Last Month at the Federal Circuit

August 2007

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Spotlight Info

- In this month's issue, on remand from the Supreme Court, the Federal Circuit held that accused infringing activities by Merck KGaA fell within the FDA "Safe Harbor" Exemption under 35 U.S.C. § 271(e)(1) because the research activities were reasonably related to the development and submission of information to the FDA. *Integra Lifesciences I, Ltd. v. Merck KGaA*, Nos. 02-1052, -1065 (Fed. Cir. July 27, 2007).

- Also in this month's issue, the Federal Circuit overturned a jury verdict and held that two patents covering the collection, cryopreservation, and use of stem cells from umbilical cord blood were invalid for obviousness, despite the fact that the patents had survived multiple reexaminations at the PTO. Judge Newman dissented, contending that the majority's decision reconstructed the inventions by selection and inference, with perfect hindsight of the discoveries. *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, Nos. 05-1490, -1551 (Fed. Cir. July 9, 2007).

- *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, No. 05-1492 (Fed. Cir. July 5, 2007), once again returns to the Federal Circuit, ending a twenty-year litigation saga resulting in a judgment of noninfringement because SMC Pneumatics, Inc.'s aluminum sleeve was a foreseeable alternative to Festo Corporation's magnetizable sleeve and prosecution history estoppel applied. Judge Newman again dissented strongly, insisting that the majority's "new rule further erodes the residue of the doctrine of equivalents, for its foreseeable result is to deprive amended claims of access to the doctrine of equivalents." See the full summary in this issue.

Broader Claim Construction Upheld: Specification and Prosecution History Indicate That When the Patentees Wrote "Heading," They Meant "Bearing"

John M. Mulcahy

Judges: Bryson (author), Plager (dissenting), Gajarsa

[Appealed from D. Del., Judge Thynge]

In *Honeywell International, Inc. v. Universal Avionics Systems Corp.*, Nos. 06-1406, -1435 (Fed. Cir. July 3, 2007), the Federal Circuit affirmed the district court's construction of disputed terms and upheld the jury's verdict that Universal Avionics Systems Corporation ("Universal") had infringed Honeywell International, Inc.'s ("Honeywell") patent.

Honeywell asserted U.S. Patent No. 4,914,436 ("the '436 patent") against Universal. The '436 patent is drawn to a system that enables an aircraft's ground proximity warning system during final approach to a runway. The patented system stores the coordinates of various runways and defines an area (called the "enabling envelope") around each runway, within which an aircraft is deemed to be on final approach. In order to better discriminate whether the aircraft is actually on final approach, the system also determines whether the aircraft is aligned with the runway and expands the radius of the enabling envelope. When the system determines that the aircraft has entered the enabling envelope, the ground proximity warning system is enabled.

The parties disputed the proper construction of the terms "heading of the aircraft," "enabling envelope," and "ground proximity warning system," as used in claim 1 of the '436 patent (the only claim at issue). The district court uniformly adopted Honeywell's constructions and denied Universal's motion for SJ of noninfringement. At trial, the jury found that Universal infringed claim 1 and the district court entered judgment accordingly. Universal appealed.

> "To hold otherwise would not include within the scope of the claim a preferred embodiment that the patentees labeled an 'important feature of the present invention' and would ignore the patentees' definition of the term 'heading' and their consistent use of that term throughout the prosecution history." Slip op. at 8.

The term "heading of the aircraft" was not used in the original specification, but was added to claim 1 of the '436 patent during prosecution in order to distinguish the prior art. Although the claim term "heading of the aircraft" conventionally indicates the compass direction the aircraft is flying, the district court construed the phrase

to refer instead to the direction to the aircraft from a runway, which would normally be referred to as the aircraft's "bearing" from the runway.

On appeal, the Federal Circuit affirmed the district court's construction. The Court noted that the specification referred to the calculation of the alignment of the aircraft with the runway as an "important feature of the present invention." The Court found that "[i]f Universal's construction were adopted, the disclosed embodiment would not relate to any limitation of the claimed invention, despite the clear link between the alignment computation discussed in the specification and the alignment computation called for by the claims." Slip op. at 6. The Court also concluded that "[t]he prosecution history confirms that when the patentees wrote 'heading,' they meant 'bearing.'" *Id.*

With respect to the term "enabling envelope," Universal argued that arguments made during prosecution disclaimed coverage of a system, like the accused system, that issues a ground proximity alert based on the aircraft's distance from the airport. The Federal Circuit, however, affirmed the district court's broader construction of the term. The Court found that the arguments cited by Universal could be read to support both Universal's and Honeywell's proposed constructions. "Because the passage is ambiguous, we conclude that it does not constitute a sufficiently clear and deliberate statement to meet the high standard for finding a disclaimer of claim scope." *Id.* at 11-12.

Universal further argued that the term "ground proximity warning system" should have been construed to exclude systems that issue ground proximity alerts based on airport distance. The Federal Circuit, however, held that the '436 patent used this term generically to describe any system that warns of ground proximity. Thus, the Court held that "the district court properly declined to limit the term 'ground proximity warning system'" as proposed by Universal.

In a dissenting opinion, Judge Plager wrote that the patentee "did not clearly signal the necessary intent to depart from the ordinary meaning of 'heading.'" Plager Dissent at 3. Judge Plager noted that, during prosecution, the patentee had also used the term "heading" in its conventional sense. "This inconsistent usage undercuts the argument that the applicants intended to adopt a different definition for the term 'heading.'" *Id.* at 2. Judge Plager concluded that "[t]his is not a case . . . in which the patentee implicitly redefined a claim term by using it throughout the written description in a manner consistent with an unconventional meaning. Here the patentees did not use the term at all in the written description." *Id.* (citation omitted).

Accused CPR System Does Not Infringe Patent or Copyrights

Andrew P. Riley

Judges: Michel, Newman (author), Dyk

[Appealed from D. Mass., Judge Ponsor]

In *Hutchins v. Zoll Medical Corp.*, No. 06-1539 (Fed. Cir. July 3, 2007), the Federal Circuit affirmed the district court's grant of SJ of noninfringement of (1) Donald C. Hutchins's U.S. Patent No. 5,913,685 ("the '685 patent"); (2) his copyright for the "text of a computer program"; and (3) his copyright for a "Script and Word List." The Federal Circuit also affirmed the district court's denial of Hutchins's motion under Fed. R. Civ. P. 60(b)(3).

The '685 patent relates to a computer system for use in administering cardiopulmonary resuscitation ("CPR"). The computer system prompts rescue personnel to provide inputs corresponding to the victim's age and whether the victim is conscious or not. The computer system then outputs the proper procedures for the rescuer to administer CPR to the victim. These outputs may include visual displays and voice commands.

The district court found that the accused Zoll Medical Corporation ("Zoll") device was not a "general computer system" and lacked an "interactive display input," as required by the asserted claims of the '685 patent. The district court accordingly entered SJ of noninfringement.

> "[T]he placing of standard words and phrases in digital form does not impart copyright exclusivity against all digitized usages of the words and phrases." Slip op. at 11.

On appeal, Hutchins argued that the Zoll device, which uses a dedicated microprocessor with limited functionality, is intended to interface and work in conjunction with a standard personal computer ("PC"), which is a general purpose computer, for purposes of review and archiving of data associated with a rescue. Rejecting this argument, the Federal Circuit concluded that Hutchins was estopped from reading the term "general purpose computer" to include a dedicated microprocessor because Hutchins added the term "general purpose computer" to the claims during prosecution to distinguish prior art with dedicated microprocessors. The Court further rejected Hutchins's argument that the term "general purpose computer" was not present in each claim of the '685 patent, because the term was recited in each independent claim and accordingly is incorporated into every dependent claim.

For the term "interactive display unit," Hutchins argued on appeal that the district court failed to examine the allegedly infringing Zoll system and failed to compare the Zoll system to the patent claims. The parties agreed the term meant "a device for communicating with a computer which allows a user to respond to options presented by the computer by selecting from a menu displayed on a screen." Slip op. at 6. Rejecting Hutchins's arguments, the Federal Circuit agreed with the district court's finding "that a reasonable jury could not find that the Zoll system employs an interactive display input as described in the '685 patent, for the Zoll rescuer provides no input, but simply follows the instructions issued by the system on monitoring the victim." *Id*. at 7. Specifically, the Federal Circuit noted that the Zoll system monitors the victim through electrical contacts placed on the victim, not through inputs provided by the rescuer.

Hutchins also argued that his copyright for a computer program covered systems that provide computerized display of CPR instructions and that the Zoll system "perform[ed] the same task in the same way." *Id*. at 9. The Federal Circuit disagreed, finding that the district court "correctly held that Mr. Hutchins'[s] copyright is limited to preventing the copying of the specific computer program that he developed, and does not include coverage of all programs that guide the performance of CPR derived from information in the public domain." *Id*. Specifically, the Federal Circuit stated that Hutchins failed to prove his "specific computer program, or any original aspects of his display in audio or video, was copied." *Id*.

Hutchins also argued that the district court erred in not finding that the Zoll system infringed the "digital electronic programming" and "copyrighted digitized phrases" embodied in his copyright for a "Script and Word List" containing CPR-related words and phrases. Specifically, Hutchins argued that the Zoll system copied twenty-seven phrases from his "Script and Word List" copyright. The district court found only two identical phrases in common between the Zoll system and Hutchins's "Script and Word List" copyright: "call for help" and "check breathing." The district court also found three similar phrases in common between Hutchins's copyright and the Zoll system: Hutchins's "stay calm" (Zoll's "remain calm"); "if no pulse, start CPR" (Zoll's "if no pulse, continue"); and "give two breaths" (Zoll's "start with two breaths").

The Federal Circuit found no error in the district court's determination that Hutchins's "Script and Word List" contained standard CPR instructions. The Federal Circuit noted that "[c]opyright does not protect individual words and 'fragmentary' phrases when removed from their form of presentation and compilation." *Id*. at 11. The Court stated that "the placing of standard words and phrases in digital form does not impart copyright exclusivity against all digitized usages of the words and phrases." *Id*. In particular, the Court noted that "[t]he standard instructions for performing CPR are indispensable for applying CPR, and remain in the public domain." *Id*. at 12. The use of these same or similar CPR instructions in the Zoll system did not prove Zoll copied original expressions copyrighted by Hutchins.

Hutchins also sought review of the district court's denial of his motion under Rule 60(b)(3), which states that "the court may relieve a party or a party's legal representative from a final judgment, order, or proceeding for . . . fraud (whether heretofore denominated intrinsic or extrinsic), misrepresentation, or other misconduct of an adverse party." Hutchins argued that Zoll committed fraud by failing to disclose a new version of the accused system during discovery and that the Zoll system was the subject of another litigation involving a cross-licensee of Hutchins. The Federal Circuit found that the district court did not abuse its discretion in denying Hutchins's motion "[i]n view of the stage of the litigation, the nature of the subject matter that was assertedly withheld, the district court's familiarity with the events, and the timing of the motion, ..." *Id*. at 13.

The Function/Way/Result Test or Insubstantial Differences Test Is Inapplicable to the Question of Foreseeability of Equivalents

Molly R. Silfen

Judges: Michel, Newman (dissenting), Dyk (author)

[Appealed from D. Mass., Judge Saris]

In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, No. 05-1492 (Fed. Cir. July 5, 2007), the Federal Circuit affirmed the district court's judgment in favor of Shoketsu Kinzoku Kogyo Kabushiki Company, Ltd. and SMC Pneumatics, Inc. (collectively "SMC") of lack of infringement of U.S. Patent No. 4,354,125 ("the '125 patent").

Festo Corporation ("Festo") sued SMC for infringement of the '125 patent. The '125 patent, entitled "Magnetically Coupled Arrangement for a Driving and a Driven Member," claims a "small gap," magnetically coupled rodless cylinder. A "magnetically coupled rodless cylinder" contains a piston that is forced through a cylinder and is magnetically coupled to a driven member or driven assembly, which is then attached to a carriage that can

move goods. Thus, when the piston moves through the cylinder, the magnetic force moves the driven member, which moves the attached carriage. At the time of the invention, such conveyance machines were known in the art. The invention claimed in the '125 patent is a "small gap," magnetically coupled rodless cylinder, meaning that the gap between the piston and the driven member is kept as small as possible so that the magnetic coupling force is particularly strong. Claim 1 of the '125 patent requires, among other things, "a cylindrical sleeve made of magnetizable material" and "first sealing rings." Both of these limitations were added during prosecution of the '125 patent, but Festo never explained why these limitations were added.

"An equivalent is foreseeable if one skilled in the art would have known that the alternative existed in the field of art as defined by the original claim scope, even if the suitability of the alternative for the particular purposes defined by the amended claim scope were unknown." Slip op. at 21.

"Today's new rule further erodes the residue of the doctrine of equivalents, for its foreseeable result is to deprive amended claims of access to the doctrine of equivalents." Newman Dissent at 1-2.

SMC's accused device is also a magnetically coupled rodless cylinder containing a piston, a cylinder, and a driven member. In the SMC device, however, the sleeve on the driven member is made of a nonmagnetizable material, aluminum alloy. In addition, the SMC device uses only one sealing ring. Because of these two features, the parties agreed that the SMC device did not literally infringe the '125 patent. Festo argued, however, that the SMC device infringed under DOE. In response, SMC argued that its device did not so infringe because it did not satisfy the function/way/result test and because the claim amendments discussed above invoked the doctrine of prosecution history estoppel.

The district court held that prosecution history estoppel did not apply and a jury subsequently found infringement under DOE. On appeal, the Federal Circuit affirmed, but the Supreme Court granted certiorari and remanded for consideration of the prosecution history estoppel question in light of *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997). The Federal Circuit considered this question en banc and held that "the amendments [in this case] were presumed to be related to patentability and therefore created an absolute bar to the invocation of the doctrine of equivalents." Slip op. at 8. The Supreme Court again vacated and remanded, holding that "an amendment did not raise a complete bar" and that there were three exceptions, namely: "(1) the equivalent was 'unforeseeable at the time of the application,' (2) 'the rationale underlying the amendment [bears] no more than a tangential relation to the equivalent in question,' or (3) that 'some other reason suggest[s] that the patentee could not reasonably be expected to have described the insubstantial substitute in question.'" *Id.* at 8-9 (alterations in original) (citation omitted).

Again, hearing the case en banc, the Federal Circuit held that the "tangential" and "some other reason" exceptions were legal questions to be determined based on the prosecution history and that neither exception applied in this case. With respect to the first exception, the Court concluded that it too was a legal question, but held that district courts may hear expert testimony and consider other evidence relating to the foreseeability analysis. Because no record on the issue of foreseeability had been made in the earlier district court proceeding, the Court remanded for the district court to determine (1) whether an ordinarily skilled artisan would have thought an aluminum sleeve to be an unforeseeable equivalent of a magnetizable sleeve in the context of the invention; and (2) whether a person of ordinary skill in the art would have considered the accused two-way sealing ring to be an unforeseeable equivalent of the recited pair of sealing rings.

On remand, the district court held a bench trial on the foreseeability issue. It found that Festo had failed to rebut the presumption for either the magnetizable sleeve or the sealing rings. Specifically, the district court found that the use of an aluminum alloy sleeve and a single sealing ring was foreseeable. Accordingly, the district court entered judgment of noninfringement in favor of SMC. Festo appealed.

On appeal, the Federal Circuit affirmed, stating that the sole question before it was whether the equivalent was unforeseeable at the time of the amendment. It noted that it had previously determined on remand from the Supreme Court that "unforeseeable at the time of the amendment" meant "whether the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of the amendment." *Id.* at 13-14 (citation omitted). It reiterated that "later-developed technology or technology that was not known in the pertinent prior art was 'usually' not foreseeable," but that "old technology, while not always foreseeable, would more likely have been foreseeable." *Id.* at 14. The Court observed that it has "consistently held that an equivalent is foreseeable when the equivalent is known in the pertinent prior art at the

time of amendment." *Id.* In so doing, the Court rejected Festo's argument that the foreseeability test required application of the function/way/result or insubstantial differences test. Specifically, Festo argued that the proper unforeseeability test was to "determine whether the proven equivalent would have been foreseeable to a person of ordinary skill in the art to accomplish the claimed invention, i.e., perform the same function in substantially the same way to achieve the same result, looking only at the information available at the time of the amendment." *Id.* at 15-16.

The Court reasoned that Festo's argument seemed inconsistent with the basic concept of the doctrine of equivalents. Festo was essentially arguing that "a patentee should be able to capture through equivalents a device that was novel, i.e., separately patentable, because of the novelty of the equivalent features." *Id.* at 17. The Court noted that the theory of DOE, however, is that "an applicant through the doctrine of equivalents should only be able to protect the scope of his invention, . . . not to expand the protectable scope of the claimed invention to cover a new and unclaimed invention." *Id.* (citation omitted). Thus, explained the Court, "there is a strong argument that an equivalent cannot be both non-obvious and insubstantial." *Id.*

The Court added that neither the Supreme Court's earlier decision nor its own en banc decision supported Festo's argument. To the contrary, noted the Court, those decisions "make clear that an equivalent is foreseeable if the equivalent was generally known to those skilled in the art at the time of amendment as available in the field of the invention as defined by the pre-amendment claim scope." *Id.* at 18.

The Court stated that Festo had offered no persuasive theory as to why the function/way/result test should be used to determine foreseeability. It observed that the function/way/result and insubstantial differences tests are "not designed to determine whether prosecution history estoppel applies as a result of a limiting amendment." *Id.* at 19. The Court reasoned that "accepting Festo's view of foreseeability would likely eliminate prosecution history estoppel as a restriction on the doctrine of equivalents in most cases." *Id.* "Prosecution history estoppel would apply only if the applicant in adopting the narrowing amendment was aware or should have been aware that the equivalent would be an equivalent to the claimed feature for purposes of the invention as defined by the amended claim." *Id*. Beyond this being rare in itself, added the Court, "it would be rarer still that the applicant, aware of such an alternative, would have failed to claim it in the first instance." *Id*. The Court also stated that applying the test at the time of infringement to determine equivalency and then at the time of amendment to determine foreseeability would lead to "endless bickering" and that adding to the confusion, the parties' roles would be reversed for each application of the test. *Id.* at 19-20.

The Court observed that "[t]he question is not whether *after* the narrowing amendment the alternative was a known equivalent, but rather whether it was a known equivalent *before* the narrowing amendment." *Id.* at 20. It explained that "[i]f at the time of the amendment, the equivalent was known in the pertinent prior art, the applicant should not be able to recapture it simply by establishing that a property of the equivalent—irrelevant to the broader claim before amendment—was relevant but unknown with respect to the objectives of the narrower amended claim." *Id.*

Accordingly, the Federal Circuit concluded that "the function/way/result test or insubstantial differences test is inapplicable to the question of foreseeability" and that "[a]n equivalent is foreseeable if one skilled in the art would have known that the alternative existed in the field of art as defined by the original claim scope, even if the suitability of the alternative for the particular purposes defined by the amended claim scope were unknown." *Id.* at 21.

Applying the above principles to the SMC's aluminum alloy sleeves, the Court found that "[n]ot only was the use of a non-magnetic sleeve disclosed in the prior art, the '125 patent application itself clearly recognized the possibility of using a non-magnetic material for the sleeve." *Id.* at 23. Thus, the Court held that the use of an aluminum alloy sleeve was foreseeable at the time of the amendment, and the equivalent was surrendered by amendment. Given its conclusion with respect to the sleeve, the Federal Circuit noted that it need not determine whether the use of a single sealing ring was foreseeable.

Judge Newman dissented. She noted that the majority's "new rule further erodes the residue of the doctrine of equivalents, for its foreseeable result is to deprive amended claims of access to the doctrine of equivalents." Newman Dissent at 1-2. She opined that under the majority's opinion, "even if unforeseeable as a matter of fact, even if technologically unexpected or unlikely, the equivalent must be ruled to be foreseeable if the structure is later found to be a usable equivalent." *Id.* at 2. She observed that "the panel majority rules that the aluminum alloy shield was retrospectively foreseeable at the time of the amendment because it later was used as an equivalent, although it was not known to be equivalent and would not have been deemed equivalent at the time of the amendment." *Id.* at 4. She added that "[h]indsight is not foreseeability." *Id.* According to her, no error had been shown in the district court's finding that persons of skill in the field of the invention would not have deemed

magnetizable and nonmagnetizable sleeves to be equivalent at the time the '125 patent application was filed and prosecuted. She stated that "[i]t cannot be irrelevant that the then-existing knowledge in the field of the invention would not have deemed an aluminum alloy sleeve equivalent to a magnetizable metal sleeve . . . ." *Id.* at 4-5. She noted that "[e]vidence of foreseeability must be limited to prior art, not future art," *id.* at 5, and that the majority was incorrect in ruling that "the foreseeability requirement does not require the knowledge that the equivalent would satisfy the function/way/result test or the insubstantial differences test." *Id.* at 6. She concluded that the majority's holding "strays from controlling precedent as well as from logic." *Id.* at 7.

Stem Cell Patents Held to Be Obvious Despite Successful Reexaminations and Jury Verdict to the Contrary

Larry L. Ilag

Judges: Newman (dissenting), Bryson (author), Prost

[Appealed from D. Del., Chief Judge Sleet]

In *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, Nos. 05-1490, -1551 (Fed. Cir. July 9, 2007), the Federal Circuit affirmed the district court's JMOL orders of noninfringement, while reversing the district court's refusal to grant JMOL of patent invalidity.

In the district court, PharmaStem Therapeutics, Inc. ("PharmaStem") alleged that the defendants had infringed two of its patents, U.S. Patent Nos. 5,004,681 ("the '681 patent") and 5,192,553 ("the '553 patent"). These patents relate to the use of hematopoietic stem cells in reconstituting, upon transplantation, a recipient's entire blood and immune ("hematopoietic") system that may have been previously ravaged by disease or medical treatment. Hematopoietic stem cells are capable of maturing into the various specialized cells of the blood and immune system, thereby making them suitable for such purpose. The asserted '681 patent claims cover compositions that contain hematopoietic stem cells "derived from the umbilical cord blood . . . of a single human . . . in which said cells are present in an amount sufficient to effect hematopoietic reconstitution of a human adult; . . . ." The asserted '553 patent claims were directed to methods for hematopoietic reconstitution of a human, wherein human fetal blood components containing hematopoietic stem cells are isolated, cryopreserved, thawed, and introduced into a suitable human host. Defendants in this case engaged in the business of collecting and cryopreserving umbilical cord blood for possible future therapeutic use.

The district court concluded that PharmaStem failed to prove infringement of either patent. Accordingly, after the jury's verdict of infringement, the district court granted the defendants' JMOL motions and entered a noninfringement judgment for both patents. As to the issue of patent validity, the district court upheld the jury's verdict that the patents were not invalid for obviousness, anticipation, or indefiniteness.

PharmaStem appealed the district court's JMOL orders of noninfringement, while four of the six defendants below appealed the patent validity judgment. The issue on appeal regarding the '681 patent infringement focused on the limitation requiring that the claimed composition contain fetal hematopoietic stem cells "in an amount sufficient to effect hematopoietic reconstitution of a human adult." The Federal Circuit agreed with the trial court that statements in defendants' advertising and other materials touting the potential therapeutic usefulness of cord blood were not a sufficient basis for finding infringement. The Court noted that none of those statements represented that the stem cells in any of the defendants' cryopreserved cord blood samples were sufficient in number to effect hematopoietic reconstitution of an adult, as required by the asserted claims. The Court also found that neither defendants' cord blood testing prior to cryopreservation nor scientific evidence presented at trial addressed whether defendants' cord blood samples contained sufficient stem cells for adult reconstitution.

The Federal Circuit also held that the district court did not abuse its discretion in excluding the testimony of PharmaStem's expert witness on infringement. The Court concluded that the expert's inference of infringement from the marketing materials was unreasonable, given that the materials only represented that cord blood was of potential use for adults, but fell "significantly short of a representation that the individual cryopreserved cord blood samples each contained enough stem cells to reconstitute an adult," slip op. at 19, as required by the asserted claims.

Regarding the '553 patent infringement, the issue on appeal concerned the sufficiency of evidence to support the jury's finding that defendants contributorily infringed by selling or offering to sell cryopreserved cord blood. The Federal Circuit affirmed the district court's finding that such evidence was insufficient, given that, in light of the legislative background of the contributory infringement statute, section 271(c), the district court properly determined that contributory infringement only applied to a sale of "a material or apparatus for use in practicing a patented process," and not to the provision of a service for compensation, as was the case with the present defendants. The Court noted that the defendants

were never owners of the cord blood. Donors did not sell cord blood to defendants, nor did defendants sell the cord blood to transplant physicians; "[t]he defendants simply transferred the cord blood units to designated transplanters upon direction from the families." *Id*. at 27.

"Admissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness." Slip op. at 33.

"The discoveries of these inventors were met with universal acclaim and widespread utilization, including the founding of many commercial enterprises, all of which are reported to have licensed the patents except for these defendants. Unimpressed by these considerations, my colleagues on this panel now reconstruct these inventions by selection and inference, with perfect hindsight of the discoveries." Newman Dissent at 2.

As to the patent validity cross-appeal, the Court found that the district court should have granted defendants' motion for JMOL on obviousness grounds, and then declined to address defendants' other invalidity arguments based on anticipation and indefiniteness. To establish obviousness, the Court explained, defendants had to show by clear and convincing evidence "that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *Id*. at 28-29. The Court found the "reason to attempt" element easily established, while the "reasonable expectation of success" element presented a more difficult question.

In arguing the invention's nonobviousness, PharmaStem mainly contended that those in the field of hematopoietic reconstitution would not have expected cord blood to be a successful transplant tissue. Here, PharmaStem relied on testimony from its expert, Dr. Irwin Bernstein, who cited to problems with transplant tissues that had been used previously and asserted that it was not known at the time that cord blood contained stem cells. The Federal Circuit, however, found the expert's testimony inconsistent with the prior art and the inventors' statements in the patent specification, which strongly suggested or explicitly represented the presence of stem cells in cord blood. Under Federal Circuit law, "[a]dmissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness." *Id.* at 33. The Court thus found that "the inventors merely used routine research methods to prove what was already believed to be the case," *id.* at 36, and accordingly concluded that a reasonable jury could not have found the invention nonobvious.

In deciding the obviousness issue, the Court did not find PharmaStem's secondary considerations persuasive. Evidence regarding the pioneering role of the inventors in the use of cord blood did not establish any inventive contributions they made. Neither was Dr. Bernstein's surprise at the successful human cord blood transplantation in 1988 probative, given that Dr. Bernstein may have been unaware of pertinent prior art, and that Dr. Bernstein tied the "surprise" to the success of the 1988 transplant, not to the results reported in the patents. The Court also gave little weight to the fact that the patents had survived several examinations by the PTO, finding fault with the PTO's analysis of the prior art. The Court therefore reversed the denial of JMOL on the obviousness issue and remanded to the district court for entry of judgment in the defendants' favor.

Writing in dissent, Judge Newman disagreed with the majority's obviousness holding contrary to the jury's verdict, citing to "undisputed evidence at trial . . . that these long-sought life-saving inventions were achieved amid general scientific skepticism." Newman Dissent at 2. She also noted that the majority did not give due deference to the PTO's review of the prior art. She also took issue with the majority's interpretation that the inventors themselves conceded in the specification that the prior art disclosed the presence of stem cells in cord blood, citing to Dr. Bernstein's testimony that no prior art showed that cord blood contained stem cells, and that at the time of the patent application filing, the differences between stem cells and progenitor cells (which arise from stem cells) could not be measured and were not well understood. The jury thus could have reasonably concluded that the prior art did not show that there were stem cells in cord blood, and that one of ordinary skill in this field would not have had a reasonable expectation of successful use of cord blood to reconstitute a human adult.

Judge Newman addressed the anticipation and indefiniteness issues that were appealed, and noted that the majority should have done so as well, in the interest of finality. She concluded that there was substantial evidence to support the jury's verdict that the patents-in-suit were neither anticipated nor indefinite.

Judge Newman disputed the majority's and district court's noninfringement holdings, asserting that these were based on a ruling of law and evidence not presented to the jury. Dr. Hendrix's expert testimony was also inappropriately rejected, since there was no criticism of the expert's scientific credentials or her analysis of the prior art and the state of the science.

Judge Newman also found substantial evidence to support the jury's infringement verdicts, given that defendants tested their cord blood samples to ensure that there was a sufficient amount of stem cell content to be therapeutically useful. With regard to the asserted '553 patent method claims, there was substantial evidence that each step of the claimed invention was performed by the defendants followed by a transplant surgeon, and "[t]he principles of patent infringement are not negated when the steps of a method claim are performed by more than one entity." *Id.* at 30. Judge Newman noted that PharmaStem received special verdicts of both direct joint infringement and contributory infringement, and no objection was raised to the verdict questions. Similarly, no objection was raised to the jury instructions, which did not include an instruction as to the legal impossibility of liability as to the '553 patent.

A Patentee's Dismissal of Its Infringement Claims May Destroy the "Immediacy and Reality" Required Under the Declaratory Judgment Act for Jurisdiction over Counterclaims of Invalidity or Unenforceability

Courtney B. Casp

Judges: Rader, Dyk (dissenting), Whyte (author, District Judge sitting by designation)

[Appealed from D. Del., Judge Farnan, Jr.]

In *Benitec Australia, Ltd. v. Nucleonics, Inc.*, No. 06-1122 (Fed. Cir. July 20, 2007), the Federal Circuit affirmed the district court's dismissal of Nucleonics, Inc.'s ("Nucleonics") DJ counterclaims against Benitec Australia, Ltd. ("Benitec") for lack of subject matter jurisdiction.

Benitec sued Nucleonics for infringement of U.S. Patent No. 6,573,099, which relates to RNA-based disease therapy known as RNA interference ("RNAi") gene silencing. Nucleonics moved to dismiss Benitec's complaint for lack of jurisdiction and for failure to state a claim upon which relief can be granted, arguing that its allegedly infringing activities were directed toward developing and submitting information to the FDA and were thus exempted from infringement under 35 U.S.C. § 271(e)(1). The district court denied this motion, but without prejudice to reconsideration depending upon the outcome of the Supreme Court's review of *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003). Subsequently, Nucleonics filed a motion to amend its answer, seeking to add DJ counterclaims of invalidity and unenforceability based on alleged inventorship fraud. The district court granted this motion.

In June 2005, the Supreme Court issued its holding in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), regarding the pharmaceutical research exception of § 271(e)(1). Benitec then moved to dismiss its complaint against Nucleonics without prejudice, asserting that it had no presently viable infringement claim in view of *Merck*. The district court granted Benitec's motion to dismiss without prejudice and dismissed Nucleonics's counterclaims for lack of jurisdiction under the DJ Act, 28 U.S.C. §§ 2201-02. Nucleonics appealed the dismissal of its counterclaims. In its appeal brief, Benitec "covenant[ed] and promis[ed] not to sue Nucleonics for patent infringement arising from activities and/or products occurring on or before the date dismissal was entered in this action—September 29, 2005." Slip op. at 4.

> "The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since." Slip op. at 6.
>
> "The effect of [the majority's] decision is to limit the availability of declaratory jurisdiction to challenge invalid and unenforceable patents by allowing patentees to moot such controversies by dismissing the original infringement action and covenanting not to bring suit on existing products, without any showing that the controversy will not recur in the future." Dyk Dissent at 11.

The Federal Circuit evaluated Nucleonics's jurisdiction claim in accordance with the standards articulated by the Supreme Court in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007). The Court noted that in *MedImmune*, the Supreme Court rejected its "reasonable apprehension of imminent suit" test for determining DJ jurisdiction and that under *MedImmune*, the question is "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Slip op. at 6 (quoting *MedImmune*, 127 S. Ct. at 771). The Court also noted that "[t]he burden is on the party claiming declaratory judgment jurisdiction

to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since." *Id.* Applying these principles, the Federal Circuit held that DJ jurisdiction existed at the time Nucleonics filed its counterclaims because Benitec's patent infringement claims were still pending. The Court, however, held that there was no DJ jurisdiction over Nucleonics's counterclaims at the present time.

The Court observed that both parties have taken the position that in light of *Merck*, Nucleonics's activities related to the human medical application of RNAi are not infringing, and cannot become infringing until Nucleonics files a new drug application with the FDA. The Court noted that Nucleonics does not even anticipate filing a new drug application before "at least 2010-2012, if ever." *Id*. at 10. Based on these facts, the Court held that Nucleonics's activities of developing and submitting information to the FDA related to human application of RNAi did not constitute a case or controversy of "sufficient immediacy and reality to warrant declaratory judgment jurisdiction" over its counterclaims. *Id.* The Court also relied on the fact that Benitec made its covenant and sought dismissal of its infringement claim after it concluded that *Merck* precluded an infringement claim based upon the activities of Nucleonics on which Benitec had instituted its suit.

Nucleonics also argued that it planned to expand its use of RNAi technology into the field of veterinary products and that such use would not be exempted under § 271(e)(1). As evidence of its intent, Nucleonics submitted a declaration from its president in which he stated that Nucleonics had entered into discussions with a supplier regarding future use of its technology for animal husbandry and veterinary products. The Court, however, found that these discussions did not meet the "immediacy and reality" requirements of *MedImmune*. In reaching this conclusion, the Court noted there was no evidence that Nucleonics had made or sold the infringing product, nor was there a definite offer made to the supplier. The Court also noted that Nucleonics did not present sufficient evidence to assess whether or not the future animal work could also fall under the § 271(e)(1) exemption. In addition, the Court noted that although Benitec originally argued that animal testing for human use was infringing activity, it had now concluded that such testing falls within § 271(e)(1)'s protection. Accordingly, the Court concluded that Nucleonics had not made a showing of "sufficient immediacy and reality" to support DJ jurisdiction. *Id.* at 16.

Judge Dyk dissented. He agreed with the majority that a case and controversy must exist at all stages of the litigation, but in his view, a different test for determining whether there is a case or controversy applies when the allegation of infringement is withdrawn during the course of litigation. Specifically, he opined that Supreme Court precedent requires that, "if a patentee files an infringement lawsuit and the particular claim of infringement is mooted, a counterclaim for invalidity should not be dismissed unless the patentee demonstrates that there is no possibility of a future controversy with respect to invalidity." Dyk Dissent at 1 (citing *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 98 (1993)). According to him, Benitec made no such showing. In addition, he reasoned that there is a strong public interest in permitting accused infringers to challenge invalid or unenforceable patents and that the DJ Act plays an important role in facilitating such challenges by preventing patent holders from threatening enforcement while avoiding litigation that might render the patent invalid or unenforceable. He concluded that "[t]he effect of [the majority's] decision is to limit the availability of declaratory jurisdiction to challenge invalid and unenforceable patents by allowing patentees to moot such controversies by dismissing the original infringement action and covenanting not to bring suit on existing products, without any showing that the controversy will not recur in the future." *Id.* at 11.

A Patent Is Invalid for Obviousness-Type Double Patenting When an Earlier Claim to a Combination Sets Forth a Later Claimed Element

Natalie D.E. Aitken

Judges: Mayer, Schall (dissenting-in-part), Gajarsa (author)

[Appealed from E.D. Mo., Judge Sippel]

In *In re Metoprolol Succinate Patent Litigation*, No. 06-1254 (Fed. Cir. July 23, 2007), the Federal Circuit affirmed the district court's holding of invalidity based on double patenting, but vacated its holding of inequitable conduct and remanded.

AstraZeneca AB, Aktiebolaget Hässle, and AstraZeneca LP (collectively "Astra") manufacture and market metoprolol succinate in "extended release" forms under the brand name Toprol-XL®. Metoprolol is used in the treatment of angina, hypertension, and congestive heart failure.

In 1971, an Astra employee, Toivo Nitenberg, synthesized metoprolol succinate at Astra's facilities in Sweden. In 1983, two Astra employees, Curt Appelgren and Christina Eskilsson, left Astra to join another company, Lejus

Medical AB ("Lejus"), which filed a patent application with the Swedish Patent Office, describing "delayed and extended release dosage forms of pharmaceutical compositions, including metoprolol succinate" and naming Appelgren and Eskilsson as inventors. Slip op. at 3. Lejus subsequently filed U.S. Application Serial No. 690,197 ("the '197 application"), claiming priority from the Swedish application. When Astra noticed the publication of the Swedish application, Astra commenced a transfer of ownership action with the Swedish Patent Office asserting that Nitenberg, not Appelgren and Eskilsson, invented metoprolol succinate. Astra and Lejus subsequently settled this ownership dispute. Lejus agreed to divide claims to "metoprolol succinate" and to a "pharmaceutical composition, characterized in that the active substance is metoprolol succinate" from the '197 application and to assign the divided claims to Astra. *Id.* Astra agreed that Lejus retained the rights to the '197 application that did not include the divided claims. The '197 application subsequently issued as U.S. Patent No. 4,780,318 ("the '318 patent").

"[A]dopting Astra's argument that there can never be 'double patenting simply because a later claimed element is set forth in an earlier claim to the combination,' . . . would require that this court eviscerate obviousness-type double patenting, thereby reducing invalidity based on double patenting to the § 101 statutory prohibition against claims of the same invention." Slip op. at 12-13 (citation omitted).

In accordance with the settlement agreement, Lejus filed U.S. Application Serial No. 172,897 ("the '897 application"), which is a continuation-in-part of the '197 application. Lejus named Appelgren and Eskilsson as inventors. Both before and after the filing of the '897 application, Astra's in-house counsel asserted to Lejus that Nitenberg, not Appelgren and Eskilsson, was the inventor of metoprolol succinate. Similarly, after Lejus transferred the prosecution of the '897 application to Astra, Astra's in-house counsel asserted that "there remains an open question who is the proper inventor." *Id.* at 4. In March 1991, the '897 application issued as U.S. Patent No. 5,001,161 ("the '161 patent"). The only claim of the '161 patent reads: "A pharmaceutical composition comprising metoprolol succinate together with a sustained release pharmaceutically acceptable carrier." *Id.* In January 1992, a continuation of the '897 application issued as U.S. Patent No. 5,081,154 ("the '154 patent"), the only claim of which simply reads "Metoprolol succinate." *Id.* The '161 and '154 patents both list Appelgren and Eskilsson as the inventors, and Astra as the assignee. Astra never revealed the inventorship issue to the PTO.

Astra filed multiple suits in various district courts asserting that the ANDAs filed by KV Pharmaceutical Company, Andrx Pharmaceuticals, LLC and Andrx Corporation, and Eon Labs, Inc., which were seeking approval to market generic versions of Toprol-XL®, infringed Astra's '161 and '154 patents. The Judicial Panel on Multidistrict Litigation consolidated the suits in the U.S. District Court for the Eastern District of Missouri. All three defendants moved for SJ of invalidity of the '161 and '154 patents based on double patenting in view of Lejus's '318 patent and of unenforceability of the '161 and '154 patents based on Astra's failure to notify the PTO of the inventorship dispute. The district court granted both motions. Astra appealed the grant of SJ of invalidity based on double patenting with respect to only the '154 patent and the grant of SJ for unenforceability of both patents based on inequitable conduct.

On appeal, the Federal Circuit affirmed the district court's holding of invalidity based on double patenting. The Court observed that the purpose of the nonstatutory or obviousness-type double patenting doctrine is "to prevent claims in separate applications or patents 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." *Id.* at 8 (citation omitted). The Court stated that an obviousness-type double patenting analysis entails two steps: "First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences. Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct." *Id.* (citation omitted).

Applying this two-part test, the Federal Circuit noted that the parties agreed with the district court's claim constructions and that it did not perceive any error in the district court's claim constructions. Therefore, the Court noted that the only issue on appeal regarding the invalidity of the '154 patent is whether the district court correctly found the claims to be not patentably distinct. The Federal Circuit observed that the district court found that claim 8 of the '318 patent "is directed to certain pharmaceutical compositions containing metoprolol succinate" and that the '154 patent "broadly claims any pharmaceutical compositions containing metoprolol succinate." *Id.* at 8-9. As a result, the district court concluded that the '154 patent is a genus of the species claimed by the '318 patent and that since the species claimed by the '318 patent issued

prior to the genus claimed by the '154 patent, the '154 patent was invalid for double patenting because it is not patentably distinct from claim 8 of the '318 patent.

Astra argued that the district court erred in concluding that claim 8 of the '318 patent and claim 1 of the '154 patent recited a species/genus relationship and that the claims instead define an element/combination relationship. The Federal Circuit rejected this argument, however, stating that such disputes about the characterization of the relation between the two claims in a double patenting context are irrelevant. The Court observed that "Claim 1 of the '154 Patent claiming a compound (A1) is an obvious variation of Claim 8 of the '318 Patent claiming a composition compris[ing] of one compound of an enumerated list (A1, A2, A3, etc.), an inner layer (B), and an outer layer (C)." *Id.* at 10. It stated that "it would have been an obvious variation of Claim 8 of the '318 Patent to omit the inner layer (B) and the outer layer (C)." *Id.*

The Court also rejected Astra's argument that certain decisions of the Court of Customs and Patent Appeals, one of its predecessors, stand for the proposition that there is no double patenting because an earlier claim to a combination sets forth a later claimed element. The Court explained that while the cases cited by Astra do appear to support this proposition, a later issued decision by that same court refutes Astra's argument and that this later issued decision controls because "the Court of Customs and Patent Appeals always sat in banc and therefore later decisions overcome earlier inconsistent ones." *Id.* at 11 (citation omitted). In addition, the Court reasoned that "adopting Astra's argument that there can never be 'double patenting simply because a later claimed element is set forth in an earlier claim to the combination,' . . . would require that this court eviscerate obviousness-type double patenting, thereby reducing invalidity based on double patenting to the § 101 statutory prohibition against claims of the same invention." *Id.* at 12-13 (citation omitted). Accordingly, it affirmed the district court's SJ holding that the '154 patent is invalid over the '308 patent for obviousness-type double patenting.

On the issue of inequitable conduct, the Federal Circuit found that the district court erred in holding on SJ that the '161 and '154 patents were unenforceable based on inequitable conduct. The Court focused its analysis on the district court's finding of intent to deceive. It noted that the district court inferred intent to deceive based on an analysis of what could have happened if Astra had disclosed the inventorship dispute to the PTO. Relying on this "but for" analysis, the district court found by clear and convincing evidence that Astra's motivation to not reveal the dispute was great based on the risk of losing its metoprolol inventions as anticipated by prior art and that the intent to deceive was clearly present. The Federal Circuit held that "[e]ven assuming arguendo that the patents at issue would have been invalid based on anticipation if Astra had disclosed the inventorship dispute to the U.S. Patent & Trademark Office, the district court erred in equating the presence of an incentive with an intent to deceive on summary judgment." *Id.* at 16. The Court observed that because the deposition of Astra's in-house patent counsel indicated that he did not know of and was not concerned about the incentives identified by the district court in its "but for" analysis, the record revealed a genuine factual dispute of whether Astra had an intent to deceive the PTO. The Court concluded that the district court incorrectly resolved this factual dispute on SJ and thus vacated the district court's inequitable conduct finding and remanded.

Judge Schall agreed with the majority's decision regarding inequitable conduct, but disagreed with its decision finding the '154 patent invalid based on double patenting. In his view, claim 1 of the '154 patent is patentably distinct from claim 8 of the '318 patent. He stated that "[f]ar from claiming an obvious variation on the three-element composition claimed in the '318 patent, the '154 patent . . . lacks any semblance to the second two elements in the three-element composition of claim 8." Schall Dissent at 4-5. He disagreed with the majority's reading of the case law and opined that "the law is that there is no double patenting simply because a later claimed element is set forth in an earlier claim to a combination." *Id.* He added that allowance of claim 1 of the '154 patent to metoprolol succinate will not result in the improper extension of the patent for the invention claimed in the '318 patent because in this case, "each patent is capable of being practiced by itself, without infringing the other." *Id.* at 10.

The PTO Has Discretion to Determine Whether and How a Trademark Registration Should Include a More Particularized Statement of the Goods for Which the Mark Is to Be Used

Stephanie H. Bald

Judges: Newman (author), Friedman, Dyk

[Appealed from TTAB]

In *In re Omega SA (Omega AG) (Omega Ltd.)*, No. 06-1234 (Fed. Cir. July 23, 2007), the Federal Circuit affirmed the TTAB's decision sustaining the Trademark Attorney's refusal to register Omega S.A.'s ("Omega") trademark AQUA TERRA for "jewelry, precious stones; watches, watch straps, watch bracelets and parts thereof; chronometers, chronographs, watches made of precious metals, watches partly or entirely set with precious stones

in International Class 14," unless Omega amended its application to limit "chronographs" to "chronographs for use as watches."

"We confirm the general rule that the definition of goods in one registration does not taint the definition of similar goods in any other registration." Slip op. at 4-5.

The Trademark Attorney refused Omega's application to register AQUA TERRA in Class 14 on the ground that the term "chronographs" can refer not only to watches in Class 14, but also to time-recording instruments in Class 9. Omega refused to amend its application, arguing that it already had several registered trademarks in Class 14 for "watches and chronographs," and that the term "chronographs" includes timepieces such as watches, regardless of whether "chronographs" is also used for time-recording instruments. The TTAB sustained the Trademark Attorney's decision. Omega appealed.

The Federal Circuit affirmed, noting that the scope of the term "chronographs" is ambiguous for registration purposes, for it includes both watches and time-recording devices. The Court explained that "[t]he PTO has discretion to determine whether and how a trademark registration should include a more particularized statement of the goods for which the mark is to be used" and that the PTO did not abuse its discretion in determining that the term "chronographs" should be restricted to those "for use as watches." Slip op. at 6. In so doing, the Court noted that the International Classification used by the PTO does not prohibit the imposition of additional requirements for national registration. It reasoned that treaty and statute do not prohibit domestic requirements that do not significantly diverge from the International Classification.

The Court rejected Omega's argument that the PTO's requirement for amendment to "chronographs for use as watches" will adversely affect Omega's other trademarks. The Court explained that in general, "the definition of goods in one registration does not taint the definition of similar goods in any other registration." *Id.* at 4-5. In addition, while the Court agreed with Omega that consistency in the examining process is highly desirable and that the time and expense of complying with inconsistent applications burdens both the PTO and the public, the requirement imposed by the Trademark Attorney to amend "chronographs" to "chronographs for use as watches" was not "so extreme or unreasonable as to warrant judicial intervention into the internal procedures and requirements of PTO trademark examination." *Id.* at 5. Accordingly, the Court affirmed the decision of the TTAB.

FDA "Safe Harbor" Provision Applied to Experiments Not Ultimately Submitted to the FDA

Zarema E. Gunnels, Ph.D.

Judges: Newman (author), Rader (dissenting-in-part and concurring-in-part), Prost

[Remanded from Sup. Ct.]

In *Integra Lifesciences I, Ltd. v. Merck KGaA*, Nos. 02-1052, -1065 (Fed. Cir. July 27, 2007), the Federal Circuit reversed the district court's judgment of infringement, holding that no reasonable jury could find other than that the accused activities were within the FDA Exemption under 35 U.S.C. § 271(e)(1) and rendering JMOL in favor of Merck KGaA ("Merck").

The subject patents, owned by Integra Lifesciences Corporation ("Integra"), involved peptides that contained an RGD sequence of amino acids, i.e., a contiguous sequence of arginine (R), glycine (G), and aspartic acid (D), within a peptide chain. The peptides modulate cell interactions with the extracellular peptide matrix, and thus they can promote, block, or disrupt cell attachment, a process that is important for angiogenesis (the development of blood vessels).

Merck and Scripps Research Institute ("Scripps") collaborated in research on the inhibition of angiogenesis that was conducted by Dr. David Cheresh and others at Scripps. In 1994, while evaluating a cyclic RGD peptide provided by Merck, Dr. Cheresh discovered that the compound was effective in inhibiting angiogenesis. It meant that RGD peptides could have a potential to treat such conditions as solid tumor cancers, rheumatoid arthritis, and diabetic retinopathy, all of which are characterized by the development and growth of undesired blood vessels. As a result, Merck and Scripps entered into a sponsorship agreement, ultimately planning to file an Investigative New Drug ("IND") application to seek FDA approval for clinical trial with human subjects.

During the collaboration with Merck, Dr. Cheresh and other Scripps scientists conducted *in vitro* and *in vivo* experiments that focused on the efficacy, mechanism of action, pharmacology, pharmacokinetics, and safety of three structurally related RGD peptides. The researchers ultimately selected one peptide, EMD 121974, as the optimum drug candidate and in 1998 proceeded to clinical trials using that particular compound.

Integra filed a patent infringement suit against Merck, Scripps, and Dr. Cheresh, alleging that the use of the patented compounds in preclinical testing constituted patent infringement. In its defense, Merck argued that the accused experiments qualified for the FDA "Safe Harbor"

Exemption under 35 U.S.C. § 271(e)(1), as the studies were conducted in furtherance of drug development and the projected clinical trials. Nonetheless, the jury found infringement, and the district court sustained the jury verdict, holding that the safe harbor provision did not apply to Merck's use of the RGD peptides. A split panel of the Federal Circuit affirmed the district court's ruling. It held that "the Scripps work sponsored by Merck was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds."

"[S]tudies of compounds that are not ultimately proposed for clinical trials are within the FDA Exemption, when there was a reasonable basis for identifying the compounds as working through a particular biological process to produce a particular physiological effect." Slip op. at 11.

The Supreme Court, however, granted certiorari. The Court limited its review to the infringement status of experiments using the two RGD peptides that were not selected for clinical trials as well as studies using EMD 121974 that were not submitted to the FDA. Interpreting the scope of § 271(e)(1), the Court ruled that "the FDA Exemption includes experimentation on products that are not ultimately the subject of an FDA submission, provided that the particular biological process and physiological effect had been identified and the work was reasonably related to that appropriate for inclusion in an IND application." Slip op. at 10. Therefore, the Supreme Court vacated and remanded the Federal Circuit's ruling.

On remand, the Federal Circuit's focus was to apply the Supreme Court's statutory interpretation of § 271(e)(1). Integra argued that Scripps's experiments on the two RGD peptides other than EMD 121974 were not within the "safe harbor" FDA provision because the two peptides were not included in the IND application. The Federal Circuit, following the Supreme Court's statutory interpretation, rejected Integra's argument. Studies of compounds that are not ultimately used in the clinical trials are within the FDA Exemption, the Federal Circuit stated, "when there was a reasonable basis for identifying the compounds as working through a particular biological process to produce a particular physiological effect." *Id*. at 11. Thus, the Court concluded that the FDA Exemption applied to Scripps's experiments aimed at selecting the optimum candidate drug, including the experiments with the two RGD peptides other than EMD 121974.

Integra also contended that at the IND application stage, the FDA Exemption applies only to experiments designed to show that the candidate drug is safe for administration to humans. The Federal Circuit emphasized that the Supreme Court rejected this position, stating that, besides safety, the FDA requires that applicants include information in an IND about the drug's efficacy, structure, toxicology, mode of action, side effects, its administration, formulation, and like information. The Federal Circuit pointed to the testimony at trial of Merck's and Scripps's witnesses that the experiments, including the animal tests, all yielded information concerning efficacy, pharmacology, pharmacokinetics, and mechanism of action of the studied RGD compounds. The Supreme Court recognized that such data were relevant to FDA approval, and that qualified the experiments for the FDA Exemption. According to the Supreme Court, the absence of FDA certification as to all three RGD peptides did not defeat the "safe harbor" provision.

As the Federal Circuit was reviewing the jury verdict for support by "substantial evidence," it refused to ignore the evidence that did not support the verdict. Instead, the Court gave credence to the evidence favoring the nonmoving party as well as "that 'evidence supporting the moving party that is uncontradicted and unimpeached.'" *Id*. at 19 (citation omitted). Thus, the Federal Circuit pointed out that at trial, Integra did not present evidence to contradict Merck's evidence that all of the accused experiments were conducted after it had been discovered that an RGD peptide inhibited angiogenesis and thus shrank tumors in an animal model. Neither did Integra dispute the relevance of the experiments to efficacy, mechanism of action, pharmacology, and pharmacokinetics, i.e., subjects that are relevant to an IND submission to the FDA. Thus, after reviewing the entirety of record, the Federal Circuit pointed out the absence of substantial evidence to support the jury verdict of infringement. The Court, therefore, rendered JMOL in favor of Merck.

In a dissenting-in-part and concurring-in-part opinion, Judge Rader insisted that the Federal Circuit expanded the FDA Exemption beyond the Supreme Court's limits on the provision and thus eliminated protection for research tool inventions. Judge Rader wrote that the Federal Circuit should have first construed the patent claims. According to him, two of the patents at issue apply only to laboratory methods without any possibility of submission to the FDA; therefore, the two patents are directed to research tools. Since the Supreme Court did not extend the FDA "safe harbor" provision to encompass research tools, Judge Rader dissented with respect to two of the litigated patents, while concurring with the majority as to the remaining patents.

Filing of Motion to Dismiss Did Not Toll Time to Respond to Amended Complaint

Monica Gorman

Judges: Bryson, Clevenger, Linn (author)

[Appealed from D. Minn., Judge Ericksen]

In *General Mills, Inc. v. Kraft Foods Global, Inc.*, Nos. 06-1569, -1606 (Fed. Cir. July 31, 2007), on petition for rehearing, the Federal Circuit reaffirmed, but clarified, its earlier holding that the time for answering an amended complaint was not tolled under Fed. R. Civ. P. 12(a)(4) when there was no time left to respond to the original pleading.

General Mills, Inc. ("General Mills") served a complaint on Kraft Foods Global, Inc. ("Kraft"). Kraft answered and asserted a counterclaim. General Mills subsequently filed an amended complaint, which Kraft moved to dismiss but did not answer. The district court granted the motion to dismiss and declined to exercise jurisdiction over Kraft's counterclaim. The district court concluded that because Kraft did not answer the amended complaint or reassert its counterclaim, the counterclaim was not pending at the time judgment was entered.

In an opinion dated May 16, 2007, the Federal Circuit affirmed, holding that Kraft's filing of its motion to dismiss the amended complaint did not toll the time it had to answer the amended complaint. *General Mills, Inc. v. Kraft Foods Global, Inc*., 487 F.3d 1368 (Fed. Cir. 2007). On Kraft's petition for rehearing, the Federal Circuit reaffirmed, but clarified, its original holding.

In its petition for rehearing, Kraft argued that the Federal Circuit's decions undermined the "clearly expressed intent" of Rule 12 of the Federal Rules of Civil Procedure. The Federal Circuit disagreed, stating that "where the meaning of Rule 12 is unambiguous, we decline to ignore the text of the rule in service of a purported purpose." Slip op. at 2. The Federal Circuit instead agreed with the district court, explaining that the period of time allotted to respond to an amended complaint is governed by Fed. R. Civ. P. 15(a). Fed. R. Civ. P. 15(a) states that a party must respond either within "the time remaining for the response to the original pleading," or "within 10 days after service of the amended pleading." Fed. R. Civ. P. 12(a)(4) alters the periods of time allotted for responses described in Fed. R. Civ. P. 12(a)(1)-(3). The periods of time described in Fed. R. Civ. P. 12(a)(1)-(3) include the period within which a party must respond to a complaint, but do not include the period within which a party must respond to an amended complaint. Therefore, if the period of time allotted to respond to an amended complaint under Fed. R. Civ. P. 15(a) is within "the time remaining for the response to the original pleading," this time will be tolled under Fed. R. Civ. P. 12(a)(4). If, on the other hand, the period of time allotted to respond to an amended complaint is "within 10 days after service of the amended pleading," this time will not be tolled under Fed. R. Civ. P. 12(a)(4). The Federal Circuit noted that all of the cases cited by Kraft were consistent with its holding.

In the current case, there was no "time remaining for the response to the original pleading" because Kraft had answered the complaint. Therefore, the time for response was not tolled by Fed. R. Civ. P. 12(a)(4) and Kraft was required to respond within ten days. As it failed to do so, the Federal Circuit held that it did not have a counterclaim pending when the judgment of dismissal was entered.

The Federal Circuit did agree with Kraft's challenge to its characterization that it "abandoned" its counterclaim. The Court therefore amended its original opinion to replace the characterization that Kraft had abandoned its counterclaim with a statement that Kraft's counterclaim was not pending when judgment was entered.

Abbreviations | Acronyms

ALJ	Administrative Law Judge
ANDA	Abbreviated New Drug Application
APA	Administrative Procedures Act
APJ	Administrative Patent Judge
Board	Board of Patent Appeals and Interferences
Commissioner	Commissioner of Patents and Trademarks
CIP	Continuation-in-Part
DJ	Declaratory Judgment
DOE	Doctrine of Equivalents
FDA	Food & Drug Administration
IDS	Information Disclosure Statement
IP	Intellectual Property
ITC	International Trade Commission
JMOL	Judgment as a Matter of Law
MPEP	Manual of Patent Examining Procedure
PCT	Patent Cooperation Treaty
PTO	United States Patent and Trademark Office
SEC	Securities and Exchange Commission
SJ	Summary Judgment
SM	Special Master
TTAB	Trademark Trial and Appeal Board

Looking Ahead

- In *MercExchange, L.L.C. v. eBay, Inc.*, No. 2:01cv736 (E.D. Va. July 27, 2007), the district court denied MercExchange, L.L.C.'s ("MercExchange") motion for entry of a permanent injunction in light of *eBay, Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006). The district court had previously denied MercExchange's motion for a permanent injunction. MercExchange appealed to the Federal Circuit, which reversed, holding that injunctions should essentially issue as a matter of course in patent infringement actions upon a finding of validity and infringement. The Supreme Court granted certiorari and vacated the Federal Circuit's injunction ruling, establishing that the traditional four-factor equitable test should be used for the injunction analysis in all cases, including patent disputes, and remanded so that the district court could apply the traditional four-factor test. On remand, the district court, following the Supreme Court's decision, noted that to obtain a permanent injunction in any case, the plaintiff must demonstrate (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. In applying this traditional four-factor test, the district court found that MercExchange had simply failed to establish irreparable harm or that damages at law would not adequately compensate it for eBay, Inc.'s infringement. In addition, the district court found that the "balancing of harms" factor did not favor either party and that the "public interest" factor favored denial of MercExchange's motion for an injunction. Accordingly, the district court concluded that an injunction was not warranted and denied MercExchange's motion.

- In *Lucent Technologies Inc. v. Gateway, Inc.*, Nos. 02CV2060-B (CAB), 03CV06990B (CAB), 03CV1108-B (CAB) (S.D. Ca. Aug. 6, 2007), the district court vacated a jury verdict of over $1.5 billion against Microsoft Corporation ("Microsoft") and in favor of Lucent Technologies Inc. ("Lucent"). A jury found that Microsoft's Windows Media Player software infringed U.S. Patent No. 5,341,457 ("the '457 patent") and U.S. Patent No. RE 39,080 ("the '080 patent"). The jury awarded Lucent the amount of $769,028,351 for infringement of each patent. The district court, however, ruled as a matter of law that Microsoft did not infringe the '457 patent and that Lucent lacked standing to sue on the '080 patent since it was not the sole owner of that patent. The district court also found that Microsoft was not liable for infringement of the '080 patent because it had a license to it. Since Microsoft had no liability for infringement of either the '457 or the '080 patent, the district court held that Lucent was not entitled to any damages from Microsoft. Accordingly, it vacated the jury's damage award and entered judgment in favor of Microsoft and against Lucent.

- Look ahead for these two decisions to wind their way up to the Federal Circuit.

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Last Month at the Federal Circuit

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