jurisdiction existed at the time the claim was filed, and that it has continued since. The party challenging the jurisdiction may have the burden of bringing forth further information, but the actual burden of proof

remains with the party seeking declaratory judgment jurisdiction.

The Federal Circuit determined that declaratory judgment jurisdiction was present at the time Nucleonics filed its counterclaims for declarations of invalidity and unenforceability because Nucleonics had been charged with infringing Benitec's patent. This is supported by *Cardinal Chem. Co. v. Morton Int'l Inc.*, 508 U.S. 83 (1993), which held that an actual charge of infringement of a patent is necessarily a case or controversy adequate to support jurisdiction. However, the Federal Circuit determined there was no declaratory judgment jurisdiction at the present time.

Specifically, the Federal Circuit pointed to *SuperSack Mfg. Corp. v. Chase Packing Corp.*, 57 F.3d. 1054 (Fed. Cir. 1995) and *Amana Refrigeration Inc. v. Quadlux, Inc.*, 172 F.3d. 852 (Fed. Cir. 1999) on this issue. In *Super Sack*, an unconditional agreement "not to sue Chase for infringement as to any claim of the patent-in-suit based on the products currently manufactured and sold by Chase" was sufficient to divest the court of jurisdiction over Chase's counterclaims of invalidity and unenforceability. Chase was engaged in no "present activity" placing it at risk for infringement, and the residual possibility of a lawsuit was too speculative to serve as basis for jurisdiction. In *Amana Refrigeration*, Amana sued Quadlux for declaratory judgment of patent invalidity and noninfringement, and Quadlux responded with a promise not to sue Amana for infringement based on the patent-in-suit. The Federal Circuit held such promise diverted the district court's jurisdiction. Although both *Super Sack* and *Amana* applied the "reasonable apprehension of imminent suit" test rejected in *MedImmune*, the Federal Circuit stressed that it based its analysis of whether jurisdiction is currently present over Nucleonics under the framework of *MedImmune*.

Under §271(e)(1) of Title 35 of the United States Code:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal

law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

Both parties agree that under *Merk* and §271(e)(1), Nucleonics' activities related to human medical application of RNAi are not infringing and cannot become infringing until Nucleonics files a new drug application. However, Nucleonics does not expect to file a new drug application until 2010-2012 if ever; consequently, Nucleonics' activities of developing a human application of RNAi and submitting information to the FDA do not present a case and controversy of sufficient immediacy and reality to warrant a declaratory judgment jurisdiction over the enforceability of the '099 patent.

Nucleonics argued that *Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340 (Fed. Cir. 2005) supports its position of jurisdiction. *Fort James* sued *Solo Cup* for infringement of three patents, and *Solo Cup* counterclaimed seeking declaration that the patents were invalid, unenforceable, and not infringed. The district court bifurcated the trial, which meant all issues were to be resolved by the jury first, except for *Solo Cup's* unenforceability counterclaim. The jury determined that one of the patents-in-suit was neither invalid nor infringed. *Fort James* then promised not to sue *Solo Cup* or attempt to overturn the jury's verdict. Nonetheless, the Federal Circuit held that there was still declaratory judgment jurisdiction over *Solo Cup* counterclaim. However, in that case the controversy had already been resolved, as opposed to in the present case where no trial of infringement has taken place.

The Federal Circuit also pointed to *SanDisk*, where the court did hold that *STMicroelectronics's* (ST) statement that it "ha[d] absolutely no plan whatsoever to sue *SanDisk*" did not eliminate the justiciable controversy. However, ST's course of conduct showed that it was willing to enforce its patent rights regardless of the statement made. 480 F.3d at 1382. Here, *Benitec* sought dismissal of the infringement claim after it concluded that the *Merk* decision would preclude such

claim. Consequently, there is no controversy between the parties regarding infringement by Nucleonics and its human applications of RNAi technology.

Regarding animal application of RNAi, Nucleonics argues that such products would not be protected from infringement under §271(e)(1) because they fall within "new animal drug or veterinary biological product" exception. The Federal Circuit held that for Nucleonics to be liable for infringement, it has to have the authority to make, use, offer to sell, or sell a product that infringes the '099 patent. However, there is no evidence of such infringing product. The Federal Circuit also indicated that the declaration by Nucleonics' president to an unnamed supplier regarding its desire to expand its efforts into animal markets does not amount to an offer to sell. In addition, Nucleonics has not shown use of such a product. Nucleonics has failed to meet its burden of showing that it has engaged in an activity that could subject to it to an infringement claim by *Benitec*; consequently, Nucleonics has not satisfied *MedImmune's* real and immediacy requirement.

The Federal Circuit also concluded that Nucleonics failed to show that its future plans meet the *MedImmune* standard for three main reasons. First, discussions and execution of an undisclosed confidentiality agreement with an unnamed potential customer indicate mere expectations to begin work "shortly". Second, there is not sufficient evidence to indicate that Nucleonics future activities would fall within §271(e)(1)'s parenthetical exception for animal drugs. Third, *Benitec* has not challenged the use of the technology for animal use, and claims another company owns a right to do so.

The Federal Circuit concluded that there is no substantial controversy between *Benitec* and Nucleonics of sufficient immediacy and reality to warrant declaratory judgment under the *MedImmune* standard. Consequently, the Federal Circuit affirmed the district court's dismissal for lack of subject matter jurisdiction.

FEDERAL CIRCUIT FINDS EVIDENCE REQUIRED TO SUPPORT CONCLUSION OF "OBVIOUS TO TRY" UNDER KSR TEST

In *Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd.*, 83 U.S.P.Q.2d 1169 (Fed. Cir. 2007), *Takeda* developed the drug ACTOS®, which is used to control blood sugar in patients who suffer from Type 2 diabetes. ACTOS® uses a specific TZD compound that is covered by U.S. Patent 4,687,777 (the "'777 patent"). *Alphapharm*

filed an Abbreviated New Drug Application ("ANDA") pursuant to the Hatch-Waxman Act in order to manufacture a generic version of ACTOS®. As such, *Takeda* filed suit against *Alphapharm* for infringement of the '777 patent.

As a defense, Alphapharm asserted that the '777 patent was obvious under 35 U.S.C. §103 as the patented TZD compound would have been obvious to try in light of an existing compound admitted to be in the prior art and which is structurally similar to the patented TZD compound: compound b,. The District Court found that Alphapharm had not provided sufficient evidence to maintain a *prima facie* obviousness defense as there was insufficient evidence as to why compound b would have been modified to meet the requirements of the claimed compound. The District Court further noted that the prior art taught away from the use of the compound b. Lastly, the District Court found that there was un rebutted evidence of unexpected results, which further supported a finding of non-obviousness.

On appeal, the Federal Circuit affirmed the findings of the District Court. In reviewing the Supreme Court's decision in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007), the Federal Circuit affirmed that mere structural similarity is not sufficient to make out a *prima facie* obviousness defense as set forth in *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). As characterized by the Federal Circuit, *In re Deuel* stands for the proposition that "close or established '[s]tructural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds.'" However, while "a known compound may suggest its homolog, analog, or isomer because such compounds 'often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties' ... in order to find a *prima facie* case of unpatentability in such instances, a showing that the 'prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention' was also required."

The Federal Circuit held that such evidence of suggestion remained after *KSR* since the Supreme Court in *KSR* "acknowledged the importance of identifying 'a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination." As such, the Federal Circuit found that there needs to be evidence as to "some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound."

Since Alphapharm did not provide any such evidence, the District Court was correct in finding nonobviousness based solely on compound b. Specifically, the District Court noted that the evidence of record indicated that

there were "hundreds of millions of TZD compounds" and the prior art "specifically identified fifty-four compounds, including compound b, that were synthesized according to the procedures described in the patent, but did not disclose experimental data or test results for any of those compounds." Further, the District Court relied upon a prior art article which reviewed 101 TZD compounds, including compound b, recommended three other compounds for use instead of compound b, and specifically criticized compound b. Lastly, testimony from witnesses, including Alphapharm's head of intellectual property department, admitted that, especially in light of the prior art article, there was no suggestion as to why compound b would be investigated as opposed to the three more promising TZD compounds identified in the article. As such, based upon the record as a whole, there was insufficient evidence as to why, out of the TZD compounds, compound b would have been used or why a chemist would have investigate compound b to obtain the claimed TZD compound in the '777 patent.

Moreover, the Federal Circuit rejected Alphapharm's argument that adjusting compound b to achieve the claimed TZD compound would have been "obvious to try." Specifically, the Federal Circuit found that the Supreme Court, in analyzing whether a combination would be obvious to try, limited such a situation to "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions [such that] a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.'" In applying the factors outlined in *KSR*, the Federal Circuit noted that the prior art identified more than a few predictable solutions since there were "a broad selection of compounds" and "any one of which [of the broad selection of compounds] could have been selected as a lead compound for further investigation."

Lastly, the Federal Circuit found that, even if compound b were chosen, there was insufficient evidence that one skilled in the art would typically make modifications to the TZD compounds to achieve the patented TZD compound. There was no evidence that there would have been an expectation of success in making a specific substitution or structural change to compound b to achieve the patented TZD compound, and the prior art article actually suggested that other changes should be made instead. Thus, the Federal Circuit also found that the art was not predictable and that the number of solutions was more than finite, as would be required to find obviousness under the Supreme Court's test in *KSR*.

FEDERAL CIRCUIT FINDS NO PUBLIC USE

In *Motionless Keyboard Co. v. Microsoft et al.*, 486 F.3d 1376; 82 U.S.P.Q.2D 1801 (Fed. Cir. 2007), Motionless appealed a summary judgment finding that there was no infringement of Motionless' two keyboard patents, U.S. Patent No. 5,332,322 (the '322 patent) and U.S. Patent No. 5,178,477 (the '477 patent), based on claim construction and finding that the patents were invalid based on public use and the later patent invalid for obviousness. Motionless appealed the claim construction of U.S. the '322 patent and the finding of invalidity of the '477 patent, and the 322 patent.

The Federal Circuit affirmed the narrow claim construction, construing "a concavity in said housing at said key actuation position, and a thumb-associable cluster of keys forming a keyboard within said concavity" to mean a depression within the housing within which the keys were placed. This claim construction was supported by the specification and the renderings. The Federal Circuit reversed the public use application in this case because the disclosures to potential inventors did not demonstrate the device in actual use, and merely showed the design and was never used "in the normal course of business." The Federal Circuit also reversed the finding of obviousness because a terminal disclaimer to make a patent coterminous is "simply not an admission of obviousness."

FACTS

The two patents at issue were developed by an independent inventor working in his spare time to create an ergonomic keyboard. While the device was in development, it was disclosed to several potential investors under a two-year non-disclosure agreement (NDA) in 1987. The device was also disclosed to a friend in 1987, who did not sign a NDA. In none of these disclosures was the device connected to a computer or demonstrated the ability to input data to a computer. On July 25, 1990, a typist was asked to test the device, which was connected to a computer. The typist did not sign a NDA before testing the device, but did sign one later that day.

The patent application for the '477 patent was filed on June 6, 1991. The application for the '322 patent was filed as a continuation-in-part on January 11, 1993. In addition, a terminal disclaimer was filed for the '322 patent to make it coterminous with the '477 patent.

Subsequently, the inventor's assignee, Motionless Keyboard Company (MKC), sued Microsoft Corp. and Saitek Industries Ltd. each for manufacturing an

infringing joystick, and Nokia, Inc, for manufacturing an infringing cell phone.

The district court granted summary judgment finding that there was no infringement, either directly or through the doctrine of equivalents and that the patents were invalid due to public use and the '322 patent was additionally invalid due to obviousness. Motionless appealed finding of no infringement for the '322 patent and the invalidity of both patents.

CLAIM CONSTRUCTION

The independent claim of patent '322 whose construction is at issue claims: 1. A hand-held device for entering information into an electronic system via a keyboard, the device comprising: ... a concavity in said housing at said key-actuation position, and a thumb-associable cluster of keys forming a keyboard within said concavity, each of the plurality of keys in said cluster being selectively actuatable via mixed lateral and slight endo, translation of a thumb within said concavity, whereby information is entered into an electronic system.

The district court construed the '322 claim to mean "that the concavity must be formed by a depression in the housing of the device, and that all keys comprising the keyboard must be contained entirely within the concave area and sunk below the surface of the housing, so that the thumb movement occurs within the concave area."

On appeal, MKC argued that the concavity described means "that the tops of the keys themselves can form a concavity within the housing." The Federal Circuit, agreed with the district court's narrower reading, finding the limitations in the phrases "a concavity in said housing" and "a keyboard within said concavity" to define a "depression within the housing of the device and set the keyboard entirely within that depression." The court also references the specification, which reads: "a keyboard is positioned in a concavity or depression in the housing" (emphasis in opinion), and the renderings, which all show a "concavity in the housing of the device with the keyboard totally within the concavity." As such, the Federal Circuit found that the district court properly used the intrinsic evidence in the specification to define the claim term "concavity."

DIRECT INFRINGEMENT

In applying the claim construction the Federal Circuit affirmed the district court's finding that there was no

infringement. Neither Microsoft's nor Saitek's joysticks contain a concavity, nor do the keys of any joysticks extend beyond the surface of the housing. In the Nokia phone, the keys protrude through an opening in the housing. Though some phones do "contain keys with slight depressions, these keys do not constitute a concavity in the housing according to the '322 patent."

DOCTRINE OF EQUIVALENTS

The Federal Circuit found that MKC failed to present particularized evidence that linked the accused products to the patent. The Federal Circuit, citing *PC Connector Solutions LLC v. SmartDisk Corp.*, 406 F.3d 1359, 1364, which cites *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567, requires a patentee to "show particularized evidence and linking argument as to the 'insubstantiality of the differences' between the claimed invention and the accused device, or with respect to the 'function, way, result' test."

As applied to the joysticks, the Federal Circuit found that MKC used only the claim charts to show substantial similarities of form, function, and result. This does not constitute particularized evidence of insubstantial differences, or the same 'function, way, result' test. Without particularized evidence, the court did not need to further address the doctrine of equivalents.

As applied to the Nokia phones, the Nokia phones were not activated in the same way as the MKC patent. "While the patentee's invention points to actuation of the keys by thumb movement within the concavity, a user would actuate the Nokia keys by pressing them downward." Without particularized testimony to specifically show the keys work in the same way, the Federal Circuit affirmed the district court's ruling on equivalency.

PUBLIC USE

The district court held that because the invention was disclosed to investors prior to the critical dates (June 1991 and January 1992) and the inventor's business partner was not under an obligation to keep the invention secret, the invention had entered public domain. The district court found the NDAs inconsequential because "a confidentiality agreement will not preclude application of the public use doctrine, if the device was disclosed for commercial purposes," citing *Kinzenbaw v. Deere & Co.*, 741 F.2d 383, 390. The Federal Circuit reversed the finding of public use

with respect to both patents. The Federal Circuit cites the policy considerations from *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005) (quoting *Plaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998)) that public use arises from the "reluctance to allow an inventor to remove existing knowledge from public use." However, such policy does not automatically render every use a public use.

The Federal Circuit determined that the disclosures to potential investors, a friend, and a business partner did not constitute public use. This result was even though the applicable NDAs, in the case of the potential investors, had expired before the critical dates. These disclosures "only provided a visual view of the new keyboard design without any disclosure of the [invention's] ability to translate finger movements into actuation of keys to transmit data. In essence, these disclosures visually displayed the keyboard design without putting it into use."

The Federal Circuit distinguished the disclosure to the typing tester from the situations in *Egbert*, in which an inventor gave two samples of the invention to a friend who used them for two years, and *Electric Storage Battery*, in which the "ordinary use of a machine [. . .] in a factory in the usual course of producing articles for commercial purposes." In both cases, in which public use was found, the invention was used for its intended purpose before the critical date. Here, the invention was not used in public, for its intended purpose, nor given to anyone else for such purposes. "In this case, the one time typing test coupled with a signed NDA and no record of continued use of the [invention] by [the typing tester] after [the day tests were performed] did not elevate to the level of public use."

OBVIOUSNESS BASED UPON FILING OF A TERMINAL DISCLAIMER

The district court determined the '322 patent was invalid for obviousness because a terminal disclaimer was filed to make the '322 patent coterminous with the '477 patent, reasoning that it was a concession of obviousness. Citing *Quad Env'tl. Tech Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991), the Federal Circuit reversed, because "[a] terminal disclaimer simply is not an admission that a later-filed invention is obvious." As such, the mere filing of a terminal disclaimer does not represent an admission of obviousness.

FEDERAL CIRCUIT FINDS TESTING OF PROTOTYPE AND PUBLICATION ABOUT TEST ARE EXPERIMENTAL AND NOT PUBLIC USE OR ON SALE BARS UNDER 35 U.S.C. § 102(B)

In its opinion in *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982 ;82 U.S.P.Q.2d 1886 (Fed Cir. 2007), the United States Court of Appeals for the Federal Circuit affirmed in part, vacated in part, and remanded the Delaware District Court's decision invalidating certain claims and finding no infringement of Honeywell patents involving aviation electronic and terrain warning systems.

BACKGROUND

In the field of terrain warning technology for aviation, known "ground proximity warning systems" (GPWSs) have significantly reduced accidents resulting from planes flying into terrain since the 1970's. GPWSs use radio waves to measure the distance from the plane to the ground, which worked well for gradual changes in terrain. However, GPWSs do not provide information regarding the terrain in front of a plane. As a result, Honeywell began research in the 1980 to develop a "look ahead" terrain warning system. Honeywell came up with a virtual system, which compared the plane's position with a map of the earth terrain. In 1995, Honeywell received U.S. Patent Nos. 5,839,080 (the '080 patent), 6,092,009 (the '009 patent), 6,122,570 (the '570 patent), 6,138,060 (the '060 patent), and 6,219,592 (the '592 patent).

The accident that claimed the life of Ron Brown, Commerce Secretary, led to the FAA requiring that all commercial aircraft be equipped with a look ahead warning system. Consequently, Universal and Sandel began developing such systems. Honeywell then brought suit against both Universal and Sandel alleging infringement of the Honeywell patents. The district court granted the defendant's summary judgment motions of invalidity of claims withdrawn from litigation and of non-infringement; however, the court denied all of the defendant's remaining counterclaims.

The Federal Circuit addressed several issues during appeal. After determining that material issues remained as to whether there was infringement such that the summary judgment was inappropriate, the Federal Circuit went on to review whether the claims were invalid under 35 U.S.C. § 102(b) for being "in public use or on sale in this country, more than one year

prior to the date of the application for patent in the United States."

Section 102 (b) states that "[a] person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . ." The district court found that Honeywell claims were not invalidated by public use or commercial sale, and the Federal Circuit agreed.

NO ON SALE BAR SINCE TRANSFER WAS FOR EXPERIMENTAL USE AND WAS NOT COMMERCIAL

According to *Pfaff v. Wells Elec. Inc.*, 525 U.S. 55 (1998), for there to be an on sale bar, an invention must 1) be the subject of a commercial sale or offer for sale, and 2) be ready for patenting at the time of the sale or offer, to be unpatentable under the on-sale bar. In reviewing the facts of the case, in 1994, Honeywell conducted negotiations with Gulfstream and Canadair to incorporate the Honeywell system into luxury planes. However, these projects were for experimental purposes so that Honeywell could test the systems with human pilots in real cockpit setting. Also, Honeywell did not refer to the system as ready for sale and the record shows that negotiations and proposals before the critical date were for experimentation purposes. As such, there was no commercial sale pending in 1994.

Additionally, the record indicates that Honeywell's invention was not ready for patenting before the critical date. According to the Federal Circuit, an invention is ready for patenting "when evidence shows that the invention was reduced to practice or described in a written description sufficient to permit one of ordinary skill in the art to practice the invention without undue experimentation". The record shows a videotape of Honeywell's system on an aircraft before the critical date and other documentation, including an article (the "George article") published in June 2004 and which described a flight with this developmental system. However, the testing of the system was conducted to reduce the invention to practice, rather than to show

actual reduction of the invention. Thus, this evidence merely demonstrates that the invention was not ready for patenting at that time. As such, the 1994 negotiations were not an on sale bar for purposes of 35 U.S.C. 102(b).

NO PUBLIC USE SINCE USE WAS EXPERIMENTAL

Regarding the George article, Universal argues that it demonstrates public disclosure, but the district court concluded that the "George article clearly indicates that the system is in its developmental phase." A patent will be barred by public use when the invention has been in public use for more than one year before the filing of the patent, and such use does not have confidentiality restrictions and does not involve permitted

experimentation. *Allied Colloids Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570 (Fed. Cir. 1995). In order to determine when a use is a public use as opposed to an experimental use for purposes of 35 U.S.C. 102(b), the Supreme Court stated that "a bona fide effort to bring [the] invention to perfection, or to ascertain whether it will answer the purpose intended" does not constitute "public use." *City of Elizabeth v. Am. Nicholson Pave Co.*, 97 U.S. 126, 137 (1877). In the present case, Honeywell conducted demonstrations of its system to industry people aboard an aircraft using a laptop computer with the demonstration system. While these test flights did result in the George article, these demonstrations were performed to demonstrate the workability of the system, and thus were experimental and not public uses which would bar patentability of the invention.

FEDERAL CIRCUIT FINDS BOARD CANNOT RELY ON OWN EXPERTISE AS EVIDENCE IN CONTESTED PROCEEDINGS

In *Brand v. Miller*, 487 F.3d 862; 82 U.S.P.Q.2d 1705 (Fed Cir. 2007), Brand and Miller were involved in an interference related to a method of cutting veneer from logs. Generally, to produce veneer, logs are first cut lengthwise into pairs of flitches, and each pair is mounted into a "staylog" of a veneer cutting machine. Each flitch is mounted using "dogs", which hold the veneer in place on the rotating staylog and allow the veneer to be cut from the rotating flitch. Because each flitch is tapered due to the shape of the tree, conventional machines required that the butt ends be removed to have a roughly uniform shape.

The invention in dispute centered on a machine which removes veneer from a tapered flitch, thus not requiring the removal of the butt end of the flitch. Robert Brand, inventor for U.S. Patent Application No. 09/377,120 (the '120 application), and Thomas Miller, inventor for U.S. Patent No. 5,865,232 (the '232 patent), used a new type of dog to mount the tapered flitch onto the staylog. Since the '120 application and the '232 patent contained the same claim, an interference was declared.

During the interference, Miller was the junior party and the Board denied Miller's attempt to show an earlier invention date. As such, Miller claimed that Brand derived the '232 patent from Miller's earlier work. Miller claimed that he had shown Brand a drawing of his work (exhibit MX2001) at a meeting on October 12, 1994, which was before Brand's conception date, that did not show any dogs or holes in the flitch for receiving the dogs. Miller also produced a fax (exhibit MX2002),

which was sent to Brand on October 7, 1994 and shows a "bugle-headed screw dog." However, the only evidence indicating that Brand was informed of how the MX2001 and MX2002 drawings should be used together to form the invention was from Miller's uncorroborated testimony.

The Board rejected this testimony, but still found derivation based upon its own reasoning that "one skilled in the art ... would have recognized [the] suitability [of the bugle-headed screw dogs] for securely supporting a tapered flitch in the position depicted in [MX2001]." There was no support in the record, and the Board instead merely stated that "[t]he ability of the bugle-headed screw dogs to tightly clamp the flitch would have been readily apparent." In the alternative, and also without support in the record, the Board held that there was derivation because the MX2001 drawing alone showed the needed positions of the tapered flitch relative to a veneer-cutting knife since it was "clear that the position of the flitch is due to the fact that the dogging holes have different depths" and since "it is apparent that the flitch [not shown in the MX2001] is supported [in the required position]."

On appeal, the Federal Circuit analyzed the court's findings under the Administrative Procedures Act, 5 U.S.C. §554 and §556-57, as required under the Supreme Court's decision in *Dickinson v. Zurko*, 527 U.S. 150 (1999). Citing *In re Gartside*, 203 F.3d 1305 (Fed. Cir. 2000), the Federal Circuit noted that most PTO proceedings are not "formal adjudications" governed by

5 U.S.C. §556-57 because most PTO proceedings allow applicants to obtain a new trial, *de novo*, under 35 U.S.C. §§145-146. However, the Federal Circuit held that most PTO proceedings are still governed by judicial review as set forth in 5 U.S.C. §§701-706. After reviewing the various review standards set forth in 5 U.S.C. §706, and noting that all reviews of Board actions are required by 35 U.S.C. §144 to be appeals "on the record," the Federal Circuit held that the review was under 5 U.S.C. §706(2)(E). The standard under 5 U.S.C. §706(2)(E) requires a determination of whether the agency decision was "unsupported by *substantial evidence* in a case subject to sections 556 and 557 of this title or *otherwise reviewed on the record of an agency hearing provided by statute*."

Based upon this review, the Federal Circuit reviewed the Board's findings to determine if the record revealed substantial evidence to justify the Board's conclusions about derivation. First, the Federal Circuit noted that, especially in a contested proceeding like an interference, the record must be closed. Citing the Supreme Court in *Baltimore & Ohio R.R. Co. v. Aberdeen & Rockfish R.R. Co.*, 393 U.S. 87, 92 (1968), the Federal Circuit held that an agency cannot rely on its own expertise in a contested case because, without evidence, any administrative decision "would become lost in the haze of so-called expertise." The Federal Circuit also noted that the interference proceedings themselves highlight the importance of an administrative record. Based upon these rules of law and the regulations of the United States Patent and

Trademark Office, the Federal Circuit held that agency expertise cannot substitute for evidence to meet the substantial evidence standard. The Federal Circuit explicitly noted, however, that it is reserving judgment of "the extent to which the Board in *ex parte* proceedings is so limited."

Based upon this determination, Federal Circuit held that the Board's reliance on its expertise was improper and that, other than Miller's uncorroborated testimony that the Board also rejected, there was no evidence to show how one of ordinary skill in the art would have understood the drawings MX2001 and MX2002 or to show whether there was a communication regarding how the invention should be practiced. Instead, the Board improperly substituted its expertise to fill in these gaps, and did not "anchor in the record" its conclusions. As such, the Federal Circuit reversed the Board's decision.

IMPACT ON PATENT PROSECUTION

While *Brand* explicitly only reflects contested proceedings and the need for evidence in such proceedings for purposes of review under the Administrative Procedures Act, it is likely that similar logic would be followed during *ex parte* prosecution. Therefore, *Brand* is consistent with the above decisions relating to obviousness and the need for evidence (as opposed to unsupported conclusory statements) to substantiate a rejection.

RECENT PRECEDENTIAL BOARD DECISIONS RELATING TO OBVIOUSNESS AFTER *KSR*

EX PARTE SMITH

In *Ex Parte Smith*, 83 U.S.P.Q.2d 1509 (BPAI 2007) (precedential), the Board affirmed the examiner's rejection of claims based on anticipation based upon inherency, and obviousness in light of *KSR v. Teleflex*, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385, (2007). In *Smith*, the invention was a pocket insert for a book where the pocket was for supplemental material that cannot be easily bound to the book binding (i.e., a disk or CD).

OBVIOUSNESS REJECTION OF CLAIMS 1 AND 10

On appeal, claim 1 was rejected as obvious in light of two patents: U.S. Patent No. 5,540,513 (the Wyant patent) and U.S. Patent No. 1,495,953 (the Dick patent). Claim 10 was rejected as obvious in light of the Wyant patent, the Dick patent, and U.S. 4,965,948 (the Ruebens patent).

In reviewing the law of obviousness, the Board applied the test for obviousness in light of the Supreme Court's decision in *KSR v. Teleflex*, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385, (2007) that "the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." Moreover, the Board noted that, in applying the test for obviousness after *KSR*, the Supreme Court requires that "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established function." Lastly, the Board relied upon the Federal Circuit's recent decision in *Leapfrog Ent., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161, 82 U.S.P.Q.2d 1687, 1690-91 (Fed. Cir. 2007) to require the patent owner to present evidence to rebut evidence that a particular combination would have been common sense.

1. ANALYSIS OF CLAIM 1:

Claim 1 recites "continuous two-ply seams", which the applicants argued was not suggested in the prior art pocket inserts. The finding of fact showed that the Wyant patent taught forming a pocket insert with "two glued, two-ply seams separated by a folded edge," and thus did not have continuous seams around the edge of an insert pocket. The Dick patent taught another way to form the seams using a two-ply pocket formed by securing three edges of two sheets with a continuous two-ply seam by stitching or otherwise securing the edges. Thus, both the Dick patent and the Wyant patent teach predictable results using different mechanisms for forming a pocket of an insert.

The Board found that the combination of the Wyant and Dick patents would be obvious to a practitioner because: (1) each of the claimed elements is within the prior art, (2) one skilled in the art could have combined the elements known at the time, and (3) it would be recognized to yield predictable results. The Board did not rely on an explicit teaching as to why the seal in the Wyant patent should be combined with the continuous seal in the Dick patent. Instead, the Board relied upon the Supreme Court's decision in *KSR* in concluding that the "substitution of the continuous, two-ply seam of Dick for the folded seam of Wyant thus is no more than 'the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.'" The Board took note that the applicants did not provide contrary evidence that it would have been difficult or uniquely challenging to use the continuous seam taught by the Dick patent with the pocket taught by the Wyant patent.

The Board next rejected the applicant's argument that the Wyant patent teaches away from the Dick patent. The applicant claimed that the use of the Dick patent seams would render the Wyant patent unusable for its primary purpose (selectively foldable tabs). However, the examiner found, and the Board agreed, that using the construction of the Dick patent would allow the possibility of tabs foldable along the perimeter as in the Wyant patent such that the modification would not render the combination unsuitable. While the Wyant patent did not specifically describe this possibility, there was no suggestion or requirement that this method was the only method. Further, the Wyant patent did not actually teach against the use of a pocket constructed on one side surface of a base sheet, on which the examiner relied. Instead, the Board held that merely because the "art is silent on the capabilities or function of any particular item, that is not teaching away from its use." Thus, the Board held that this

minor modification of the method described in the Wyant patent fell within the type of "common sense" modification that one skilled in the art would have made, and is thus consistent with the Supreme Court's decision in *KSR*. As such, the Board found that there was sufficient evidence to maintain the *prima facie* obviousness rejection since selection between the two-ply seam of Dick and folded seam of Wyatt was "a choice between viable alternatives."

2. ANALYSIS OF CLAIM 10:

The applicants further argued that the combination of the Wyant patent, the Dick patent, and the Ruebens patent did not disclose or suggest that "the base sheet and the pocket sheet are further adhered to one another along a strip parallel to the third and fourth edges of the sheets, so as to separate two pockets formed between the sheets" as recited in claim 10. In finding claim 10 obvious in light of these references, the Board found that the Ruebens patent discloses a photo album having a top sheet adhered to a base sheet along a strip to separate a pocket sheet into two pockets. Using this same adhesive strip to create separate pockets is the identical use as was in the prior art and would yield predictable results. The Board also highlighted that it was not a unique challenge or difficulty, and that the use of a line of adhesive to separate a pocket into two in a photo album would be recognized to improve similar devices. Thus, based upon the Supreme Court's ruling in *KSR*, as claim 10 recites elements well known in the art and for which the combination was within the skill of one of ordinary skill in the art yielding predictable results, claim 10 was obvious.

ANTICIPATION REJECTION OF CLAIM 35

Claim 35 was rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,141,252 (the Michlin patent). Claim 35 recited, among other features, "an adhesive between the base sheet and the pocket sheet to bond the base sheet to the pocket sheet to form a pocket with an opening facing the binding edge, the pocket insert having a thickness rendering the insert passable through a copier or printer in sequence with a sheet of paper having the given width and length, the thickness of the pocket insert being at its maximum equal to a combined thickness of the base sheet single thickness, the pocket sheet single sheet thickness and the adhesive."

In order to further understand the recited "thickness rendering the insert passable through a copier or printer in sequence," the Board reviewed the Specification. The Specification discloses a method of creating a pocket insert capable of being collated along with other

materials in a copier, but “provides no detailed description of what thickness is required to render the insert passable through a copier or printer in sequence with a sheet of paper other than to say that ‘the pocket insert should be assembled of standard weight paper.’” (Finding of fact 6).

In affirming the examiner's rejection, the Board found that, for purposes of inherency, a result must necessarily follow from the disclosed prior art. *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349, 64 U.S.P.Q.2d 1202, 1206 (Fed. Cir. 2002). The fact that a result may occur is not sufficient for purposes of inherency since “[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1951 (Fed. Cir. 1999).” In reviewing the record in light of this test, the Board noted that the defined thickness in the claim is simply a thickness using standard materials and is not a specific thickness. Similarly, the Michlin patent discloses a preprinted insert which necessarily was printed using a printer. As such, the fact that the Michlin patent discloses a preprinted insert which otherwise meets the remaining features established a *prima facie* case of anticipation based upon inherency. Since there was no evidence to rebut this *prima facie* case of anticipation in order to show that the disclosed preprinted insert did not inherently disclose such a feature, claim 35 was properly rejected under 35 U.S.C. §102(b) as being inherently anticipated by the Michlin patent.

EX PARTE CATAN

In *Ex Parte Catan*, 83 U.S.P.Q.2d 1569 (BPAI, July 3, 2007) (precedential), the Board affirmed a rejection of the applicant's claims based on obviousness under 35 U.S.C. §103 in light of the Supreme Court's decision in *KSR v. Teleflex*, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385, (2007). The applicant claims a consumer electronics device which uses bioauthentication for authenticating use of a sub-credit line account. Applicant's claim 5, on which the applicant's application stands or falls, reads:

5. A consumer electronics device, comprising: A memory which stores account information for an account holder and sub-credit limits and bioauthentication information for authorized users of the account; A bioauthentication device which provides bioauthentication information to the memory; A communication link; and A processor, which compares received bioauthentication information to stored bioauthentication information to detect a match, and finds an associate sub-credit limit corresponding to the received

bioauthentication information, to enable a purchase over the response network via a communication network up to a maximum of the sub-credit limit, the processor sending the account holder information over the communication link only if the match is detected and the sub-credit limit is not exceeded.

The examiner rejected claim 5 in light of three prior patents: U.S. Patent 5,485,260 (the Nakano patent), U.S. Patent No. 4,837,422 (the Dethloff patent), and U.S. Patent No. 5,721,583 (the Harada patent). The examiner found that the Nakano patent discloses all of the elements except that Nakano's authentication was using a PIN, whereas the claims recite bioauthentication. Further, the examiner found that the Nakano patent does not disclose a local storage device for memory, where the memory is part of the consumer electronics device.

However, the Board rejected the examiner's narrow interpretation of the recited location of the memory within a consumer electronics device. Specifically, the Board found that the preamble does not require a unitary body. Therefore, claim 5, when read broadly, did not require a local storage for memory. The Board relied upon the frequency with which various components in consumer electronics devices are not in unitary devices, such as where a base station is sold with a remote control. The Board further relied upon the Specification, which describes a remote server processing the bioauthentication data such that the device itself is not necessarily limited to a single body. Without this requirement for a local memory as opposed to a memory, the Board found that the Nakano patent disclosed a memory within the meaning of claim 5. Hence, the only limitation not found in the Nakano patent is that Nakano's authentication is provided by a password and not a bioauthentication device as in claim 5.

The examiner also found that the Harada patent discloses a remote control which uses bio-authentication information in the form of a fingerprint gathered on the remote itself. Thus, the Harada patent discloses “the use of a bioauthentication device (fingerprint sensor) on a consumer electronics device (remote control) to provide bioauthentication information (fingerprint)”

The examiner also found that the Dethloff patent discloses a consumer electronics device which uses a voice sensor as bioauthentication in use with sub-account activation. The Dethloff patent, therefore, teaches “substitut[ing] a PIN authentication with bioauthentication to enable a user to access credit via a consumer electronics device.”

The examiner's finding of fact also concluded that Dethloff and Nakano indicated the art suggested a common usage of personal codes or personal identification numbers to identify or authenticate users and that Harada and Dethloff indicated one of ordinary skill would be familiar with using bioauthentication interchangeably with PINs to authenticate users.

In affirming the examiner's decision to reject the claims, the Board reviewed the "functional approach" of *Hotchkiss*, 11 How. 248 as reaffirmed by the Supreme Court in *KSR v. Teleflex*, 127 S. Ct. 1728, 82 U.S.P.Q.2d 1385 (2007). Under this functional approach, the obviousness inquiry uses a flexible view that a combination patent is not obvious when "the improvement is more than the predictable use of prior art elements according to their established functions." When a patent is altered by substitution of one element for another known in the field, "the combination must do more than yield a predictable result" in order to be non-obvious. *United States v. Adams*, 383 U.S. 39, 40, 148 USPQ 479, 480 (1966) (cited with approval in *KSR* as an illustrative example of the functional approach).

In reviewing the examiner's decision, the applicant made no suggestion that using bioauthentication in this invention yielded an unexpected result or that it was beyond the skill of one having ordinary skill in the art. The Specification did not contain a detailed description of implementation in hardware or software for the device, and was written in generalities. Such generality supported the finding that including a bioauthentication device into a consumer electronic device was not uniquely challenging.

In light of the Nakano and Harada patents, the Board found it was obvious to "update the Nakano device with the modern authentication components of the Harada bioauthentication means and thereby gaining, predictably, the common understood benefits of such adaptation, that is, a secure and reliable authentication procedure." The Board further supported its decision

because the Dethloff patent shows substituting PIN authentication with voice authentication, which is a form of bioauthentication. Moreover, there was evidence that bioauthentication was known in the art of authentication at the time of the invention as well as the interchangeability and substitutability was known in the art. Thus, this known substitutability indicated it was known to replace PIN authentication with bioauthentication for the purpose of enabling a user access to credit.

The Board rejected applicant's "repeated" arguments that there must be a teaching, suggestion, or motivation (TSM) in the prior art directing one skilled to make the improvement. The TSM test was recognized as useful by the Supreme Court in *KSR*, but was not a necessary finding to support obviousness. Instead, a court may "take account of the inferences and creative steps that a person of ordinary skill in the art would employ." As such, while the TSM test was not required to find obviousness, the Board went on to find a motivation to use bioauthentication in light of the numerous advantages of bioauthentication over other forms of authentication as disclosed in the Harada patent. These advantages included reliability, and ensuring use by an authorized user. The finding of facts also found that the advantages of bioauthentication included protection against theft and that it was not susceptible to a user's forgetfulness. Thus there was motivation to combine because "Dethloff teaches that one can substitute bioauthentication information for PIN information, and Harada teaches that it was a common problem at the time of the invention to create a remote control that would reliably ensure that the appropriate person was given access to the system. The use of a fingerprint scanner, such as disclosed in Harada, was an obvious solution to provide a more reliable means of identification than the PIN code in Nakano." Thus, the Board found that there was a motivation to make the combination, which further supported the obviousness rejection.

FEATURE COMMENT: STRATEGIC RESPONSES TO THE NEWLY-ISSUED USPTO CONTINUATION AND CLAIM LIMITATION RULES

By James G. McEwen¹

BACKGROUND

Under prior rules, an applicant was entitled to file as many continuation applications as needed to ensure that the invention was properly claimed and to prevent inadvertently narrow limitations from precluding literal infringement. The only limitation on the number of continuations was generally set by matters of equity or where an applicant was not attempting to advance prosecution by amending the claims. The applicant could also attempt to ensure such coverage using a single application which included as many claims as needed. The limitation on the number of claims in a single application was set by the Examiner, who could issue a restriction if the number of claims being examined was deemed too burdensome for a single application. In an effort to reduce the number of outstanding applications, application pendency, and the claims for each application, the United States Patent and Trademark Office has instituted a new rule package. Effective as of November 1, 2007, the new rule package is designed to change existing patent prosecution strategies, which relied upon unlimited continuations and claims to obtain appropriate coverage for an invention. In order to create this change in behavior, the United States Patent and Trademark Office is effectively limiting the number of continuations and claims. As will be set forth below, this new rule package will have a dramatic effect on prosecution of both pending and new applications, and will significantly impact prosecution strategy.

CHANGES TO CLAIM RULES

5/25 RULE FOR SINGLE APPLICATIONS

In order to reduce the number of claims in a single application, the United States Patent and Trademark Office revised 37 CFR 1.75 to implement a new effective limitation. The purpose of this rule is to force applicants to choose only the best claims as opposed to

filing a multitude of claims in a single application. Under 37 CFR 1.75(b)(1), applications can contain no more than five (5) independent claims and twenty five (25) total claims. This rule is referred to as the 5/25 rule. As will be detailed below, while there are exceptions to the 5/25 rule, these exceptions are extremely limited.

As will also be re-emphasized below, this rule will be effective for all new applications filed on or after November 1, 2007, and will be retroactively effective for pending applications which have not received a first Office Action on the merits as of November 1, 2007. (72 Fed. Reg. 46716 (August 21, 2007)). Moreover, while not affecting reexamination applications, the new rule also affects reissue applications, including reissue applications that are currently pending and have not received a first Office Action on the merits as of November 1, 2007. Therefore, the scope of this new rule will impact both claims in applications to be filed as well as applications which have already been filed.

5/25 RULE AFFECTS COPENDING COMMONLY-OWNED APPLICATIONS

Of special importance in this rule is a new feature: patentably indistinct claims in other commonly-owned applications will be counted against this 5/25 rule as if all are in a single application. Specifically, 37 CFR 1.75(b)(4) applies to copending applications that contain patentably indistinct claims. If 37 CFR 1.75(b)(4) applies, the combined number of claims in all applications will be counted and the USPTO will treat, for purposes of the 5/25 rule, the combined number as if a single application had that combined number of claims. For example, if a first application has twenty (20) total claims and three (3) independent claims, and a second application has ten (10) total claims and two (2) independent claims that are patentably indistinct. Under 37 CFR 1.75(b)(4), both the first and second applications have violated the 5/25 rule under 37 CFR 1.75(b)(1) since the combined number of indistinct claims is thirty (30) total claims. Thus, applicants cannot avoid the 5/25 rule by, instead of including the claims in a single application, filing more applications (whether continuations or not), with each application individually compliant with 37 CFR 1.75(b)(1).

In so far as what is considered patentably distinct, MPEP 802.01 instructs that claims are patentably distinct

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where "the inventions *as claimed* are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER (though they may each be unpatentable over the prior art)." As such, distinctiveness versus indistinctiveness is based upon a comparison of the claims in the applications, and a determination that any difference in the claims would have been obvious to one of ordinary skill in the art. This test is likely to be followed, with one major exception.

In contrast to the distinctiveness analysis for purposes of obviousness type double patenting, for purposes of 37 CFR 1.75(b)(4), the filing dates of the applications are not considered. As such, while under the conventional test where a later filed species claim may be distinct over an earlier filed genus claim, whereas a later filed genus claim may be indistinct over an earlier filed species claim, under 37 CFR 1.75(b)(4), the species claim and genus claim are indistinct no matter which was filed first, so long as both are in different pending applications. As such, for purposes of 37 CFR 1.75(b)(4), there does not appear to be a one way versus two way distinctiveness test as occurs in the conventional indistinctiveness analysis for purposes of obviousness type double patenting.

Lastly, in addition to generally following the conventional indistinctiveness analysis, the definition of copending for the purposes of 37 CFR 1.75(b)(4) is restricted to applications under examination. Specifically, as interpreted by the United States Patent and Trademark Office, copending means any application that has not yet been allowed. (72 Fed. Reg. 46735 (August 21, 2007)). As such, 37 CFR 1.75(b)(4) provides a disincentive to prosecute multiple related applications at the same time, but would allow prosecution serially (i.e., filing a continuation application *after* the allowance of the parent application).

EXCEPTION TO 5/25 RULE

In general, the applicant is required to comply with 37 CFR 1.75(b) on filing of the application. As such, unless one of the below exceptions applies, the applicants will be forced to cancel claims to ensure that the number of pending and considered claims meets the 5/25 rule. For all applications filed on or after November 1, 2007, a Notice will be sent out giving the applicants a choice between claim cancellation and filing an Examination Support Document (ESD). Applicants can only elect one of the choices where the failure to make the election prior to the Notice was inadvertent. 37 CFR 1.75(b)(3). In contrast, for applications pending prior to November

1, 2007, a different Notice will be sent out which allows the applicant a choice between filing the ESD, a Suggested Restriction Requirement (SRR), or to cancel claims to meet the 5/25 rule and there is no similar inadvertence requirement. (72 Fed. Reg. 46728 (August 21, 2007)).

3. FILING EXAMINATION SUPPORT DOCUMENT (ESD)

Under the 5/25 rule, the applicant can exceed the 5/25 limit by filing an ESD compliant with 37 CFR 1.265. The ESD is very similar to an accelerated examination document, and requires a pre-examination search, a listing of the most relevant references, an analysis as to which claim elements are described in which reference, an explanation of the patentability of the independent claims over the most relevant references, and an identification of where the claims are supported under 35 U.S.C. §112. If any update is made during prosecution, either through the submission of an Information Disclosure Statement or by amendment to the claims, the ESD must be updated to reflect this change. Lastly, the Examiner can reject the ESD as insufficient if, in the sole opinion of the Examiner, the search was insufficient.

Further, unless the ESD is filed prior to the first Office Action, the claims cannot be amended to include more than the five (5) independent claims and the twenty-five (25) total claims.

While the cost of the ESD is not yet known, the cost would likely be similar to the filing of a reexamination request. According to the AIPLA Economic Survey (2007), a typical cost of a reexamination request is \$9,500. In addition, estimates for a search alone used to compile an ESD are between \$10,000 and \$12,000. Thus, the combined search based upon these numbers would be between \$19,500 and \$21,500.

However, this estimate is likely low since, while both a reexamination request and an ESD require an element by element claim comparison, the ESD has additional requirements in regards to search strategies and support in the specification. Moreover, from acceptance rates based upon anecdotal experience with the Accelerated Examination program, it appears that up to 80% of the original ESDs will be considered deficient in some manner, thus requiring a supplemental ESD to correct the error or a cancellation of claims. Thus, for a single application, the timing and cost of the ESD specified in 37 CFR 1.265 will ensure applicants do not typically exceed the 5/25 rule.

4. FILING SUGGESTED RESTRICTION REQUIREMENT (SRR)

Under 37 CFR 1.142(C), the applicant can include an SRR in order to suggest how the claims can be separated into separate inventions. When the SRR is filed, the applicant must elect one of the claim sets, and assign restricted claim sets as being withdrawn. Since the 5/25 rule only applies to claims under examination, the non-elected claims of the SRR are not counted towards the 5/25 limit. Thus, by filing an SRR to break the claims into sets of claims that are compliant with the 5/25 rule, applicants can present multiple claim sets in one application.

If the Examiner adopts the SRR, the withdrawn claims can be used in a divisional application, which is generally beneficial for reasons set forth below in relation to the limits on continuation applications. Since the divisional application has patentably distinct claims, by definition, the 5/25 rule will not apply to the restricted claims. Thus, the SRR can be used to allow an applicant to, without filing an ESD, have more than five (5) independent claims and twenty five (25) total claims in a single copending patent application family.

However, the Examiner is not required to adopt the applicant's SRR, and can substitute an independent restriction requirement. Therefore, if the Examiner does not accept the SRR or if the substituted restriction requirement does not reduce the claims to within the 5/25 rule, the Examiner will issue a notice requiring compliance with 37 CFR 1.75(b)(1). At this point, the applicant will need to either cancel the claims to meet the 5/25 rule, or file the ESD.

5. DEMONSTRATING DISTINCTIVENESS BETWEEN COPENDING APPLICATION CLAIMS

Where the applicant receives a Notice that claims are patentably indistinct, the applicant has the ability to traverse this requirement. As noted above, the test for distinctiveness is essentially an obviousness inquiry, where a comparison is made of the claims, and distinctiveness is shown where the differences would not have been obvious to one of ordinary skill in the art. This requirement is similar to the applicant's ability to traverse an obviousness-type double patenting rejection with one important distinction: the traversal is by Petition as opposed to Appeal. This is because the United States Patent and Trademark Office views the 5/25 rule as purely procedural. (72 Fed. Reg. 46785-86 (August 21, 2007)). Therefore, when faced with such a finding under 37 CFR 1.75(b), the applicant can Petition under 37 CFR 1.181 this finding of indistinctiveness to force a restriction between the applications in the same

manner that an applicant can Petition under 37 CFR 1.181 to *prevent* restriction under current practice.

6. CANCELLING CLAIMS

Where an applicant receives a Notice that claims violate the 5/25 rule or that patentably indistinct claims in multiple applications violate the 5/25 rule, the applicant can cancel the claims. It is noted that the USPTO appears to be encouraging cancellation since the rules regarding requesting refunds under 37 CFR 1.117 specifically allow for refunds of extra claims fees for claims cancelled prior to examination. Additionally, where the 5/25 rule is violated due to patentably indistinct claims existing in multiple applications, the USPTO appears to be encouraging cancellation between multiple applications since the Examiner can require cancellation of patentably indistinct claims from all but one application under 37 CFR 1.78(f)(3).

However, it should be cautioned that the claim refunds only apply for fees paid after December 8, 2004.

7. APPLICATIONS HAVING FIRST OFFICE ACTION AS OF NOVEMBER 1, 2007

Under the applicability rules, the 5/25 rule does not apply to pending applications which have received a first Office Action on the merits by November 1, 2007. (72 Fed. Reg. 46716 (August 21, 2007)). However, the 5/25 can apply to other copending applications instead of the pending application having the first Office Action. For instance, if there is an Office Action in a first application, but no Office Action in a second application having patentably indistinct claims, the 5/25 rule will not apply to the first application, but will apply to the second application. As such, the applicant might be forced to either file an ESD in the second application, or cancel the patentably indistinct claims in the second application that exceed the 5/25 limit and add the cancelled claims in the first application.

CHANGES TO CONTINUATION RULES

TWO CONTINUATION APPLICATION RULE

Under 37 CFR 1.78(d), no more than two non-provisional applications can claim the benefit under 35 U.S.C. §120 of a common parent application. A third application can be made on approval by a Petition under 37 CFR 1.78(d)(1)(vi) as will be discussed below. Voluntary divisionals are considered continuation applications such that, unless there is a restriction requirement, merely labeling a new application as a divisional does not avoid the restrictions under 37 CFR 1.78(d). This rule is effectively retroactive since the rules do not make a distinction between when the benefit is claimed. Thus, regardless of when a parent application was first filed or

priority was first claimed, the applicant cannot file another continuation application after November 1, 2007 if two other applications already claimed priority to the parent application.

Further, this limitation on continuations also applies to continuation-in-part applications. As defined under 37 CFR 1.78(a)(4), a continuation-in-part (CIP) is a new application that includes additional subject matter not included in a parent application. The applicant is required under 37 CFR 1.78(d)(3) to identify any claim which is supported by the original specification (as opposed to claims only supported by the newly added matter). As such, if no claims can obtain a benefit under 35 U.S.C. §120 from the parent application, the United States Patent and Trademark Office will allow the benefit claim, but strongly recommends that the CIP application instead be filed as a new application since the applicant is not receiving a true benefit of the parent application relative to the prior art, and is instead merely losing term under 35 U.S.C. §154, and is using up one of the two continuations allowed under 37 CFR 1.78(d). *Frequently Asked Questions: Questions and Answers Claims and Continuations Final Rule*, B9 (September 5, 2007) (<http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/ccfrfaq.pdf>).

Where such a priority is claimed and no exception exists, the office will not recognize the priority claim and require removal of any such benefit claim. 37 CFR 1.78(d)(1).

ONE REQUEST FOR CONTINUED EXAMINATION (RCE) RULE

Similarly, 37 CFR 1.114 has been revised to only allow a single RCE per family of applications. An additional RCE may be allowed on showing of a Petition under 37 CFR 1.114(g), as will be discussed below. This restriction on the number of RCEs not only applies to a single application, but limits the number for an entire family of related applications. As set forth in 37 CFR 1.114(f)(1), a new RCE can only be filed after November 1, 2007 where no other RCE has been filed in the same application or any application for which the application claims benefit under 35 U.S.C. §§120, 121 or 365(c). Therefore, unless an exception applies, applicants can only obtain a single RCE under 37 CFR 1.114 for an entire family of applications.

While only a single RCE can be filed, the applicants can use one of their two continuations under 37 CFR 1.78 as, in effect, an RCE using a Request for Streamlined Docketing Procedure expedited procedure. In this way, a continuation application can be filed, but the new application will not be treated as a new application and instead will be treated as an RCE to expedite

consideration of the new application. This procedure is reminiscent of the prior Continued Prosecution Application (CPA) procedures which the RCE replaced.

DIVISIONAL APPLICATION EXCEPTION

Since the United States Patent and Trademark Office only wants to limit the number of claims and continuations relative to a single invention, there is no limit on the number of divisional applications for patentably distinct inventions. Therefore, each new divisional application is treated, in effect, as a new application entitled to two continuation applications under 37 CFR 1.78 and one RCE under 1.114. The divisional application can be filed at any time during the pendency of the initial application, or any continuation application under 35 U.S.C. §120. Thus, applicants are encouraged to, if multiple patents are to be obtained, restrict the claims in order to help the Examiner focus the examination in each application on patentably distinct inventions.

ONE EXTRA CONTINUATION EXCEPTION

In order to prevent a filing stampede, the implementing rules allow an exception to the two continuation application rule: another continuation application can be filed so long as no further continuation application was filed after August 21, 2007. As such, patent families that already have two continuation applications can file one more continuation application after November 1, 2007 without a Petition under 37 CFR 1.78(d)(1)(vi) assuming that no other continuation application was filed between August 21 and November 1, 2007. (72 Fed. Reg. 46717 (August 21, 2007)). Therefore, using this provision, unless a continuation application has already been filed after August 21 for a family containing more than two continuation applications or where whole new sets of continuations are to be filed, there is no benefit in filing only one additional continuation application before November 1, 2007.

PETITION EXCEPTION

In order to obtain a third continuation or a second RCE, the applicant must file a Petition under 37 CFR 1.78(d)(1)(vi) for the third continuation, or a Petition under 37 CFR 1.114(g) in order to obtain the second RCE. In each Petition, the applicants must pay the \$400 petition fee under 37 CFR 1.17(f), as well as provide "a showing that the amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application." The United States Patent and Trademark Office has indicated that these Petitions will not be readily granted since the continuation and RCE should not be a substitute for an appeal or a Petition to withdraw a final Office Action. If granted, the continuation application

will be entitled to maintain its priority claim, or the RCE will be entitled to continue examination.

Since these Petitions will not toll an outstanding requirement, filing such a Petition for the RCE would generally not be advisable since it is unclear whether the Petition will be acted upon prior to the six month statutory due date. Thus, a pending application could go abandoned if the Petition is denied after the six month period has ended.

BY-PASS APPLICATION EXCEPTION

Recognizing that some applicants will file a continuation off of a PCT application instead of entering the National Phase, the rules create an exception to the two continuation rule by giving such bypass application an extra continuation. 37 CFR 1.78(d)(1)(iv). However, the exception only applies where the PCT application itself does not enter the national stage. Therefore, the applicant is in the same position, for the purposes of 37 CFR 1.78(d), as if the application had entered the national stage directly as opposed to using the bypass route.

CONTINUATIONS FROM APPLICATIONS ABANDONED FOR FAILURE TO RESPOND TO A NOTICE OF MISSING PARTS

Recognizing that some applicants will file a continuation off of an application which is being abandoned for failure to respond to a Notice of Missing Parts instead of complying with the Notice of Missing Parts, the rules create another exception to the two continuation rule by giving such a continuation application an extra continuation. 37 CFR 1.78(d)(1)(v). However, the exception only applies where the abandoned application was abandoned for failure to respond to a Notice under 37 CFR 1.53(f). Therefore, the applicant is in the same position, for the purposes of 37 CFR 1.78(d), as if the application had complied with the Notice as opposed to filing a continuation application.

NOTIFICATION OF PENDING APPLICATIONS

IDENTIFICATION OF RELATED APPLICATIONS HAVING A SIMILAR DATE

One of the overlooked aspects of the new rules most affecting law firms and corporations is the notification requirement under 37 CFR 1.78(f)(1). Under 37 CFR 1.78(f)(1), for each application that is pending, the applicant needs to provide a listing of each application meeting the following criteria:

1. is commonly-owned with the filed application;
2. has at least one inventor in common with the filed application; and

3. has at least one filing or priority date within two months of the filed application or a priority date of the filed application.

This identification must be filed within the later of four months from the filing date for the filed application or two months from the mailing of the filing receipt. Moreover, this identification is in addition to any necessary identification of related applications for purposes of a normal Information Disclosure Statement under 37 CFR 1.56. (72 Fed. Reg. 46779 (August 21, 2007)).

While criterion 1 and criterion 2 are somewhat straightforward, criterion 3 presents a challenge since it requires correlating the filing date of the application, and any domestic or foreign priority dates for the filed application, with any other filing dates or priority dates for any other application worked on *for each inventor*. For example, if an application to be filed has a foreign priority date and a domestic priority date, the database needs to be able to detect, for each inventor of the application to be filed, any other continuations, divisionals, original applications, and foreign applications having corresponding U.S. applications for which the inventor is a named inventor and whether these priority dates overlap the foreign priority and domestic priority date of the application to be filed.

Since most law firms do not handle all applications for a single owner, this duty will fall directly on the patent owner/applicant. However, in commenting on this rule, the United States Patent and Trademark Office has threatened to refer registered practitioners who do not comply with this rule for disciplinary proceedings. (72 Fed. Reg. 46779 (August 21, 2007)). Therefore, a certain amount of this duty will also be required for practitioners for at least those cases docketed to that law firm.

Moreover, since this rule will apply to any application that has not been allowed as of November 1, 2007, the identification under 37 CFR 1.78(f)(1) will need to be applied for most pending applications. The United States Patent and Trademark Office will require this identification to be filed, for all existing applications, on or before February 1, 2008.

IDENTIFICATION OF RELATED APPLICATION HAVING A SAME DATE

Like 37 CFR 1.78(f)(1), 37 CFR 1.78(f)(2) applies to commonly-owned applications having a common inventor. Unlike 37 CFR 1.78(f)(1), 37 CFR 1.78(f)(2) applies only to those applications which have a common date with the filed application and where there is "substantially overlapping disclosure" between the other

applications and the filed application. The shared date means that there is a common filing or priority date in both the filed application and the other applications. Further, for there to be "substantially overlapping disclosure," there is no need for claims to *actually* exist in both applications that are patentably indistinct so long as a claim in the filed application *could* be supported by the disclosure in the other application having a shared date. By way of example, if a first application is filed having a first foreign priority date, a first domestic filing date, and a first divisional filing date, and a second application to be filed has a second foreign filing date that is the same as the first divisional filing date, a 37 CFR 1.78(f)(2) Identification may be required. This Identification is separate from the 37 CFR 1.78(f)(1) Identification as well as from the normal Information Disclosure Statement required under 37 CFR 1.56.

In this situation, there is a presumption that the claims are patentably indistinct since it is assumed that the filed application is based upon the same basic invention. In order to rebut this presumption, the applicant, prior to an Office Action, must submit a Statement explaining how the claims are patentably distinct. If the applicant does not want to rebut the presumption, the applicant must, prior to an Office Action, submit a terminal disclaimer and provide an explanation as to why the patentably indistinct applications should exist in multiple applications. However, not just any explanation will do since this reason must satisfy 37 CFR 1.78(f)(3).

This Identification and rebuttal must be filed within the later of four months from the filing date for the filed application or two months from the mailing of the filing receipt.

Like the problems identified with regard to 37 CFR 1.78(f)(1), the Identification and rebuttal requirement presents a challenge since it requires correlating the filing date of the application, and any domestic or foreign priority dates for the filed application, with any other filing dates or priority dates for any other application worked on *for each inventor*. Since most law firms do not handle all applications for a single owner, this duty will fall directly on the patent owner/applicant. However, in commenting on this rule, the United States Patent and Trademark Office has threatened to refer registered practitioners who do not comply with this rule for disciplinary proceedings. (72 Fed. Reg. 46779 (August 21, 2007)). Therefore, a certain amount of this duty will also be required for practitioners for at least those cases docketed to that law firm.

Lastly, since this rule will apply to any application that has not been allowed as of November 1, 2007, the 37 CFR 1.78(f)(2) Identification will need to be applied for most pending applications. The United States Patent and Trademark Office will require this Identification to be filed, for all existing applications, on or before February 1, 2008.

ELIMINATION OF PATENTABLY INDISTINCT CLAIMS IN COPENDING APPLICATIONS

Under 37 CFR 1.78(f)(3), where no "good and sufficient reason" exists to allow the patentably indistinct applications to exist, the office can require "elimination of the patentably indistinct claims from all but one of the applications." This requirement appears to work in tandem with the 5/25 rule of 37 CFR 1.75(b)(4), which counts patentably indistinct claims in copending (i.e., non-allowed) applications against the 5/25 limitations, and further encourages only one pending application to have one patentably indistinct application at a time. However, in contrast to the 5/25 rule of 37 CFR 1.75(b)(4), the cancellation allowed under 37 CFR 1.78(f)(3) is not dependent on the combined number of claims exceeding the 5/25 limitation.

INTERACTION OF THE CLAIMS AND CONTINUATION RULES

As is evident from the above, the interplay of the changes in the claims rules under 37 CFR 1.75 and the continuation rules under 37 CFR 1.78 effectively blocks an applicant's ability to have multiple copending applications with patentably indistinct claims while also preventing a rush to file continuations. Specifically, since 37 CFR 1.78(f)(3) can require cancellation of patentably indistinct claims in related applications, there is little advantage to filing a large number of copending applications before November 1, 2007 since it remains within the discretion of the Examiner to cancel these claims, and since the applicants must rebut, in advance, a finding of indistinctiveness for these applications under 37 CFR 1.78(f)(2).

EFFECTIVE DATES

The effective date for the new rules is nominally November 1, 2007. However, these rules are effectively retroactive since they will affect all pending applications. The major exception will be that the 5/25 rule does not apply to existing applications currently under examination (i.e., have not received an Office Action on the merits). Otherwise, all the remaining limitations outlined above will affect the both new and pending applications alike.

POSSIBLE STRATEGIES TO MEET CHALLENGE

PRIOR TO NOVEMBER 1, 2007

Since the new rules go into effect on November 1, below are some interim strategies that take advantage of the current rules as well as the transitional rules set forth in the new rules package.

PENDING APPLICATIONS PRIOR TO NOVEMBER 1**1. PENDING APPLICATIONS EXCEEDING THE 5/25 RULE**

If an application is already filed with claims that exceed the 5/25 rule, instead of immediately filing an ESD or cancelling claims, file an SRR in order to determine if the Examiner will restrict the claims to an elected claim set consistent with the 5/25 rule. By including the SRR, it may be possible to provoke a divisional application which would allow greater flexibility in ensuring adequate patent coverage for the non-elected claims without having to file the ESD.

2. CANCEL CLAIMS PRIOR TO EXAMINATION AND REQUEST REFUND

If the application has claims in excess of the 5/25 rule but has not received an Office Action on the merits, the applicant can still cancel claims prior to being required to file an ESD or being forced to cancel indistinct claims under 37 CFR 1.78(f)(3). Such can either be due to a Notice sent from the United States Patent and Trademark Office requiring the ESD or SRR, or can be done in advance of such notice. If done prior to examination, a refund can be obtained under 37 CFR 1.117. These cancelled claims can be reserved for filing in a continuation application at the conclusion of the prosecution for the instant application.

However, it should be cautioned that the claim refunds only apply for fees paid after December 8, 2004.

3. MOVE CLAIMS IN PENDING APPLICATIONS TO APPLICATIONS UNDER ACTIVE EXAMINATION

Since the 5/25 rule of 37 CFR 1.75 does not apply to applications having received a first Office Action by November 1, 2007, these applications are in the best position to receive new claims. Thus, if multiple applications are copending and have patentably indistinct claims, the patentably indistinct claims can be cancelled from those applications that are merely pending (with the refund requested under 37 CFR 1.117), and reintroduced in those applications which are under active examination.

In addition, even where the original application that is merely pending has arguably patentably distinct claims, by moving the claims to the application that is actively

under examination, the introduction of new claims can be used to provoke a restriction to the new claims under 37 CFR 1.145. This can be suggested as the claims are being added using an SRR pursuant to 37 CFR 1.142(c). In this way, it may be possible to re-characterize the original application as a divisional application, and therefore obtain an additional two continuations and an RCE for the original application (and avoid having to rebut the presumption under 37 CFR 1.78(f)(2)).

4. MOVE CLAIMS IN PENDING APPLICATIONS TO APPLICATIONS UNDER ACTIVE EXAMINATION IN RESPONSE TO OBVIOUSNESS TYPE DOUBLE PATENTING REJECTIONS

Under 37 CFR 1.78(f)(3), there needs to be good and sufficient reasons to allow patentably indistinct claims to exist in multiple applications, and the Examiner can require elimination of these indistinct claims. As such, the mere filing of a terminal disclaimer is insufficient to prevent such cancellation. Therefore, unless filing such a terminal disclaimer would result in immediate allowance of the application before November 1, 2007, if an obviousness type double patenting rejection is issued between multiple copending applications, overcome the rejection by moving the copending claims to the application being currently examined and cancelling the claims from the copending application. This is especially suggested where the copending claims in the related applications have not yet been examined, and would therefore be subject to the 5/25 rule.

5. APPLICATIONS UNDER FINAL OFFICE ACTION PRIOR TO NOVEMBER 1, 2007 AND HAVING ALREADY FILED AN RCE

If there is already an RCE filed in a family of applications, and the application is currently under a final Office Action, it would be advisable to file an RCE prior to November 1 since it will be the applicant's last chance to file such an RCE without the Petition under 37 CFR 1.114(g). This might also be a mechanism by which new claims from copending applications can be introduced to prevent cancellation under 37 CFR 1.78(f)(3) and/or to help force a restriction under 37 CFR 1.145.

6. MULTIPLE APPLICATIONS OF A FAMILY UNDER SEPARATE FINAL OFFICE ACTIONS PRIOR TO NOVEMBER 1, 2007

Regardless of whether an RCE has already been filed in a family of applications, if all or multiple members of the family of applications are currently under final Office Actions, it would be advisable to file an RCE in each case prior to November 1. Otherwise, after November 1, the applicant will only be able to file one RCE in the family and will not be able to another RCEs for each

application under final Office Action without the Petition under 37 CFR 1.114(g). This might also be a mechanism by which new claims from copending applications can be introduced to prevent cancellation under 37 CFR 1.78(f)(3) and/or to help force a restriction under 37 CFR 1.145.

NEW APPLICATIONS PRIOR TO NOVEMBER 1

1. FILE NEW APPLICATIONS BEFORE NOVEMBER 1, 2007

While not practical for applications which are not substantially ready for filing, applicants should ensure that applications which are substantially completed are filed before November 1, 2007. The benefits are multiple. First, since the requirement to file an SRR or ESD with the application is not applicable for applications filed before November 1, 2007, by filing the application early, applicants have a chance to wait until the issuance of a Notice requiring cancellation of claims, filing the SRR, or filing the ESD. Second, unlike applicants receiving a similar Notice for applications filed on or after November 1, applicants can reply to the Notice using the SRR where the application was filed prior to November 1. Third, since the deadline for compliance with the 37 CFR 1.78(f) reporting requirement is delayed to February 1, 2008 for applications filed prior to November 1, this delay will further allow additional time for the applicant to upgrade existing docketing systems to ensure compliance with this procedure. Fourth, by allowing for the delay between the filing of the application and the Notice, it is more likely that other copending applications having arguably patentably indistinct claims will become allowable, thus reducing the number of issued under 37 CFR 1.75 and 37 CFR 1.78. In this manner, by filing substantially completed applications prior to November 1, applicants will have additional time to implement a strategy for compliance with both the 5/25 rule and the reporting requirements under 37 CFR 1.78, will have increased flexibility in how to respond, and may actually lessen the impact of these rules.

2. FILE NEW CONTINUATION APPLICATIONS WHERE FAMILY INCLUDES MORE THAN TWO CONTINUATION APPLICATIONS BEFORE NOVEMBER 1, 2007

As noted above, applicants can file as many continuation applications as they deemed necessary before November 1, 2007. As also noted above, 37 CFR 1.75 and 37 CFR 1.78 contain provisions which may result in cancellation of claims in these copending applications, and thus warn against filing such applications to prevent later complications. At the same time, if applicants have already filed more than two continuation applications

and wish to file multiple continuation applications to ensure that applications remain pending, applicants could take advantage of their present ability to file multiple continuations prior to November 1, noting that the applicants will still need to address the substantial hurdles posed by 37 CFR 1.75 and 37 CFR 1.78 when these issues are later raised by the Examiner.

GENERAL STRATEGIES BEFORE AND AFTER NOVEMBER 1, 2007

In order to account for these changes, the following are potential strategies for both pending and new applications. These strategies are applicable both to existing applications and new applications filed after November 1, 2007.

PENDING APPLICATIONS

1. CONSERVE RCEs AND CONTINUATIONS THROUGH PETITION AND APPEAL

One of the justifications for the new rule package is that applicants have been relying on RCEs and continuations to avoid appeals and Petitions. In essence, instead of fighting an improper final Office Action using a Petition or an improper rejection using an Appeal, applicants found it more cost effective to simply file an RCE or continuation to drag on prosecution. However, since the number of RCEs and continuations is limited, the United States Patent and Trademark Office is forcing applicants to file petitions and appeals. Since the new rules make filing multiple RCEs and more than three continuations cost prohibitive, applicants need to be careful in determining when to use their one RCE and their two continuations. Thus, in pending applications where there is a final Office Action, the applicants should be more aggressive in Petitioning the finality of the Office Action or non-entry of amendments after final.

Moreover, applicants should ensure that, prior to filing the RCE, careful consideration is given to filing an appeal. It is important to ensure that, if any defects are found on appeal, an RCE or continuation is available to correct the deficiency. Otherwise, where all of the RCEs and continuations have been used, an expensive Petition under 37 CFR 1.78(d)(1)(vi) for the third continuation or a Petition under 37 CFR 1.114(g) for a second RCE is needed, and it is uncertain to the extent that the Petition will be granted.

2. CONDUCT EXAMINER INTERVIEWS PRIOR TO FINAL OFFICE ACTION

Since many rejections are the result of Examiner confusion over the prior art or are merely a matter of disputes of terminology, it is often helpful to conduct an Examiner interview in order to reduce confusion during

prosecution. In the past, such interviews might have been conducted after the issuance of a final Office Action or only after an RCE had been filed. However, since applicants no longer have the right to multiple RCEs, applicants should consider conducting such interviews on the first Office Action. In this way, the issues can be narrowed and simplified, thereby reducing the need for using the only RCE allowed by right merely to conduct an interview (or implement the results of the interview). Further, such interviews can be useful in reducing issues on appeal, thereby reducing costs associated with such appeals.

3. CANCEL CLAIMS PRIOR TO EXAMINATION AND REQUEST REFUND

If the application is pending but has not been examined (i.e., received an Office Action on the merits), the applicant can still cancel claims prior to being required to file an ESD or being forced to cancel indistinct claims under 37 CFR 1.78(f)(3). Such cancellation might result from an accidental filing of claims in excess of the 5/25 rule, due to the claims being found patentably indistinct with claims in a related application, where a restriction requirement is successfully traversed, or where the Examiner does not accept an applicant's SRR. If done prior to examination, a refund can be obtained under 37 CFR 1.117. These cancelled claims can be reserved for filing in a continuation application at the conclusion of the prosecution for the instant application.

However, it should be cautioned that the claim refunds only apply for fees paid after December 8, 2004.

4. CANCEL CLAIMS SUBJECT TO RESTRICTION REQUIREMENT

Under existing practice, it is permissible to maintain non-elected claims in an application after a restriction or election requirement is imposed. Where the non-elected claims depend from an elected claim, if the elected claim becomes allowable, the non-elected claims are rejoined and examined. If the non-elected claims do not depend from an elected claim, the Examiner can require cancellation after allowance of the elected claims. However, under the new rules, where such non-elected claims are maintained in the application and the elected claim becomes allowable, the rejoinder can result in the application claims exceeding the 5/25 rule. Since the ESD cannot be filed after a first Office Action, if the rejoinder of the non-elected claims would result in the claims exceeding the 5/25 rule, it is more likely that the applicant would be forced to cancel the non-elected claims. Moreover, as the rejoinder is technically a withdrawal of the original restriction requirement, the applicant would not be able to file a divisional application for the claims needing to

be cancelled, and must instead use any remaining continuation application. Thus, where the application is subject to a restriction requirement, the withdrawn claims should be immediately cancelled, both to ensure that a divisional application can be filed to the non-elected claims and to ensure that the applicants do not accidentally maintain claims that can violate the 5/25 rule should any generic claim become allowable.

5. MOVE CLAIMS IN PENDING APPLICATIONS TO APPLICATIONS UNDER ACTIVE EXAMINATION IN RESPONSE TO OBVIOUSNESS TYPE DOUBLE PATENTING REJECTIONS

Under current practice, terminal disclaimers are typically filed in applications under active examination where a provisional obviousness type double patenting rejection is issued. However, under 37 CFR 1.78(f)(3), there needs to be good and sufficient reasons to allow patentably indistinct claims to exist in multiple applications, and the Examiner can require elimination of these indistinct claims. As such, the mere filing of a terminal disclaimer is insufficient to prevent such cancellation. Therefore, if an obviousness type double patenting rejection is issued between multiple copending applications, overcome the rejection by moving the copending claims to the application being currently examined and cancelling the claims from the copending application. In this way, the applicants can avoid both filing the terminal disclaimer and issues related to 37 CFR 1.78(f)(2) statements or 37 CFR 1.78(f)(3) claim eliminations.

6. ADD CLAIMS TO APPLICATIONS UNDER ACTIVE EXAMINATION TO PROVOKE RESTRICTION

Under 37 CFR 1.145, the Examiner can restrict newly presented claims where an Office Action has already been issued. This rule is consistent with existing practice based upon 37 CFR 1.145 which, while rarely used, does allow a similar process. Further, by including an SRR with the newly presented claims, it may be possible to provoke a divisional application which would allow greater flexibility in ensuring adequate patent coverage.

7. CONDUCT EXAMINER INTERVIEW TO AGREE THAT CLAIMS ARE PATENTABLY DISTINCT

When a new continuation application is to be filed or where multiple copending applications already exist, and it is unclear if the claims would be considered patentably distinct, it might be possible to obtain an agreement from the Examiner that the new claims, if added in a pending application before the Examiner, would be restricted as patentably distinct. Grounds for

distinctiveness could be 37 CFR 1.145, which would apply if the new claims were added during prosecution. Whatever the basis, applicants could contact the Examiner and see if the Examiner would agree, in an interview, to a restriction for a pending application. Such a procedure would be similar to the existing telephone restriction procedure, by which Examiners contact applicants to determine if the applicants will elect a species without traverse orally as opposed to requiring a formal phone call. Once such an agreement is reached on the record, 37 CFR 1.78(f)(3) would not be usable to eliminate claims, and the 5/25 rule of 37 CFR 1.75(b)(4) would not apply since a restriction has been preemptively issued. Moreover, such a copending application might, arguably, then be re-categorized as a divisional application as opposed to a continuation application since the claims in the copending application have been arguably restricted from the parent application through the interview. Such an approach might be preferable to a formal SRR, and might be performed during a regular Examiner Interview which is being conducted for other purposes.

B. ENSURE A DOCKETING SYSTEM TRACKS ALL APPLICATIONS FILED AND IS SEARCHABLE BY AT LEAST INVENTOR

In order to comply with the reporting requirements of 37 CFR 1.78(f), there needs to be a single docketing system which tracks, for each assignee and inventor, the application number and the filing date. For small clients, a single law firm likely has all of this information and can ensure compliance with 37 CFR 1.78(f). However, for other clients, no single law firm has such information. As such, prior to November 1, such clients will need to upgrade their docketing system to ensure that the system tracks, for each inventor, which applications were filed, when the applications were filed.

NEW APPLICATIONS

1. FILE SRR IN NEW APPLICATIONS EXCEEDING THE 5/25 RULE WHERE AN ESD IS NOT TO BE FILED

If an application is to be filed with claims that exceed the 5/25 rule, instead of immediately filing an ESD or cancelling claims, file an SRR in order to determine if the Examiner will restrict the claims to an elected claim set consistent with the 5/25 rule. By including the SRR, it may be possible to provoke a divisional application which would allow greater flexibility in ensuring adequate patent coverage for the non-elected claims without having to file the ESD.

2. FILE A PETITION FOR ACCELERATED EXAMINATION IN NEW APPLICATIONS

IMPORTANT ENOUGH TO CONSIDER FILING THE ESD

As noted above, given the costs and risks of filing the ESD, it is anticipated that few applicants will file the ESD in all cases. However, in those cases where the ESD is to be filed, since a claim set exists that exceeds the 5/25 rule, it is noted that the ESD does not result in special consideration of the application, and the normal three to five year pendency is anticipated for these cases. Further, it is likely that the Examiner will restrict these applications, despite the ESD, using existing restriction practice, thereby further delaying issuance of any divisional applications filed to protect the restricted claims. Therefore, for cases in which the applicant is considering using the ESD, applicants should consider instead filing a Petition to Make Special Under Accelerated Examination to obtain an accelerated examination while filing the remaining claims in a continuation application using the same ESD.

Under a Petition to Make Special Under Accelerated Examination, the "USPTO will advance an application out of turn for examination ... with the goal of completing examination within twelve months of the filing date of the application." The Petition requirements are consistent with the ESD, but the application may only include three (3) or fewer independent claims, and no more than twenty (20) claims total. Moreover, the application must be directed to a single invention, and the applicant must agree to conduct an interview with the Examiner to resolve outstanding issues. The benefits of using this process are twofold: first, while an application filed with an ESD will remain pending as a normal examination and may still be restricted under current examination standards, by using the Petition, at least one portion of the claim set will have completed examination in one year. For the remaining claims, these claims can be filed in a separate application or continuation application as set forth below.

Lastly, assuming that the accelerated examination has concluded with an allowance, there would be no need to file the ESD itself in either the new continuation application or in a related non-provisional application. Instead, the applicants could merely submit the search using the normal Information Disclosure Statement process. In this manner, the continuation application and the second non-provisional application would be less likely to not be "infected" with statements against interest that might have occurred in the accelerated application due to the Petition.

A. FILE ADDITIONAL CLAIMS IN A CONTINUATION APPLICATION

While it may be tempting to file a continuation application or a separate nonprovisional application to obtain an early filing date, these approaches may be difficult due to the provisions of 37 CFR 1.78(f)(2) and 37 CFR 1.78(f)(3), which are designed to prevent copending applications. Thus, by filing a continuation or nonprovisional application during the pendency of the application under accelerated examination, the claims may be cancelled, a Statement under 37 CFR 1.78(f)(2) may be required to rebut a presumption of indistinctiveness, and/or one of the two continuations allowed under 37 CFR 1.78(d) will be used.

As an alternative, the remaining claims could be filed serially after allowance of the parent application which is undergoing accelerated examination so that 37 CFR 1.78(f)(2) does not apply. Since examination should be concluded in one year, this approach will allow the introduction of the new claims without substantive delay (assuming an allowance occurs within the one year deadline). However, this approach will still use one of the two continuations allowed under 37 CFR 1.78(d).

B. FILE ADDITIONAL CLAIMS IN A FOREIGN APPLICATION OR NON-PROVISIONAL APPLICATION

Under this strategy, it is noted that the rules under 37 CFR 1.78(f) and 37 CFR 1.75 only apply to copending applications. Further, the rules under 37 CFR 1.78(d) only apply where there is a continuation claim based upon 35 U.S.C. §§120, 121, or 365(c). As such, it is preferable to file related applications serially without claiming priority benefit of each other.

In theory, applications under accelerated examination will receive an allowance within one year of filing. At the same time, under 35 U.S.C. §119, corresponding foreign applications and provisional applications need not be filed as U.S. non-provisional applications for one year after their initial filing, which is roughly the time that the accelerated examination should conclude prosecution. Assuming that there is an allowance within one year, a new non-provisional application could be filed within the one year deadline under 35 U.S.C. §119 claiming priority from a foreign priority application or provisional application *without being filed during the pendency of the accelerated application*. In this manner, the 5/25 limitations and the reporting requirements of 37 CFR 1.78(f) and 37 CFR 1.75 would be inapplicable. Moreover, since the continuation limitations under 37 CFR 1.78(d) do not apply, applicants could use this additional application as a mechanism to obtain two further continuation

applications and another RCE. In this way, assuming no continuation applications are filed in the accelerated examination application, the entire family would include four (4) total applications without having to file an ESD in each of the four (4) applications. In this manner, the priority deadline can be maintained, the accelerated examination is concluded, an additional application has been gained for the family, and all of the remaining claims can be filed without using the new non-provisional application.

It should be noted that not all accelerated examinations result in allowance within one year of filing. According to a recent study by Stephen B. Maebius of Foley & Lardner, out of 300 accelerated examination petitions that have been considered, 241 have been denied. Based upon these statistics, it is likely that 81% of these Petitions will be rejected, thus requiring a supplemental filing. In these cases or where the accelerated examination has not otherwise resulted in an allowance by the one year deadline under 35 U.S.C. §119, applicants might consider filing a PCT application to thereby gain a full thirty months before entering national phase. The full thirty months should result in some resolution of the accelerated examination, even if the initial Petition is rejected.

3. FILE CONTINUATIONS SERIALLY

Instead of filing multiple pending applications, the continuation applications should be filed serially (i.e., one after the other). The advantage in this scenario is that the 37 CFR 1.78(f) and 37 CFR 1.75(b) problems do not occur. The disadvantage in this scenario is that the delay in issuance of the desired claims.

4. FILE AN ESD IN LAST CONTINUATION APPLICATION

Instead of filing the ESD in the original application, file an ESD in a last possible continuation allowed under 37 CFR 1.78. Since the last possible continuation application will likely be filed more than 6 years after the original parent application (assuming 3 years for the parent application, and 3 years for the first continuation application), the applicants will have had sufficient time to determine what additional claims are needed to cover newly discovered potential licensees and/or infringers. In this way, the last continuation acts as a catchall for all possible claims and claim types. An additional benefit to this strategy is that Examiners are more likely to issue a restriction when faced with large numbers of claims such that, even if the ESD is accepted, the Examiner may grant additional divisional applications, thereby granting further chances to supplement the initial coverage.

5. FILE AN SRR EVEN WHERE NO PROBLEM EXISTS FOR THE 5/25 RULE

In order to ensure that the maximum flexibility is allowed for prosecution of important cases, it would be advisable to file an SRR in order to attempt to split the application into multiple applications. In this way, the applicant is afforded the maximum number of chances to obtain protection while minimizing the effect of both the rules under 37 CFR 1.75, 1.78, and 1.114. This flexibility is since, due to the restriction, the applicant will have at least twice as many chances to obtain patentable subject matter, using the four continuation applications and 2 RCEs allowed should the application be restricted. Additionally, even where only one patent is desired, having this number of potential applications and RCEs to present new claims and evidence greatly increases the likelihood of allowance of at least one of the applications without having to file an appeal. As such, filing an SRR could mitigate the greatly reduced number of continuations and RCEs otherwise allowed by 37 CFR 1.78 if the application is not restricted.

6. USE REISSUE APPLICATIONS AFTER LAST CONTINUATION APPLICATION

Since reissue applications are considered a new application, a reissue application can be filed and will be entitled to two new continuation applications under 37 CFR 1.78 as well as the single RCE under 37 CFR 1.114 without a Petition. However, it should be noted that the reissue application will be subject to the 5/25 rule, and thus the applicant may have to cancel claims, file an SRR, or file an ESD if the total number of claims (even claims already patented) exceeds the 5/25 rule. Despite this limitation, the use of the reissue process may provide a mechanism for introducing up to two new applications into an existing family of applications.

7. BREAK APPLICATIONS FOR SYSTEMS INTO COMPONENT PIECES

Assuming the invention is for a system having multiple novel components, instead of (or in addition to) filing a single application for the entire system of components, file an application for each component and remove the descriptions of the non-claimed components. In this way, there is only support under 35 U.S.C. §112 for the one claimed component, but no support under 35 U.S.C. §112 for other components or for the system as a whole. Such a strategy would help avoid (or limit) the mandatory disclosure requirements under 37 CFR 1.78(f)(2), providing better evidence of distinctiveness of the claims, and preventing the elimination of claims under 37 CFR 1.78(f)(3) since no single application has sufficient disclosure to support all of the claims in the family.

It is noted that in a recent Federal Circuit decision, *In re Metoprolol Succinate Patent Litigation*, 83 U.S.P.Q.2d 1545 (Fed. Cir. 2007), a system claim was found patentably indistinct from a component claim. The rationale was that the system claim was a species of the broader component claim, which is a genus. For purposes of obviousness type double patenting, since the system claim issued first, the later issued component claim was patentably indistinct since an earlier species claim is patentably indistinct from a later genus claim. In the context of obviousness type double patenting, the timing of the filing is important. However, in the context of 37 CFR 1.78(f)(3), timing is not explicitly a factor in the new rule.

A. FILE SYSTEM CLAIMS AFTER APPLICATIONS FOR COMPONENT PIECES USING INCORPORATION BY REFERENCE IN COMPONENT APPLICATIONS

In order to avoid this situation, a single provisional for the entire system could be filed which describes the components. Each component application would claim priority to the single provisional, but only contain support for each component specific application. At least one of the component applications should incorporate the provisional application by reference such that, after allowance of the component specific applications, the specification could be amended to include the entire subject matter of the provisional application and claims introduced to the system.

B. FILE SYSTEM CLAIMS IN SINGLE PCT APPLICATION

As a further alternative and instead of any of using the incorporation by reference in the component applications, file a PCT application for the system claims using the provisional application, and enter the national stage at the thirty month mark. Assuming that the component applications are filed close to the same time as the provisional application and are examined or allowed within thirty months, the issues due to 37 CFR 1.78(f) and/or the affect of the 5/25 rule under 37 CFR 1.75(b)(4) could be eliminated or greatly reduced. In any event, this would delay the need for the 37 CFR 1.78(f) disclosures until the thirty month mark.

B. FILE APPLICATIONS WITH SAME INVENTOR ON DIFFERENT DAYS

37 CFR 1.78(f)(2) presumes claims in different applications are patentably indistinct when the applications are filed on the same day naming the same inventor. As such, prior to filing a new application or a continuation application, a quick check should be made to determine if one of the named inventors has another

application or continuation application being filed on the same day. In this way, application filings should be coordinated to ensure that applications with a same inventor do not have the same filing date, thus requiring a review or statement under 37 CFR 1.78(f)(2).

CONCLUSION

The changes to the continuations and claims issued on August 21, 2007 represent one of the largest changes to patent prosecution practice to occur in the past ten years. These changes present specific challenges to the way in which patents have been prosecuted in the past. The interlocking features of the rules make it especially challenging to formulate an effective strategy without

substantial study of the policies and the language of the rules. However, once such a review is done, it is apparent that applicants can still protect their inventions through aggressive combinations of restrictions, petitions, appeals, and possible accelerated examinations. Thus, while the changes are substantial, applicants still have the ability to strategically protect their patentable inventions by adapting to the rule changes and taking advantage of the above noted potential workarounds.



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