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Abbreviations

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 and Drug Administration
IDS	Information Disclosure Statement
ITC	International Trade Commission
JMOL	Judgment as a Matter of Law
MPEP	Manual of Patent Examining Procedure
NDA	New Drug Application
PCT	Patent Cooperation Treaty
PTO	United States Patent and Trademark Office
SJ	Summary Judgment
TTAB	Trademark Trial and Appeal Board

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Prosecution Statements Distinguishing Prior Art May Serve as Disclaimer of Claim Scope

Troy L. Gwartney

Judges: Lourie (author), Moore (concurring-in-part), O'Malley (concurring-in-part)
[Appealed from E.D. Tex., Judge Ward]

In *Saffran v. Johnson & Johnson*, No. 12-1043 (Fed. Cir. Apr. 4, 2013), the Federal Circuit reversed the ruling of the district court, holding that the district court misconstrued the claims of the patent-in-suit and that, under the correct construction, the defendants were entitled to JMOL of noninfringement.

Dr. Bruce N. Saffran is the owner and sole named inventor of U.S. Patent No. 5,653,760 ("the '760 patent"), which describes methods and devices for treating injured tissues by sequestering particles and macromolecules in a defined space using a selectively permeable barrier in an effort to promote healing. The specification of the '760 patent primarily describes the use of treated porous sheets for the treatment of complex bone fractures. The '760 patent also describes that the techniques may be used in conjunction with intravascular stents to promote quicker healing of blood vessels, resulting in less plaque buildup.

Saffran sued Johnson & Johnson and Cordis Corporation (collectively "Cordis") for infringing the '760 patent by manufacturing arterial stents out of a metallic open mesh structure with struts coated with a microscopic layer of polymer and the drug sirolimus. Following a *Markman* hearing, in which the district court construed a number of claim terms of the '760 patent, a jury returned a verdict in favor of Saffran, holding that the '760 patent was not invalid, that Cordis had willfully infringed the '760 patent, and that Saffran was entitled to damages. Cordis moved for JMOL on invalidity, infringement, willfulness, and damages, and the district court denied Cordis's motion for JMOL as to invalidity, infringement, and damages, but granted the motion as to willfulness. Cordis appealed, focusing on the district court's construction of the claim limitations "device" and "release means for release of an at least one treating material in a directional manner."

The Federal Circuit first addressed the "device" term and held that even though the term "device" appears in both the preamble and body of each of the independent claims, the district court misconstrued the term "device" as nonlimiting preamble language serving to give a descriptive name to the set of limitations in the body of the claim. Cordis argued that "device" should be construed to mean "a continuous sheet" to be consistent with the '760 patent specification and in view of allegedly disclaiming statements made by Saffran during prosecution. During prosecution of the '760 patent, in an argument over a cited prior art reference relating to rigid preformed chambers, Saffran had distinguished the art by describing on multiple occasions that "[t]he device used is a sheet rather than a pre formed chamber" as used in the prior art. Slip op. at 16 (alteration in original) (citations omitted).

"[A]n applicant's argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope even if the applicant distinguishes the reference on other grounds as well." Slip op. at 16 (quoting *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1374 (Fed. Cir. 2007)).

Saffran argued that the scope of disclaimer during the prosecution history should be limited to the subject matter of the prior art reference being distinguished, specifically, the use of preformed chambers in the prior art. The Court described Saffran's arguments to the examiner as containing two bases for distinguishing the prior art: (1) that his device was a sheet, and (2) that his device was not a preformed chamber. *Id.* The Court explained that even if the examiner had only relied on the disclaimer that the device was not a preformed chamber, "an applicant's argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope even if the applicant distinguishes the reference on other grounds as well." *Id.* (quoting *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1374 (Fed. Cir. 2007)). The Court further explained that Saffran's "unqualified assertion that 'the device used is a sheet' extends . . . to provide an affirmative definition for the disputed term." *Id.* at 17 (citation omitted).

Saffran argued, however, that a spray embodiment disclosed in the specification was contrary to the construction that "the device" is "a continuous sheet." The Court disagreed, holding that the spray embodiment only described the spray as both treating directly to the affected tissue and spanning open gaps between bone fragments to form a continuous sheet. The Court further determined that the specification "makes clear that restraining tissue macromolecules is not only a key feature of the invention, but also one that open mesh stents cannot provide." *Id.* at 19. Thus, the Court construed the term "device" to require a sheet and to exclude stents having open mesh holes, and reversed the district court's construction of the term "device."

Cordis also disputed the district court's construction of the "release means" recited in each independent claim of the '760 patent. Although Cordis did not dispute the claimed function identified by the district court as "to release a drug preferentially toward the damaged tissue," Cordis disagreed with the identification of the 35 U.S.C. § 112, ¶ 6, corresponding structure to carry out that function as "chemical bonds and linkages." *Id.* at 20 (citation omitted). Cordis argued that the only type of bond identified in the '760 patent for performing the release means is a hydrolyzable bond. Saffran argued that the '760 patent broadly discloses "chemical bonds and linkages" as a clear category of structures that would be readily understood by one of ordinary skill in the art as suitable for performing the claimed function. *Id.* at 21.

The Court explained that "structure disclosed in the specification is 'corresponding' structure *only* if the specification or prosecution history clearly links or associates that structure to the function recited in the claim. This duty to link or associate structure to function is the *quid pro quo* for the convenience of employing § 112, ¶ 6." *Id.* (quoting *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997)). The Court held that the types of bonds set forth in the '760 patent as corresponding to the claimed release function are limited to hydrolyzable bonds, because (1) the specification repeatedly describes the linkage between treating materials and the sheet as a hydrolyzable bond, and (2) the specification does not link any additional structures to the release function with sufficient specificity to satisfy § 112, ¶ 6. The Court found Saffran's arguments to the contrary unavailing and concluded that the district court erred in its construction of the "release means" limitation.

In view of the Court's construction of "device" and identification of the corresponding structure for the claimed "release means," the Court found two independent grounds for noninfringement as a matter of law. As to the "device," the accused devices had open holes, with the layer not being applied as a continuous sheet, but "akin to paint on a chain link fence." *Id.* at 25. As the Court's construction of

"device" required a continuous sheet and excluded stents having open mesh holes, the Court found that no reasonable jury could conclude that Cordis's accused stents infringed the '760 patent. Separately, with regard to the "release means," the Court found that the record established that the accused stents used a sirolimus coating embedded in a polymer layer held in place by hydrophobic interactions, and that Saffran had stipulated that he would not pursue any arguments that hydrophobic interactions are equivalent to hydrolyzable bonds.

Accordingly, the Court found that the district court erred in its construction of "device" and misidentified the corresponding structure for the claimed "release means." The Court therefore reversed the district court's judgment, as under either one of these proper constructions, Cordis was entitled to a judgment of noninfringement as a matter of law.

Judge Moore concurred-in-part, joining the opinion as to the construction of "device," but concluding that the district court was correct that the corresponding structure for the "release means" was the more generic "chemical bonds and linkages." Moore Concurrence at 1. Judge Moore submitted that the specification associated the claimed "release means" with a "chemical bond" structure with sufficient specificity to satisfy § 112, ¶ 6.

Judge O'Malley also concurred-in-part, joining the opinion as to the construction of "release means," but disagreeing with the construction of "device." As to the construction of "device" as a "sheet," Judge O'Malley argued that the claim language was broad and the written description disclosed several embodiments that "cannot fairly be characterized as sheets." O'Malley Concurrence at 2. Judge O'Malley also disagreed that there was a clear and unambiguous disclaimer of those embodiments in the prosecution history. Because the majority agreed that "device" was a generic term, Judge O'Malley argued that to find a "special definition mandated by the written description, a term must be 'clearly' redefined, and an 'express intent' to do so must be evident from the patent." *Id.* (citing *Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1307 (Fed. Cir. 2000)). Judge O'Malley did not find such "clear definition" of "device" or "express intent" in the '760 patent or prosecution history. *Id.* at 3. Judge O'Malley asserted instead that the majority approached claim construction incorrectly by elevating prosecution history above other claim construction factors. Judge O'Malley agreed with the majority, however, as to the construction of the "release means" limitations, noting that since the term was a means-plus-function element, the scope of the term was inherently narrowed by the disclosure and did not require examination of "the intrinsic record for a clear and unmistakable disavowal of claim scope." *Id.* at 12-13.

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Affidavits or Declarations Are Not Always Required When Submitting Arguments Concerning Lack of Enablement of Prior Art Reference

Jose M. Recio

Judges: Rader, Lourie, O'Malley (author)

[Appealed from Board]

In *In re Morsa*, No. 12-1609 (Fed. Cir. Apr. 5, 2013), the Federal Circuit vacated the Board's enablement and anticipation determinations, affirmed the Board's obviousness conclusions, and remanded to the Board for further proceedings, including an enablement analysis in accordance with the Court's instructions.

On April 12, 2001, Steve Morsa filed a patent application that disclosed a method and apparatus for receiving a benefit information request from a user, searching a benefit information database for benefits matching the user's request, and then returning benefit information to the user. During proceedings before the PTO, the examiner rejected the application as unpatentable over a single reference, Peter Martin Associates Press Release ("PMA"). The PMA is a September 27, 1999, publication that announced the release of "Help Works, Web Edition," a product that allowed consumers to use the Internet to screen themselves for benefits, services, and health risks, among other features. The examiner found that the PMA anticipated certain claims of the application and rendered obvious the remaining claims. Morsa appealed to the Board.

On appeal to the Board, Morsa made three main arguments. First, he argued that the PMA, while dated September 27, 1999, was not prior art because (1) a later publication stated that Help Works, Web Edition launched in 2001; (2) the PMA publishing website stated that it would not be held liable for publication inaccuracies; and (3) a trademark registration for HelpWorks, Web Edition stated that the mark was first used in commerce in 2001. Second, Morsa argued that the PMA was not enabling because it lacked enough detail to be able to produce or practice the claimed invention based solely on a reading of the PMA, whose two relevant paragraphs totaled only 117 words. Third, Morsa argued that the differences between the application's claims and the prior art were sufficient to support a finding of nonobviousness.

The Board concluded that the PMA was prior art, that it was presumed enabling because of a lack of evidence to the contrary, and that the examiner's anticipation rejections were proper. Regarding the examiner's obviousness rejections, the Board found that Morsa failed to present any evidence of objective factors for the Board to consider, and that the differences between the prior art and the claimed invention were not sufficient to overrule the examiner's rejections on certain claims. However, the Board indicated certain claims as patentable over the PMA. Following two requests for rehearing, which were subsequently denied by the Board, Morsa appealed.

On appeal, the Federal Circuit affirmed the Board's decision on the PMA being prior art. Since the PMA was clearly marked with a date of September 27, 1999, the Court concluded that substantial evidence supported the Board's finding on this point.

"The presumption in *Antor* is a procedural one—designed to put the burden on the applicant in the first instance to challenge cited prior art; the PTO need not come forward with evidence of enablement before it may rely upon a prior art reference as grounds for a rejection. Once an applicant makes a non-frivolous argument that cited prior art is not enabling, however, the examiner must address that challenge." *Id.* at 9-10 (citing *In re Antor Media Corp.*, 689 F.3d 1282, 1288 (Fed. Cir. 2012)).

Next, the Court turned to the Board's decisions on enablement and anticipation. In its decision on rehearing, the Board concluded that the PMA was presumed enabling because Morsa failed to provide any affidavits or declarations to support arguments to the contrary. On appeal, the PTO relied on *In re Antor Media Corp.*, 689 F.3d 1282 (Fed. Cir. 2012), which held that publications used as prior art by the PTO are presumed enabling, to support a presumption that the PMA was an enabled reference. In determining that the Board's presumption was improper, the Court held that "[t]he presumption in *Antor* is a procedural one—designed to put the burden on the applicant in the first instance to challenge cited prior art." Slip op. at 9. But "[o]nce an applicant makes a non-frivolous argument that cited prior art is not enabling, . . . the examiner must address that challenge." *Id.* at 10. The Court also held that, while an applicant must generally do more than state an unsupported belief of lack of enablement, it is not necessarily the case that the applicant must submit affidavits and submissions in support of its arguments. Since Morsa identified specific, concrete reasons why he believed the PMA was not enabling, the Court held that the Board had erred in not addressing these arguments.

The Court also found unpersuasive the Director's argument that the PMA should be considered enabling because it was "at least as enabling" as Morsa's application. *Id.* On this issue, the Court stated that "an examiner must determine if prior art is enabling by asking whether a person of ordinary skill in the art could make or use the claimed invention without undue experimentation based on the disclosure of *that particular document*." *Id.* Moreover, the Court held that "the anticipation exercise must assess the enabling nature of a prior art reference in light of the proposed claims." *Id.* The Court concluded that the application far exceeded the level of detail in the PMA and, absent a finding that the application's disclosure was unrelated to the claimed invention, the Court could not agree with the PTO's comparison between the two documents.

The Court then reviewed the examiner's and the Board's obviousness findings. During prosecution, the examiner found that it would have been obvious to one of ordinary skill in the art to configure the product described in the PMA to perform the various recitations in the claims. As to these findings, the Federal Circuit found that they were supported by substantial evidence. The Court also affirmed the Board's rejection of Morsa's argument that objective factors weighed in favor of a finding of nonobviousness. The Court explained that, although the case law requires the Board to consider evidence of objective factors in its obviousness determinations, Morsa had merely listed the objective factors without proffering any supporting evidence. Thus, the Court ruled that the Board did not err in failing to consider evidence of objective factors, since there was no evidence to consider. Finally, the Federal Circuit reviewed the examiner's factual findings regarding the PMA rendering obvious certain claims of the application, and agreed with the Board's decision that the claims would have been obvious to one of ordinary skill in the art.

Accordingly, the Court affirmed-in-part the Board's ultimate legal conclusions of obviousness. Based on the improper enablement analysis, however, the Court vacated the Board's anticipation findings and remanded for further proceedings.

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For Obviousness, a Motivation to Combine Does Not Require a Suggestion That the Claimed Combination Is Preferred or Most Desirable

Angela Y. Dai

Judges: Lourie (author), Schall, Prost

[Appealed from D. Nev., Judge Dawson]

In *Bayer Healthcare Pharmaceuticals, Inc. v. Watson Pharmaceuticals, Inc.*, Nos. 12-1397, -1398, -1400, -1424 (Fed. Cir. Apr. 16, 2013), the Federal Circuit reversed the district court's entry of SJ that asserted claims 13 and 15 of U.S. Patent No. RE37,564 ("the '564 patent") were not invalid for obviousness.

Bayer Healthcare Pharmaceuticals, Inc. and Bayer Schering Pharma AG (collectively "Bayer") own the '564 patent, directed to low-dose, extended-regimen combined oral contraceptive ("COC") products. To address the risks of side effects, "escape" ovulation, and unintended pregnancy, Bayer developed a low-dose COC containing synthetic estrogen ethinylestradiol ("EE") and synthetic progestin drospirenone ("DRSP") administered according to a dosing regimen of either twenty-four active pills followed by four pill-free days (24/4) or twenty-three active pills followed by five pill-free days (23/5), as opposed to the traditional dosing regimen of twenty-one active pills followed by seven pill-free days (21/7).

Asserted claims 13 and 15 of the '564 patent cover Bayer's COC product, marketed under the brand name YAZ®. Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Sandoz, Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. (collectively "Defendants") filed ANDAs with the FDA seeking approval to market generic versions of YAZ® and asserting that the '564 patent was invalid. Bayer responded by suing Defendants for infringement of claims 13 and 15 of the '564 patent, and Defendants counterclaimed that the asserted claims were invalid for obviousness. The district court ultimately granted SJ in favor of Bayer, concluding that the asserted claims were not invalid for obviousness. Defendants appealed.

On appeal, the Federal Circuit agreed with Defendants that the district court erred in concluding that asserted claims 13 and 15 were not invalid for obviousness. The Court first observed that it was undisputed that the cited prior art set forth every limitation required by the asserted claims.

"[A] finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggests that the combination claimed . . . is the preferred, or most desirable, combination." Slip op. at 15 (alterations in original) (quoting *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004)).

The Court also found that the prior art provided express motivation for a person of ordinary skill in the art

to combine the limitations to derive the claimed COC products with a reasonable expectation of success. The Court noted that one prior art reference expressly referenced another, which together with the first disclosed every limitation of the asserted claims. The Court also noted that several of the cited references highlighted evidence that unregulated ovarian activity occurring during a seven-day pill-free interval could achieve significant follicular development, and that those references expressed concern that inadvertently extending the traditional pill-free interval via one or more missed pills could lead to escape ovulation and unintended pregnancy. The Court also reasoned that Bayer's expert acknowledged that one of skill in the art at the time of the invention would have expected an even greater risk of such "missed pill" ovulation for users of low-dose COCs.

The Court thus concluded that missed-pill ovulation was a recognized concern with traditional 21/7 COCs, particularly for those on the market by 1993 that, like the claimed COC preparations, relied on low-dose EE. "As the Supreme Court has stated, 'any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.'" Slip op. at 13 (quoting *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007)). The Court further reasoned that the references went beyond just illuminating a known problem—they also expressly proposed the claimed solution.

The Court rejected Bayer's argument that two of the references were primarily directed to older women who reached premenopause and were in need of hormone replacement therapy such that a skilled person setting out to design an oral contraceptive using EE and DRSP would not have used the 24/4 regimen intended to achieve effective hormone replacement therapy. The Court stated that those references plainly disclosed preparations with hormone replacement *and* contraceptive applications, and that the product claims-at-issue did not distinguish between target patient populations by age or otherwise.

The Court also rejected Bayer's argument that the prior art taught away from the claimed COC preparations, focusing on statements in the "Guillebaud" reference as indicating that the conventional wisdom in the field favored 21/7 dosing for most patients and as suggesting that a reduced pill-free interval should be used together with higher-dose COCs for patients perceived to be at risk of escape ovulation. The Court reasoned that those statements did not overcome the express teachings of multiple references, including Guillebaud, that a shorter pill-free interval would improve COC efficacy. Furthermore, the Court noted that Guillebaud may have suggested condensing the pill-free interval while concurrently increasing the hormone dose for at-risk patients, but those two measures were never described as mutually dependent, and each could be expected to reduce missed-pill ovulation risks with or without the other. "[A] finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggests that the combination claimed . . . is the preferred, or most desirable, combination." *Id*. at 15 (alterations in original) (quoting *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004)). The Court stated that just because one of several references indicated a preference for using 24/4 or 23/5 dosing regimens in tandem with higher-dose COCs did not mean the same missed-pill rationale could not also motivate applying the shorter pill-free interval to similarly improve other COC preparations.

Finally, the Court held that Bayer's evidence of secondary indicia of nonobviousness, including alleged unexpected results, expert skepticism, industry praise, and copying by others, was legally insufficient. Regarding unexpected results, the Court found that data showing that 23/5 administration resulted in reduced follicular activity compared to 21/7 dosing of the same COC formulation merely confirmed that administering additional active pills resulted in additional follicular suppression, a matter of common sense.

Regarding expert skepticism, Bayer cited an FDA request for clinical safety data and data demonstrating efficacy benefits sufficient to justify the added synthetic hormone exposure required for the proposed 24/4 dosing regimen. The Court found that that request in no way indicated FDA experts would have been

surprised to receive such data, since the cited request reflected attention to the FDA's normal duties ensuring the safety and efficacy of new drugs by requiring actual data to corroborate statements in a new drug application.

Regarding industry praise, Bayer claimed that its invention was widely praised by experts in the COC field, relying on journal citations that referenced the findings stated in Bayer's published efficacy studies or discussed possible noncontraceptive indications for 24/4 COC regimens. Bayer also relied on an article that was authored by the first-named inventor of the '564 patent describing Bayer's 24/4 COC regimen as an innovative strategy. The Court found that the bare journal citations and self-referential recommendation fell well short of demonstrating true industry praise. The Court also stated that industry praise of what was clearly rendered obvious by published references was not a persuasive secondary consideration.

Regarding copying by others, the Court rejected Bayer's contention that copying of its COC preparations by the defendants and other generic manufacturers supported its validity position, noting that such evidence of copying in the ANDA context was not probative of nonobviousness because a showing of bioequivalence was required for FDA approval. Accordingly, the Court held that claims 13 and 15 of the '564 patent were invalid for obviousness in view of the cited references, and reversed the district court's SJ.

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Prosecution History Disclaimer Can Arise from an Applicant's Silence in Response to Statements by the Examiner

Ian Y. Liu

Judges: Dyk, Plager (dissenting), Reyna (author)

[Appealed from S.D. Cal., Judge Benitez]

In *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, No. 12-1120 (Fed. Cir. Apr. 16, 2013), the Federal Circuit affirmed the district court's claim construction of the claim term "anti-CD20 antibody" in U.S. Patent No. 7,682,612 ("the '612 patent"), which narrowed the term based on prosecution history disclaimer.

Biogen Idec, Inc. and Genentech, Inc. (collectively "Biogen") obtained the '612 patent directed to methods for treating patients with Chronic Lymphocytic Leukemia (CLL) involving administering a therapeutically effective amount of an anti-CD20 antibody. The '612 patent was not limited to any particular type of anti-CD20 antibody, but stated that a particularly preferred chimeric anti-CD20 antibody is Rituxan® (rituximab) and incorporated by reference U.S. Patent No. 5,736,137 ("the '137 patent"). The '137 patent defines an "anti-CD20 antibody" as used therein as "an antibody which specifically recognizes a cell surface . . . typically designated as the human B lymphocyte restricted differentiation antigen Bp35, commonly referred to as CD20." Slip op. at 4 (alteration in original) (citation omitted).

During prosecution of the '612 patent, the examiner rejected all the claims for not providing enablement for "any and all anti-CD20 antibodies, no matter the specificity or affinity for the specific epitope on the circulating tumor cells." *Id.* at 5 (citation omitted). The examiner acknowledged that the specification was enabling for Rituxan®, but that it was "silent concerning what sort of specificity and affinity would be necessary" for other anti-CD20 antibodies. *Id.* (citation omitted). In response, Biogen stated that "one of skill in the art could readily identify an antibody that binds to CD20 with similar affinity and specificity as does RITUXAN®." *Id.* (citation omitted). The examiner withdrew the enablement rejection and the claims issued.

GlaxoSmithKline LLC and Glaxo Group Ltd. (collectively "GSK") developed the anti-CD20 antibody Arzerra® (ofatumumab), which is distinctly different from Rituxan® in several respects. Arzerra® is a full human antibody that binds to a different epitope than Rituxan® and has a much greater affinity for the CD20 antigen than Rituxan®. Biogen sued GSK for infringement of the '612 patent, and GSK counterclaimed, alleging noninfringement, invalidity, and unenforceability of the asserted claims. At a *Markman* hearing, the district court adopted GSK's construction of the term "anti-CD20 antibody" as "rituximab and antibodies that bind to the same epitope of the CD20 antigen with similar affinity and specificity as rituximab," reasoning that prosecution history disclaimer applied because Biogen limited the term to overcome the enablement rejection. *Id.* at 7 (citation omitted). Biogen stipulated to noninfringement based on this construction and then appealed.

On appeal, the Federal Circuit considered whether statements in the prosecution history were sufficient to overcome the "heavy presumption" that the term carries its full ordinary and customary meaning advanced by Biogen, so as to limit the term "anti-CD20 antibody" in the '612 patent to those antibodies having similar specificity and affinity for the specific epitope to which Rituxan® binds. The Federal Circuit concluded that they were.

"If an applicant chooses, she can challenge an examiner's characterization in order to avoid any chance for disclaimer, but the applicants in this case did not directly challenge the examiner's characterization." Slip op. at 11 (citing *TorPharm Inc. v. Ranbaxy Pharm., Inc.*, 336 F.3d 1322, 1330 (Fed. Cir. 2003)).

The Court reasoned that in response to an enablement rejection, "rather than challenging the examiner's understanding of the crucial terms, the applicants argued that the specification was enabling for anti-CD20 antibodies with similar affinity and specificity as Rituxan®." *Id.* at 10. "[I]t is clear that [the applicants] were limiting their invention to what the examiner believed they enabled: antibodies that have a similar specificity and affinity for the specific epitope to which Rituxan® binds." *Id.*

The Court rejected Biogen's argument that because it never explicitly referred to any particular "epitope" and because CD20 was only thought to have one epitope at the time of filing, the applicants were merely referring to specificity and affinity in the general sense. The Court reasoned that, read in context, the full prosecution history did not support Biogen's position, as Biogen adopted the examiner's characterization of the antibodies when they limited their claims to antibodies similar to Rituxan®. "While disavowing statements must be 'so clear as to show reasonable clarity and deliberateness,' this requirement does not require the applicant to parrot back language used by the examiner when clearly and deliberately responding to a particular ground[] for rejection." *Id.* at 11 (quoting *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325 (Fed. Cir. 2003)). "If an applicant chooses, she can challenge an examiner's characterization in order to avoid any chance for disclaimer, but the applicants in this case did not directly challenge the examiner's characterization." *Id.* (citing *TorPharm Inc. v. Ranbaxy Pharm., Inc.*, 336 F.3d 1322, 1330 (Fed. Cir. 2003)).

The Court also found unpersuasive Biogen's two arguments for why the claim term's full plain and ordinary meaning should control. First, the Court rejected Biogen's claim differentiation argument, stating that, where found, prosecution history can overcome the presumption of claim differentiation. Second, the Court rejected Biogen's argument that the definition in the '137 patent, which was incorporated by reference, should control. The Court reasoned that the '137 patent expressly and uniquely defined the term for use within the '137 patent, and that the definition thus did not necessarily reflect how a person of ordinary skill in the art would understand the term in the context of the '612 patent. The Court concluded there was no basis for reversing the district court's claim construction, and affirmed that the term "anti-CD20 antibody" was limited by prosecution history disclaimer.

Judge Plager dissented, stating he did not "find anywhere in the majority opinion or in the prosecution history that clear and unmistakable evidence of a disclaimer as required by our precedents." Plager Dissent at 1. Judge Plager opined that "an applicant's silence regarding statements made by the examiner during prosecution cannot amount to a clear and unmistakable disavowal of claim scope." *Id.* at 5 (citing *Sorensen v. Int'l Trade Comm'n*, 427 F.3d 1375, 1379 (Fed. Cir. 2005); *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1345 (Fed. Cir. 2005)). Judge Plager also disagreed with the majority's treatment of the '137 patent, stating that "even assuming that the applicants of the '137 patent were acting as their own lexicographer when broadly defining the term 'anti-CD20 antibody,' the '612 patent then incorporated this 'special definition' into its own disclosure." *Id.* at 7.

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Complaints That Comply with Form 18 and Are Plausible Need Not Identify a Specific Accused Product to Satisfy Rule 8(a)

Elliot C. Cook

Judges: Moore, O'Malley (author), Wallach (concurring)

[Appealed from C.D. Cal., Judge Klausner]

In *K-Tech Telecommunications, Inc. v. Time Warner Cable, Inc.*, Nos. 12-1425, -1446 (Fed. Cir. Apr. 18, 2013), the Federal Circuit held that the district court in two separate but related actions applied the incorrect legal standard in granting the defendants' motions to dismiss under Fed. R. Civ. P. 12(b)(6). In both cases, the Federal Circuit found that the complaint complied with the applicable standard and reversed the district court's dismissal.

In 2011, K-Tech Telecommunications, Inc. ("K-Tech") brought separate cases against Time Warner Cable, Inc. ("TWC") and DirecTV, alleging infringement of four patents. The asserted patents, owned by K-Tech, are generally directed to modifying channel numbers or carrier frequencies to identify television programs. Each defendant moved to dismiss K-Tech's complaint under Fed. R. Civ. P. 12(b)(6) on the ground that K-Tech failed to plead sufficient factual content. The district court consolidated the two actions and then granted the motions, dismissing K-Tech's complaints and allowing K-Tech leave to amend. After K-Tech amended the complaints, TWC and DirecTV moved to dismiss the amended complaints on the same ground. The district court granted the motions, dismissing the amended complaints with prejudice.

On appeal, K-Tech argued that its amended complaints complied with Form 18 of the Appendix of Forms to the Federal Rules of Civil Procedure ("Form 18") and thus were sufficient under Fed. R. Civ. P. 8(a). According to K-Tech, the district court erred by focusing on the Supreme Court's decisions in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), rather than Form 18. TWC and DirecTV argued that whether a complaint complies with Form 18 must be determined in light of *Twombly* and *Iqbal*, as well as regional circuit law applying those decisions (here, Ninth Circuit law). Consequently, according to TWC and DirecTV, what Form 18 requires should differ depending on the law of the regional circuit in which the case arises. TWC and DirecTV also argued that the amended complaints failed to comply with the plain language of Form 18.

"That K-Tech cannot point to the specific device or product within TWC's or DirecTV's systems that translates the digital television signals each receives—especially when the operation of those systems is not ascertainable without discovery—should not bar K-Tech's filing of a complaint." Slip op. at 17.

The Federal Circuit held that Form 18 sets forth the applicable pleading standard for patent infringement cases. Quoting its recent decision in *R+L Carriers, Inc. v. DriverTech LLC*, 681 F.3d 1323 (Fed. Cir. 2012), the court noted that "the forms in the Appendix suffice under these rules and illustrate the simplicity and brevity that these rules contemplate," as stated in Fed. R. Civ. P. 84. Slip op. at 10. According to the Court, to the extent that there is any conflict between Form 18 and the framework of *Twombly* and *Iqbal*, Form 18 controls. Nevertheless, the Court did not find that there necessarily was a conflict. As the Court explained, "we think it clear that an implausible claim for patent infringement rightly should be dismissed." *Id.* at 12. The Court also rejected TWC and DirecTV's argument that the requirements of Form 18 could differ from circuit to circuit, since "Form 18 is a national form" and the Court's analysis was driven by Supreme Court precedent. *Id*. at 11 n.1.

The Federal Circuit also rejected TWC and DirecTV's argument that the amended complaints failed to satisfy Form 18. In particular, TWC and DirecTV argued that the amended complaints were deficient because they did not identify an allegedly infringing device or connect any allegedly infringing activity to the asserted patents. The Federal Circuit noted that, in the amended complaints, K-Tech alleged that its patents covered "systems and methods for modifying a major channel number, a minor channel number, and/or a carrier frequency to identify a television program," and alleged that TWC and DirecTV infringed the patents by doing the same. *Id.* at 5. The amended complaints also described a regulatory scheme that allegedly required the use of major channel numbers, minor channel numbers, and a carrier frequency, as claimed in the asserted patents. Further, the amended complaints referred to a DirecTV patent that allegedly described how DirecTV received its broadcast signals, presuit communications with DirecTV, and an example of a television program showing a channel assignment in both over-the-air form and with a different channel assignment as broadcasted by TWC. According to the Federal Circuit, these allegations were sufficient.

Even though K-Tech did not identify any specific accused products by name or model number, Form 18 does not require that level of specificity. "That K-Tech cannot point to the specific device or product within TWC's or DirecTV's systems that translates the digital television signals each receives—especially when the operation of those systems is not ascertainable without discovery—should not bar K-Tech's filing of a complaint." *Id.* at 17.

Judge Wallach filed a concurring opinion. He agreed with the majority's outcome and analysis regarding compliance with Form 18. Nevertheless, he disagreed with the majority's statement that the Forms appended to the Federal Rules of Civil Procedure, including Form 18, control over the Supreme Court's plausibility standard set forth in *Twombly* and *Iqbal*. According to Judge Wallach, "plausibility is always required to survive a Rule 12(b)(6) motion." Wallach Concurrence at 2. Further, as *Twombly* and *Iqbal* require, plausibility must be grounded in allegations of fact. Judge Wallach explained that, because Form 18 and *Twombly* and *Iqbal* are reconcilable, there is no need to state that Form 18 controls over those decisions.

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Prior Suit Involving Materially Identical Products and Same Claim Term Collaterally Estops Relitigation of Infringement

Hillary C. Matheson

Judges: Newman (author), Prost, Reyna

[Appealed from S.D. Fla., Judge Zloch]

In *Aspex Eyewear, Inc. v. Zenni Optical LLC*, No. 12-1318 (Fed. Cir. Apr. 19, 2013), the Federal Circuit affirmed that a first lawsuit involving certain eyewear patents collaterally estopped a second lawsuit involving the same patents, where the same claim term was dispositive of infringement.

Specifically, the Court concluded that Contour Optik, Inc. and sublicensee Aspex Eyewear, Inc. (collectively "Aspex") were collaterally estopped from suing Zenni Optical, LLC ("Zenni") for patent infringement, based on earlier litigation between Aspex and Altair Eyewear, Inc. ("Altair"). Both litigations involved the same three patents—U.S. Patent Nos. 5,737,054 ("the '054 patent"); 6,012,811 ("the '811 patent"); and 6,092,896 ("the '896 patent")—and many of the same claims. The '054, '811, and '896 patents are directed to clip-on eyewear in which magnets secure the bridge portions of the eyewear.

The *Altair* district court construed the term "retaining mechanism" in the '811 and '896 patents as requiring supporting frames, such as rims around the lenses. The *Altair* district court granted SJ of noninfringement because none of Altair's products contained a rim around the sunglass lens. After the Federal Circuit held on appeal that the term "frame" in the '054 patent was not limited to one with rims, the *Altair* district court held that the only '054 claim asserted, claim 1, was invalid for obviousness under that construction.

In the present litigation, the district court cited Eleventh Circuit precedent, under which collateral estoppel applies when (1) the issue at stake is identical to the one involved in the prior proceeding; (2) the issue was actually litigated in the prior proceeding; (3) the determination of the issue in the prior litigation was a critical and necessary part of the judgment; and (4) the party against whom collateral estoppel is asserted had a full and fair opportunity to litigate the issue in the prior proceeding. The district court held that the *Altair* decision settled the question of whether rimless magnetic clip-on sunglasses can infringe the '811 and '896 patents. The district court concluded that collateral estoppel barred this suit against Zenni because its accused rimless magnetic clip-on sunglasses were materially indistinguishable from Altair's.

On appeal, Aspex argued that the issues at stake were not identical because the claim terms construed and applied in the *Altair* litigation were not the same. Specifically, Aspex argued that the question of infringement turned on the meaning of the claim terms "primary frame," "auxiliary frame," "first frame," and "second frame," and that those terms were not at issue in the *Altair* litigation. Aspex also argued that the issues at stake were different because some of the claims of the '896 patent that were asserted against Zenni were not asserted against Altair.

"The selection of additional claims for litigation and additional terms for 'construction' does not override the holding of non-infringement. In determining whether Aspex had a full and fair opportunity to litigate the dispositive claim limitations in the prior proceeding, '[i]t is the issues litigated, not the specific claims around which the issues were framed, that is determinative.'" Slip op. at 8-9 (alteration in original) (quoting *Westwood Chem., Inc. v. United States*, 525 F.2d 1367, 1372 (Ct. Cl. 1975)).

The Federal Circuit observed that every claim asserted against Zenni contained the same "retaining mechanism" limitation, in the same context, which was dispositive of noninfringement in the *Altair* litigation. The Court held that in such circumstances, the assertion of different claims in a subsequent suit does not create a new issue to defeat preclusion. The Court determined that the construction of "retaining mechanism" was determinative of noninfringement by the Zenni eyewear and that it was irrelevant whether the additional claims contained additional terms that were not previously construed.

The Federal Circuit held that the district court correctly defined the issue as infringement by magnetic rimless clip-on eyewear in view of "retaining mechanism" being construed as requiring rims, and correctly found that Aspex had a full and fair opportunity to litigate that issue. In determining whether Aspex had a full and fair opportunity to litigate the dispositive claim limitations in the prior proceeding, the Court explained that "[i]t is the issues litigated, not the specific claims around which the issues were framed, that is determinative." Slip op. at 8-9 (quoting *Westwood Chem., Inc. v. United States*, 525 F.2d 1367, 1372 (Ct. Cl. 1975)).

On that basis, the Federal Circuit affirmed that Aspex was collaterally estopped from relitigating infringement of the patents against Zenni.

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When Party Challenging Validity Fails to Cross-Appeal, Cross-Appeal Rule Precludes Reopening Prior Validity Judgment on Remand Based on Modified Claim Construction

K. Kevin Mun

Judges: Lourie (author), Dyk (dissenting), Reyna

[Appealed from S.D.N.Y., Judge Griesa]

In *Lazare Kaplan International, Inc. v. Photoscribe Technologies, Inc.*, No. 12-1247 (Fed. Cir. Apr. 19, 2013), the Federal Circuit reversed the district court's grant of relief under Fed. R. Civ. P. 60(b), vacated the finding of invalidity, and remanded with instructions to reinstate its original judgment of validity and assess infringement.

In 2006, Lazare Kaplan International, Inc. ("Lazare") sued Photoscribe Technologies, Inc. and the Gemological Institute of America (collectively "Photoscribe"), alleging infringement of two patents, including U.S. Patent No. 6,476,351 ("the '351 patent"). Photoscribe filed counterclaims seeking declarations of invalidity. Claims 1 and 7 of the '351 patent, which were the only claims-at-issue, recite a method of microscribing a gemstone and a corresponding system, respectively. Following a claim construction ruling that resulted in a narrow construction of a key claim term, the district court granted SJ of no literal infringement of the asserted claims, and, at a later trial, the jury returned a verdict of noninfringement under the DOE and validity of the asserted claims. The district court then issued a final judgment that the asserted claims were not invalid and not infringed, either literally or under the DOE. Lazare appealed the judgment of noninfringement. Photoscribe, however, did not cross-appeal the judgment of validity. In that appeal, the Federal Circuit broadened the district court's construction of the key term, vacated both the grant of SJ and jury verdict on infringement issues, and remanded the infringement issues to the district court for determination based on the modified claim construction. *Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc.*, 628 F.3d 1359, 1369 (Fed. Cir. 2010).

On remand, the parties disputed as to whether the district court should retry on only infringement or both infringement and validity. The district court agreed with Photoscribe that, despite Photoscribe's failure to cross-appeal the adverse validity judgment, it should also retry on validity because the validity judgment in the first trial was based on a claim construction that the Federal Circuit reversed. Photoscribe then moved for SJ of invalidity and relief under Rule 60(b) from the prior validity judgment, and Lazare moved for SJ of infringement. The district court granted both of Photoscribe's motions and denied Lazare's motion as moot. Lazare appealed for a second time.

In the instant appeal, the Federal Circuit reversed the district court's grant of relief under Rule 60(b), vacated the SJ of invalidity, and remanded with instructions to reinstate its original judgment of validity and assess infringement. The parties disputed whether, on remand, the district court properly reopened the prior final judgment on validity, not appealed by either party, based on the Federal Circuit's modified

claim construction. Lazare argued that the cross-appeal rule—requiring a party to file a cross-appeal if the party seeks to lessen the rights of its adversary or to enlarge its own rights—should have barred reopening the prior judgment on validity because Photoscribe sought to lessen the rights of Lazare under that prior judgment without filing a cross-appeal. In response, Photoscribe argued that prior Federal Circuit decisions permitted the district court to address validity on remand and that the relief under either Rule 60(b)(5) or 60(b)(6) was proper.

"The cases cited by Photoscribe, however, do not involve Rule 60(b)(6), and only recite the familiar axiom that 'claims are construed the same way for both invalidity and infringement.' [Appellee Br.] 21 (quoting *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003)). That axiom, however, does not trump the Federal Rules or the cross-appeal rule, and cannot save Photoscribe from its deliberate decision not to file a cross-appeal from an adverse judgment." Slip op. at 11.

Applying the law of the Federal Circuit, the Court agreed with Lazare and concluded that the district court erred by allowing Photoscribe to address validity on remand despite its failure to file a cross-appeal from the adverse prior final judgment on validity. In reaching this conclusion, the Court emphasized the Supreme Court's long-standing recognition of the cross-appeal rule as "inveterate and certain" by reiterating that "[a]pplication of the [cross-appeal] rule promotes orderly functioning of the appellate courts by providing 'notice of issues to be litigated and encouraging repose of those that are not.'" Slip op. at 7 (quoting *El Paso Natural Gas Co. v. Neztsosie*, 526 U.S. 473, 481-82 (1999)). "[A] party will not be permitted to argue before us an issue on which it has lost and on which it has not appealed, where the result of acceptance of its argument would be reversal or modification of the judgment rather than affirmance." *Id.* (alteration in original) (quoting *Radio Steel & Mfg. Co. v. MTD Prods., Inc.*, 731 F.2d 840, 844 (Fed. Cir. 1984)). The Court also expressly rejected the district court's view that, because the issues of validity and infringement are closely interrelated, it was not necessary for Photoscribe to appeal the validity issue in order for the district court to hear the issue on remand. "Whether or not the concepts of invalidity and infringement are 'closely interrelated' is irrelevant; the relevant issue is whether a ruling reversing the validity holding would expand Photoscribe's rights or lessen [Lazare's] rights." *Id*. at 9. The Court then found that the holding of invalidity on remand would certainly expand Photoscribe's rights or lessen Lazare's rights beyond the infringement determination.

The Court also rejected all of Photoscribe's arguments that the district court properly granted relief under Rule 60(b)(5) and 60(b)(6). In particular, recognizing that relief under Rule 60(b) has long been limited to "extraordinary circumstances," the Court held that "reversal of a claim construction is hardly an 'extraordinary circumstance.'" *Id.* at 11. The Court explained that the familiar axiom that claims are construed the same way for both invalidity and infringement does not "trump the Federal Rules or the cross-appeal rule, and cannot save Photoscribe from its deliberate decision not to file a cross-appeal from an adverse judgment." *Id.* (citing *El Paso*, 526 U.S. at 480). Finally, while recognizing the district court's reasons for entertaining the validity challenge on remand, the Court explained that, although a new claim construction potentially raises new validity issues, "rules are rules, and the cross-appeal rule is firmly established in our law," thus making it an error by the district court to rely on Rule 60(b) as a substitute for a cross-appeal. *Id.* at 14.

Judge Dyk dissented from the majority, explaining that the majority declined to follow the basic patent law principle that claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses. In Judge Dyk's view, the majority's holding reverses the district court's effort to eliminate the inconsistency—i.e., "allowing the patentee to assert infringement on a broad claim construction while permitting it to defend against invalidity using a different and far narrower claim construction"—through Fed. R. Civ. P. 60(b)(5). Dyk Dissent at 1-2. In support of his view, Judge Dyk noted that the circumstance of the case is not governed by the traditional cross-appeal rule because

Photoscribe did not seek on appeal to modify the rights established by the district court judgment but only to preserve them. Citing the Supreme Court and other appellate precedent, Judge Dyk also noted that, in such a circumstance, there is no requirement that a party, who is satisfied with the judgment below, file a conditional cross-appeal even if his adversary pursues an appeal, and cross-appeal is not required to preserve the right to orderly disposition of issues that become relevant only because of reversal.

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If the Meaning of a Claim Is Discernible, the Claim Is Not Indefinite

Amanda J. Dittmar

Judges: Newman, Schall (concurring), Wallach (author)

[Appealed from S.D.N.Y., Judge Hellerstein]

In *Biosig Instruments, Inc. v. Nautilus, Inc.*, No. 12-1289 (Fed. Cir. Apr. 26, 2013), the Federal Circuit reversed and remanded the district court's judgment that U.S. Patent No. 5,337,753 ("the '753 patent"), assigned to Biosig Instruments, Inc. ("Biosig"), is invalid for indefiniteness.

The '753 patent is directed to a heart rate monitor in exercise equipment that eliminates noise signals caused by muscle movement. In addition to the capability of substantially removing noise signals, claim 1 recites a monitor, a means for measuring time intervals between heart pulses, and a means for calculating the heart rate of a user using the measured time intervals. Claim 1 includes the disputed term "spaced relationship" to describe the relationship between a live electrode and a common electrode on a cylindrical bar.

After the PTO confirmed the patentability of the '753 patent in reexamination proceedings, Biosig sued Nautilus, Inc. ("Nautilus") for infringement of independent claim 1 and dependent claim 11. The district court construed "spaced relationship" to mean "there is a defined relationship between the live electrode and the common electrode on one side of the cylindrical bar and the same or a different defined relationship between the live electrode and the common electrode on the other side of the cylindrical bar." Slip op. at 12 (citation omitted). Nautilus then moved for SJ of infringement and invalidity for indefiniteness. The district court denied the motion with respect to infringement, but held that "spaced relationship" as recited in claim 1 and referring to the spacing between the common and live electrodes was not distinctly and particularly claimed in the '753 patent in violation of 35 U.S.C. § 112, ¶ 2. Biosig appealed.

On appeal, the Federal Circuit concluded that "spaced relationship" is not indefinite because it is amenable to construction. The Court explained that indefiniteness requires a showing that a person of ordinary skill would find "spaced relationship" to be insolubly ambiguous because it fails to provide sufficient clarity delineating the bounds of the claim. In the Court's view, a skilled artisan would find such boundaries in the intrinsic evidence. Specifically, the Court cited the '753 patent's claim language, specification, and the figures illustrating the "spaced relationship" between the live and common electrodes as providing sufficient clarity as to the bounds of this term. For example, the Court found that the distance between the live electrode and the common electrode cannot be greater than the width of a user's hands because claim 1 requires the live and common electrodes to independently detect electrical signals at two distinct points of a hand. The Court also found that the distance cannot be infinitesimally small, effectively merging the live and common electrodes into a single electrode with one detection point. Thus, the Court found that the '753 patent discloses certain inherent parameters of the claimed

apparatus that may be sufficient to allow one of ordinary skill in the art to understand the metes and bounds of "spaced relationship."

"[W]e have not insisted that claims be plain on their face in order to avoid a determination of invalidity for indefiniteness. 'If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds.' In addition, '[p]rovided that the claims are enabled, and no undue experimentation is required, the fact that some experimentation may be necessary to determine the scope of the claims does not render the claims indefinite.'" Slip op. at 18 (second alteration in original) (citations omitted).

The Federal Circuit further found that the functionality of the heart rate monitor as recited in claim 1, described in the specification, and which provided the basis for overcoming the PTO's office action rejections during the reexamination, shed further light on the meaning of "spaced relationship." In particular, the Court relied on a "whereby" clause added during reexamination, which the Court found describes the function of substantially removing noise signals where the noise signals are detected between live and common electrodes in "spaced relationship" with each other. The Court further found that the "whereby" clause was a reason for overcoming the cited prior art and confirming the patentability of the asserted claims during reexamination.

Next, turning to extrinsic evidence, the Court cited a declaration by an inventor submitted to the PTO during reexamination and the declaration of an expert, both describing tests performed to measure noise signals and determine the "spaced relationship." The Court found that such tests were acceptable, stating that "we have not insisted that claims be plain on their face in order to avoid a determination of invalidity for indefiniteness." *Id*. at 18. "[O]bjections relating to the mere fact that there may be some need for experimentation to determine the scope of the claims carry little weight." *Id*.

Nautilus relied on the holding in *Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008), in support of its indefiniteness argument. In *Halliburton*, the patent-at-issue was directed to a "fragile gel" that was used in drilling. In *Halliburton*, the Federal Circuit found no disclosure as to how the claimed "fragile gel" performed differently than the prior art. Halliburton's failure to distinguish the fragileness of the drilling fluids of the invention from the close prior art, according to the Court, was fatal because it did not limit what was invented beyond the prior art. Here, the Federal Circuit distinguished *Halliburton*. The Court explained that, in the present case, the claimed apparatus has inherent parameters because the "spaced relationship" cannot be larger than the width of a user's hand. Additionally, it had been shown that skilled artisans can readily ascertain the bounds of the "spaced relationship" through tests using standard equipment. Thus, the Court concluded that the "upper bound" that was lacking in *Halliburton* is found here and that *Halliburton* fails to support Nautilus's position.

Rather, the Court found this case analogous to *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co*., 655 F.3d 1364, 1373 (Fed. Cir. 2011) ("*Star Scientific II*"). There, the disputed term was "controlled environment" as applied to the practice of tobacco curing and whether a person of ordinary skill would know how to establish a controlled environment to perform the claimed method. In *Star Scientific II*, the Federal Circuit held that the fact that the patents-at-issue did not give exact numbers measuring humidity, temperature, and airflow in a conventional curing barn was not dispositive. On the contrary, the Court found evidence showing that a person of skill in the art of tobacco curing would possess adequate understanding to manipulate these variables to create a controlled environment. Numerical values were found not necessary for one skilled in the art to implement conventional curing, and "controlled environment" was held not insolubly ambiguous.

Nautilus further argued, and the district court held, that Biosig had not articulated with specificity the dimensions or other parameters characterizing the space between the electrodes. The Federal Circuit disagreed, explaining that nothing in the Court's jurisprudence proscribes drafting or defining claims in relation to their functions. The Court found that the district court erred by viewing "spaced relationship" in a vacuum and by failing to consider the functional aspects of claim 1, e.g., how "spaced relationship" contributes to the removal of noise signals and the overall capabilities of the claimed heart rate monitor. In the Court's view, without the context provided by the intrinsic record, it would be impossible to ascertain what the inventors actually invented and intended to cover with the claim.

Finally, Nautilus argued that claims 1 and 11 are invalid as they impermissibly claim both an apparatus and a method of use. Specifically, Nautilus contended that claim 1 recites a heart rate monitor and a required step that a user holds the monitor. According to Nautilus, it is unclear whether the alleged infringement occurs when one makes a heart rate monitor having the recited structural elements, or whether infringement allegedly occurs when the user actually holds the handle and contacts the electrodes. The Federal Circuit found this contention unpersuasive because, in its view, the '753 patent recites apparatus claims with functional limitations that describe the capability of substantially removing noise signals.

In sum, because variables, including the spacing, size, shape, and material affecting the "spaced relationship" between the electrodes, can be determined by those skilled in the art, the Federal Circuit concluded that "spaced relationship" cannot be insolubly ambiguous. The Court reversed and remanded the district court's indefiniteness holding.

In a concurring opinion, Judge Schall agreed with the Court's reversal of the judgment on appeal and its remand for further proceedings. While he agreed with the Court that the district court erred in holding claims 1 and 11 of the '753 patent invalid by reason of indefiniteness, Judge Schall would have based that ruling on a more limited analysis. Judge Schall simply concluded that neither test for indefiniteness was satisfied—when it is not amenable to construction, or when, even if it can be construed, the construction remains insolubly ambiguous, meaning it fails to provide sufficient clarity delineating the metes and bounds of the claim to one of skill in the art. Judge Schall found the claim term amenable to construction because the district court construed it. Moreover, he found that the district court's construction requires a fixed spatial relationship between the live electrode and the common electrode. Judge Schall found this evidence, coupled with the disclosure in the intrinsic evidence relied on by the Court, may be sufficient for a skilled artisan to understand the metes and bounds of "spaced relationship."

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Looking Ahead

On May 1, 2013, in *Allergan, Inc. v. Sandoz Inc.*, Nos. 11-1619, -1620, -1635, -1639 (Fed. Cir. May 1, 2013), the Federal Circuit affirmed-in-part and reversed-in-part the district court's finding that Allergan, Inc.'s patent claims for its Combigan® product were not obvious. The Court first held that the district court erred in finding the claims of U.S. Patent No. 7,323,463 not obvious, reasoning that there was a motivation to combine and a reasonable expectation of success that was not overcome by secondary considerations of nonobviousness. The Court held, however, that the district court did not err in finding claim 4 of U.S. Patent No. 7,030,149 obvious, reasoning that the defendants failed to prove obviousness by clear and convincing evidence.

See next month's *Last Month at the Federal Circuit* for a full summary.

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Spotlight Info

In *Lazare Kaplan International, Inc. v. Photoscribe Technologies, Inc.*, No. 12-1247 (Fed. Cir. Apr. 19, 2013), the Federal Circuit reversed the district court's grant of relief under Fed. R. Civ. P. 60(b), vacated the finding of invalidity, and remanded with instructions to reinstate its original judgment of validity and assess infringement. Initially, the district court determined that the asserted claims were not invalid and not infringed. In that first appeal, the Federal Circuit modified the construction of certain claim terms, vacated the finding of infringement, and remanded the infringement issues to the district court for determination based on the modified claim construction. On remand, the district court found U.S. Patent No. 6,476,351 invalid, deciding to retry validity as well as infringement because the validity judgment in the first trial was based on a claim construction that the Federal Circuit had reversed. In the instant appeal, the Federal Circuit reversed the district court's determination of invalidity, among other things, because Photoscribe Technologies, Inc. had failed to file a cross-appeal during the first appeal. In reaching this conclusion, the Court emphasized the Supreme Court's long-standing recognition of the cross-appeal rule as "inveterate and certain" by reiterating that "[a]pplication of the [cross-appeal] rule promotes orderly functioning of the appellate courts by providing 'notice of issues to be litigated and encouraging repose of those that are not.'" Slip op. at 7 (quoting *El Paso Natural Gas Co. v. Neztsosie*, 526 U.S. 473, 481-82 (1999)). See this month's edition of *Last Month at the Federal Circuit* for a full summary of this decision.

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