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December 2010

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AstraZeneca LP v. Apotex, Inc.
Nos. 09-1381, -1424 (Fed. Cir. Nov. 1, 2010)
[Appealed from D.N.J., Judge Bumb]

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[Appealed from E.D. Mich., Judge Steech]

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[Appealed from D. Del., Judge Sleet]

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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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December 2010

Federal Circuit Affirms Preliminary Injunction Barring Defendant from Launching FDA-Approved Generic Drug

Danielle A. Duszczyszyn

Judges: Rader, Bryson (concurring-in-part, dissenting-in-part), Linn (author)
[Appealed from D.N.J., Judge Bumb]

In *AstraZeneca LP v. Apotex, Inc.*, Nos. 09-1381, -1424 (Fed. Cir. Nov. 1, 2010), the Federal Circuit upheld the district court's finding of no anticipation of AstraZeneca LP and AstraZeneca AB's (collectively "AstraZeneca") method claims and affirmed the district court's grant of a preliminary injunction against Apotex, Inc. and Apotex Corp. (collectively "Apotex"). The Court also affirmed the district court's invalidity finding of AstraZeneca's "kit" claims.

AstraZeneca markets its FDA-approved budesonide inhalation suspension under the name PULMICORT RESPULES®. The Orange Book entry for this budesonide product includes U.S. Patent Nos. 6,598,603 ("the '603 patent") and 6,899,099 ("the '099 patent"). Both patents have nearly identical specifications. Both patents include method claims directed to administering a budesonide composition once daily and product claims directed to a kit containing either a budesonide composition or suspension and a label indicating once-daily administration by nebulization. The label repeatedly warns patients to "titrate down" to the lowest effective dose of the medication. The FDA requires all manufacturers of inhaled corticosteroids, such as budesonide, to include this downward titration language in their labels.

Apotex submitted an ANDA seeking FDA approval to manufacture and sell a generic version of budesonide for twice-daily use, which is not claimed by either patent-in-suit. Other than minor differences, Apotex proposed an ANDA label for its generic drug identical to AstraZeneca's label. Apotex also submitted a section viii statement asserting that it was not seeking approval for the once-daily method claimed by the patents-in-suit.

The day after the FDA approved Apotex's ANDA, AstraZeneca initiated a DJ action and moved for a preliminary injunction barring Apotex from distributing its generic budesonide drug. AstraZeneca argued that Apotex would induce infringement of the specified method claims in the '603 patent. Additionally, AstraZeneca argued that Apotex would infringe certain kit claims in both patents. The district court issued a preliminary injunction finding that Apotex had the requisite specific intent to induce infringement and that AstraZeneca would suffer irreparable harm without the injunction. But the district court found it likely that Apotex would succeed in proving invalidity of the kit claims.

On appeal, the Federal Circuit concluded that the asserted method claims would likely withstand a validity challenge posed by U.S. Patent No. 5,192,528 ("the '528 patent"). The '528 patent discloses a method for treating lung conditions by administering a suspension of budesonide "entrapped" within a liposome. Slip op. at 13. Apotex argued that the '528 patent anticipated the asserted method claims. Considering intrinsic evidence from the specification and uncontested expert testimony in the record, the Court evaluated whether the term "budesonide composition" excluded the liposome embodiment in the '528 patent. The Court stated that "[w]hen a patentee uses a claim term throughout the entire patent specification in a manner consistent with only a single meaning, he has defined that term by implication." *Id.* at 16 (quoting *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1271 (Fed. Cir. 2001)) (internal quotations omitted). The Court noted the consistent use of the term "budesonide composition" throughout the specification to mean "budesonide dispersed in a solvent in the form of a solution or suspension." *Id.* Apotex argued that the district court's construction improperly excluded the specification's reference to liposome formulations in two places. The Court disagreed, explaining that "[n]either of the liposome formulations discussed in the specification use liposomes in the manner described in the '528 patent." *Id.* at 17. Moreover, the Court found it proper to rely on uncontested expert testimony to understand how the claimed invention works and to construe the disputed term in a manner consistent with that understanding, which excluded the liposome-entrapped embodiments disclosed in the '528 patent. Considered together, the Court found the intrinsic evidence and expert testimony supported the conclusion that a person skilled in the art would have understood the term "budesonide composition" to exclude the embodiment disclosed in the '528 patent. Thus, the Court held that the district court correctly found that the asserted claims would likely withstand the validity challenge posed by the '528 patent.

"Apotex and the amici make much of the Hobson's choice they contend that Apotex faced: either comply with FDA requirements and risk a patent infringement suit or remove the downward-titration language and ensure that the ANDA would not be approved. This court sees no such dilemma." Slip op. at 35.

Similarly, the Court found that the asserted method claims would likely withstand a validity challenge presented by an advertisement for AstraZeneca's budesonide drug in the British medical journal, *Thorax* ("the *Thorax* advertisement"). The *Thorax* advertisement was published before the filing of the application that issued as the '603 patent. The advertisement included a statement for twice-daily dosing where "the maintenance dose should be the lowest dose which keeps the patient symptom-free." *Id.* at 21. The Court noted that "although a reference must be enabling to be anticipatory, unlike enablement under § 112, a reference need not . . . demonstrate utility or efficacy to be enabling in the context of § 102." *Id.* at 23. The Court explained that Apotex ignored a key difference between the advertisement and the proposed label when contending the advertisement was anticipatory: the advertisement, unlike the proposed label, explicitly stated how often a maintenance dose should be given (twice daily). Additionally, the Court considered uncontested expert testimony stating that one skilled in the art would have understood the advertisement to teach about once-daily dosing but rather instructed twice-daily dosing. The Court held that the district court did not clearly err in concluding that Apotex would not be able to demonstrate by clear and convincing evidence that the *Thorax* advertisement anticipated the asserted method claims.

The Court also affirmed the district court's finding that AstraZeneca would likely prove induced infringement at trial. In reaching its decision, the Court considered Apotex's proposed label, its

compliance with the FDA's labeling requirements, and its decision to move forward with its product launch despite knowing its label presented infringement problems. The Court dismissed Apotex's argument that some users may ignore the warning in the proposed label, maintaining that the language would lead some consumers to practice the claimed method. The Court noted that active steps taken to encourage direct infringement (e.g., instructing how to engage in an infringing use) show affirmative intent for infringing use of the product. The Court then classified Apotex's compliance with FDA label requirements as immaterial, stating, "the FDA is not the arbiter of patent infringement issues." *Id.* at 35. Further, the Court emphasized that if Apotex could not create a noninfringing label, Apotex had other avenues to pursue. The Court's suggested alternatives to Apotex included waiting for the patents to expire before distributing its generic drug, filing a Paragraph IV certification challenging infringement and the validity of the asserted claims, formally appealing the FDA's labeling requirements, or filing either a suitability petition or a paper NDA seeking approval for a noninfringing strength of the drug.

The Court found no reason to disturb the district court's determination that AstraZeneca would suffer irreparable harm. Specifically, the Court assessed the potential economic harm relating to a confidential settlement agreement between AstraZeneca and Teva. Under the agreement, AstraZeneca would have market exclusivity until a certain time, after which AstraZeneca and Teva would share the market. Lacking reliable data regarding a market with only AstraZeneca and Teva's products, the Court found no error in classifying the economic damages as incalculable if Apotex began selling its generic drug. AstraZeneca's president also testified that the launch of Apotex's generic drug would result in manufacturing layoffs and U.S. workforce reduction. The Court found this undisputed testimony sufficient to support a finding of significant and unquantifiable noneconomic loss. While the Court did not find a strong showing for damages to AstraZeneca's reputation and goodwill, it could not identify any clear error with this finding.

The Court held that the district court correctly determined that the recitation in the claims of a label instructing not more than once-daily dosing is of no patentable consequence. Under § 101, the Court has generally found printed matter to fall outside its scope. But, the Court noted, an exception applies when a functional relationship exists between the printed matter and its substrate that serves to distinguish the invention from the prior art. In *In re Ngai*, 367 F.3d 1336 (Fed. Cir. 2004), the Court affirmed the rejection of a claim reciting a kit comprising instructions to amplify ribonucleic acids. The Court reasoned that the printed matter and the kit did not depend on each other since the printed matter simply taught a new use for an existing product. Seeking guidance from *Ngai*, the Court found that the claimed instructions did not function with the drug to create a new, unobvious product such that they are entitled to patentable weight. Thus, the Court affirmed the district court's invalidity determination for the kit claims.

In a separate opinion, Judge Bryson concurred with the majority's opinion on the invalidity of the kit claims. Judge Bryson, however, would have reversed the district court's grant of a preliminary injunction. Specifically, he believed that the district court's unduly narrow claim construction of the term "budesonide composition" led it to incorrectly conclude that the '528 patent did not anticipate the '603 patent claims. Additionally, Judge Bryson stated that the district court's rationale for distinguishing between the Apotex label and the *Thorax* advertisement was flawed. He suggested that even though the scientific community had yet to confirm the effectiveness of once-daily dosing at the time the advertisement circulated, the language could still suggest decreasing the frequency of the administration to achieve a reduced dose.

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Federal Circuit Declines to Rehear Double Patenting Case in a Split Decision

Jessica L.A. Marks

Judges: Rader, Newman, Lourie, Bryson, Gajarsa, Linn, Dyk, Prost, and Moore
[Appealed from E.D. Mich., Judge Steech]

In *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.*, No. 10-1105, (Fed. Cir. Nov. 1, 2010), the Federal Circuit denied Eli Lilly and Company's ("Lilly") petition for a rehearing *en banc*, in a 5-4 vote of a panel decision (*Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.*, No. 10-1105 (Fed. Cir. July 28, 2010)) holding claims defining a method of treating cancer with the compound gemcitabine invalid for obviousness-type double patenting.

The patent forming the basis for the double patenting ruling claimed gemcitabine and its antiviral use. It also disclosed, but did not claim, the use of gemcitabine to treat cancer. That disclosure was added in a continuation-in-part application filed on the same day that Lilly filed the application leading to the patent held invalid in the panel decision. The original application leading to the earlier patent was prior art under § 102(e) to the later patent.

Judges Newman, Linn, and Lourie, and Chief Judge Rader, dissented from the denial to review the panel decision *en banc*. The minority questioned the panel's ruling because it relied on what the earlier patent disclosed, rather than what it claimed. The dissenting judges noted that until recently, the law of double patenting was clear but had become distorted by divergent statements leading to the panel's flawed ruling. In the minority's opinion, the law of double patenting was previously concerned only with what is claimed. The specifications are irrelevant to this analysis, other than to guide in construing the claims, because obviousness-type double patenting occurs when the claims of a later patent are an obvious variant of the claims of an earlier patent. The minority further cautioned that the double patenting analysis occurs only when the earlier patent is not prior art against the later patent.

"Obviousness-type double patenting is a judicially created doctrine intended to prevent improper timewise extension of the patent right by prohibiting the issuance of claims in a second patent which are not 'patentably distinct' from the claims of a first patent." Slip op. at 5 (citing *In re Braat*, 937 F.2d 589, 592 (Fed. Cir. 1991)).

In this case, the minority believed that the law of double patenting was contrary to the panel's holding. The dissenting judges pointed to the Court's holding *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1277 (Fed. Cir. 1992), as establishing the rule that double-patenting is altogether a matter of what is claimed. The minority noted that this holding has been followed many times by the Court, as well as being fully established by the Court's predecessor court. In the minority's view, "[u]niformly, unlike the examination for obviousness based on prior art, the issue of obviousness-type double patenting is directed to whether the invention claimed in a later patent is an obvious variant of the invention claimed in an earlier patent." Slip op. at 4. In sum, the dissenting judges characterized the panel opinion as violating "a vast body of precedent." *Id.*

Further, the minority suggested that the panel's decision was misdirected by an overly broad statement in *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC,* 349 F.3d 1373 (Fed. Cir. 2003). In *Geneva*, the Court stated that "[o]ur predecessor court recognized that a claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use." Slip op. at 4 (citing *Geneva*, 349 F.3d at 1385-86 (citing *In re Byck*, 48 F.2d 665, 666 (CCPA 1931) ("[i]t would shock one's sense of justice if an inventor could receive a patent upon a composition matter, setting out at length in the specification the useful purposes of such composition, manufacture and sell it to the public, and then prevent the public from making any beneficial use of such product by securing patents upon each of the users to which it may be adapted."). The minority emphasized that the *Geneva* decision failed to mention the further statement in *Byck* that the case did not involve a situation where the patentee might have disclosed a use of the invention which, together with other elements, might have constituted a separate invention for which he would be entitled to a patent, in view of a prior art reference. Further, according to the minority, this statement from *Geneva* "took on a life of its own" as in *Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008), "where the court declined to apply section 121 (negating double patenting among divisional) and found double patenting despite a restriction requirement, citing *Geneva* for authority." Slip op. at 5.

Thus, the minority does not believe that *Geneva* should be extended to Lilly's situation, because *Geneva* "does not further the policy of obviousness-type double patenting." *Id.* In the dissenting judges' view, "[o]bviousness-type double patenting is a judicially created doctrine intended to prevent *improper* timewise extension of the patent right by prohibiting the issuance of claims in a second patent which are not patentably distinct from the claims of a first patent." *Id.* Here, the minority believes that the panel failed to explain how Lilly's claims to a new use for a compound, discovered after a first use was disclosed in the original application, improperly extends the patent right to the compound overall. Further, the minority noted that there was no dispute that Lilly would be entitled to a separate patent on the new use of the compound if Lilly had not included the disclosure of the new use in the specification of the continuation-in-part filed the same day. The dissenting judges challenged that such a disclosure would "improperly extend" any patent.

According to the minority, if the majority of the court now believes that the law should be changed in accordance with the panel's ruling, *en banc* treatment would be particularly appropriate. In the dissenting judges' opinion, "[t]he denial of Lilly's petition for rehearing *en banc* leaves the innovation community without guidance on which the trial courts, and the uses of the patent system, can rely." *Id.* at 7.

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Period Between Entry of Judgment and Entry of Permanent Injunction Should Be Considered When Calculating Damages

Rajiv K. Bhateja

Judges: Newman, Gajarsa, Linn (Author)
[Appealed from D. Del., Judge Sleet]

In *Finjan, Inc. v. Secure Computing Corporation*, Nos. 09-1576, -1594 (Fed. Cir. Nov. 4, 2010), the Federal Circuit affirmed the district court's finding of infringement of asserted "system" and "storage medium" claims and reversed the finding of infringement of asserted method claims. The Court also affirmed the damages award but remanded for determination of postjudgment, preinjunction damages.

Finjan, Inc. ("Finjan") owns U.S. Patent Nos. 6,092,194 ("the '194 patent"), 6,804,780 ("the '780 patent"), and 7,058,822 ("the '822 patent"). The patents relate generally to proactive scanning or techniques directed to detecting and defeating previously unknown Internet-based threats to computers, such as viruses, spyware, and adware. The asserted claims of each patent include both method and nonmethod claims. The asserted claims of the '194 patent include method claims, corresponding "system" claims, and "computer-readable storage medium claims" for performing the claimed methods. The '780 patent includes claims similar to the '194 patent, but covers "caching," or identifying previously encountered downloadable files. The '822 patent addresses "sandboxing" a potentially dangerous downloadable with protective code. It encompasses both "processor-based methods" and "processor-based systems."

Finjan sued Secure Computing Corporation, Cyberguard Corporation, and Webwasher AG (collectively "Secure Computing"). Secure Computing counterclaimed against Finjan for infringement of U.S. Patent Nos. 6,357,010 ("the '010 patent") and 7,185,361 ("the '361 patent"). A jury found all of the patents valid, that Finjan did not infringe Secure Computing's patents, and that Secure Computing willfully infringed all asserted claims of Finjan's patents. The district court awarded damages to Finjan, enhanced the award under 35 U.S.C. § 284, and entered a permanent injunction against Secure Computing. Secure Computing appealed the district court's findings of infringement and damages. Finjan cross-appealed the denial of damages for the period between the entry of judgment and the entry of the injunction.

On appeal, the Federal Circuit first considered the district court's finding of infringement of the "system" and "storage medium" claims. Secure Computing argued that it sold no infringing products, because all software modules that feature proactive scanning were "locked" unless the customer purchased the appropriate software key. The Federal Circuit dismissed this argument, reminding that, to infringe a claim

that recites capability and not actual operation, an accused device "need only be capable of operating" in the described mode. Slip op. at 10-11 (citing *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821, 832 (Fed. Cir. 1991)). The Court found the accused products capable of operating in the described mode of Finjan's patents.

"Although courts have broad discretion in determining appropriate relief for patent infringement…injunctions and damages must be tailored to the circumstances and be correlatively determined. Accordingly, we have noted that a patentee is not fully compensated if the damages award did not include future lost sales. Therefore, the district court should have awarded compensation for any infringement prior to the injunction." Slip op. at 26-27.

The Federal Circuit turned next to the method claims in the three patents. Using the standard established in *Lucent Technologies v. Gateway, Inc.*, 580 F.3d 1307 (Fed. Cir. 2009), the Court stated that "to infringe a method claim, a person must have practiced *all* steps of the claimed method." *Id.* at 13 (emphasis added). The Court found the record inadequate to show that all steps of the claimed methods of Finjan's patents were practiced. The Court concluded that Finjan at most demonstrated that Secure Computing's product performed proactive scanning on one occasion in Germany during testing based on a single debug file. In the Court's view, this was insufficient to show direct infringement in the United States as the Patent Act requires.

The Federal Circuit then considered Secure Computing's request for a new trial. Secure Computing argued that the district court erred by failing to construe the term "addressed to a client" from each asserted claim of the '194 patent. The Federal Circuit rebutted this argument by distinguishing the present case from *O2 Micro International Ltd. v. Beyond Innovation Technology Co.*, 521 F.3d 1351 (Fed. Cir. 2007). In *O2 Micro*, the Court held that the district court erred by giving the term "only if" its plain and ordinary meaning, because that definition "failed to resolve the parties' dispute." Slip op. at 15 (citing *O2 Micro Int'l*, 521 F.3d at 1361). Distinguishing the present case from *O2 Micro*, the Federal Circuit noted that the district court rejected Secure Computing's construction of the claim term in the present case, rather than failing to resolve the parties' quarrel all together, as in *O2 Micro.*

The Court subsequently considered the damages issues. Secure Computing raised two challenges to the royalty base, or total sales, that the jury used to compute damages. First, Secure Computing claimed the jury misapplied the entire market rule by using the full value of the accused products. *See Lucent*, 580 F.3d at 1336 ("For the entire market rule to apply, the patentee must prove that the patent-related feature is the basis for customer demand."). The Federal Circuit found that Secure Computing waived this argument when they did not raise it in its JMOL motion following trial. Second, Secure Computing contended the jury erroneously included sales to the United States Government. The Court found that the district court had in fact instructed the jury at trial that sales to the United States Government should not be included in any damages calculation performed. Secure Computing next argued that the jury's royalty percentages lacked support under the *Georgia-Pacific* factors. The Court found that the royalty percentages were made with substantial evidence and based on expert opinion not appropriate for second-guessing.

Finally, the Court addressed Finjan's cross-appeal of the damages award. At trial, the district court granted Finjan additional damages by multiplying the jury's royalty rates against previously uncalculated sales. However, Finjan argued that the jury did not consider damages for the period between the entry of

judgment and the imposition of the injunction seventeen months later. The Court agreed, stating that "[a]lthough courts have broad discretion in determining appropriate relief for patent infringement . . . injunctions and damages must be tailored to the circumstances and be correlatively determined." Slip op. at 26 (quoting *Carborundum Co. v. Molten Metal Equip. Innovations, Inc.*, 72 F.3d 872, 881 (Fed. Cir. 1995)). Noting that a patentee is not fully compensated if the damages award did not include future lost sales, the Court found that the district court should have awarded compensation for any infringement prior to the injunction. The case was remanded to the district court to determine appropriate damages for the seventeen-month period from the entry of judgment to the entry of the permanent injunction.

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En Banc Court Refuses to Limit New Evidence in § 145 Actions Apart from the Federal Rules of Evidence and Civil Procedure

Adam J. Sibley

Judges: Rader, Newman (concurring-in-part, dissenting-in-part), Lourie, Bryson, Gajarsa (dissenting), Linn, Dyk (dissenting), Prost, and Moore (author)

[Appealed from D.D.C., Judge Kennedy]

In *Hyatt v. Kappos*, No. 07-1066 (Fed. Cir. Nov. 8, 2010) (en banc), the Federal Circuit vacated the district court's grant of SJ relating to claim unpatentability. The Court remanded for further proceedings that allow the patent applicant, Gilbert P. Hyatt ("Hyatt"), to present new evidence in a 35 U.S.C. § 145 action that he could have submitted during the earlier administrative proceedings. In doing so, the en banc Court reversed the stance of its panel and held that § 145 "imposes no limitation on an applicant's right to introduce new evidence before the district court, apart from the evidentiary limitations applicable to all civil actions contained in the Federal Rules of Evidence and Federal Rules of Civil Procedure." Slip op. at 5.

Hyatt is the sole named inventor of U.S. Patent Application No. 08/471,702, which relates to a computerized display system for processing image information. The patent examiner issued a final office action rejecting all claims on various grounds, including failure to comply with the written description requirement. Hyatt appealed to the Board, which affirmed numerous of the examiner's rejections. The Board later dismissed Hyatt's Request for Rehearing. In the proceedings before both the examiner and the Board, Hyatt presented evidence in an effort to satisfy the written description requirement.

Hyatt then filed a civil action in the United States District Court for the District of Columbia against the Director of the Patent Office ("Director") pursuant to 35 U.S.C. § 145. The Director moved for SJ that the pending claims were invalid for failure to comply with the written description requirement. Hyatt opposed the motion and submitted a new written declaration in which he identified portions of the specification that one of skill in the art would understand to describe the limitations challenged by the Director. The district court determined that it could not consider Hyatt's new declaration and granted SJ in favor of the Director. Hyatt appealed.

The Federal Circuit agreed to hear the appeal en banc to determine, among other things: (1) whether there are any limitations on the admissibility of evidence in § 145 proceedings; and (2) what standard of review is applicable in § 145 cases.

The Court first considered the text of § 145, which provides a dissatisfied patent applicant "remedy by civil action" unless appeal has been taken to the Federal Circuit. 35 U.S.C. § 145. According to the Court, this statute provides no indication that a § 145 civil action is somehow different from a customary civil action, nor does it provide any unique rules of evidence. The Court also noted that § 145 makes clear that the civil action is distinct from an appeal, in which the applicant would be limited to the record before the PTO. Rather, the Court reasoned, the statute directs that the district court may "adjudge that such applicant is entitled to receive a patent for his invention . . . as the facts in the case appear." *Id.*

"We hold that 35 U.S.C. § 145 imposes no limitation on an applicant's right to introduce new evidence before the district court, apart from the evidentiary limitations applicable to all civil actions contained in the Federal Rules of Evidence and Federal Rules of Civil Procedure." Slip op. at 5.

Next, the Federal Circuit turned to the lengthy legislative history of the statute. In particular, the Court considered § 4915 of the Revised Statutes, a predecessor to 35 U.S.C. § 145. The Court stated that proponents and opponents of § 4915 alike recognized, and conveyed to Congress, that the remedy by bill in equity allowed an applicant to introduce new evidence in the district court, regardless of whether that evidence had been provided to the PTO in earlier proceedings. Based on the legislative history, the Court reasoned that Congress intended that applicants would be free to introduce new evidence in § 145 proceedings subject only to the rules applicable in all civil actions, the Federal Rules of Evidence, and the Federal Rules of Civil Procedure. Specifically, the Court rejected the argument that Congress intended that only evidence that could not have reasonably been presented to the PTO in the first instance should be admissible in § 145 proceedings.

The Federal Circuit further noted that no Supreme Court case had ever placed any limitations on the admissibility of evidence in a § 145 proceeding apart from the ordinary rules applicable to all civil actions. The Court found no support in Supreme Court precedent for allowing new evidence only if the evidence could not reasonably have been provided to the PTO.

Although the Court held that new evidence is generally admissible in a § 145 case, it also recognized that the proceedings before the PTO remain relevant in a § 145 action. First, the Federal Circuit explained that in adjudicating entitlement to a patent, the district court must consider the record before the PTO, as well as any new evidence admitted by the applicant. Second, although the Court noted that Hyatt did raise the written description issue before the PTO, it stated that "issues (and evidence relating to new issues) that were not raised in the Patent Office proceedings generally may not be raised in a § 145 proceeding." Slip op. at 29. Thus, the Court recast its holding and concluded that "consonant with the language of the statute, legislative history, and Supreme Court precedent, the only limitations on the admissibility of evidence in § 145 proceedings (for issues raised before the Patent Office) are the Federal Rules of Evidence and Civil Procedure." *Id.* at 30.

Even though district courts may be required to admit new evidence in § 145 cases, the Federal Circuit explained that district courts may consider the proceedings before, and findings of, the PTO in deciding what weight to afford an applicant's newly admitted evidence. The Court noted that, should the facts of a particular case cast suspicion on new evidence that an applicant failed to introduce before the PTO, the district court in a § 145 action would be within its discretion to give that evidence less weight.

Next, the Federal Circuit addressed the applicable standard of review in § 145 proceedings. The Court

explained that, if the parties to a § 145 action do not introduce any new evidence before the district court, the court reviews the case on the same record presented to the agency and the reviewing court must apply the APA's substantial evidence standard to PTO findings of fact. But when new evidence is introduced, the Federal Circuit instructed that the district court is to act as a fact finder with respect to that new evidence and make de novo factual findings if the evidence conflicts with any related PTO finding. The Court recognized, however, that the district court must still consider the administrative record in making its de novo factual findings.

In a separate opinion concurring-in-part and dissenting-in-part, Judge Newman agreed that new evidence may be provided in a civil action brought under 35 U.S.C. § 145. Judge Newman, however, stated that issues in a § 145 proceeding should receive a de novo determination, whether or not new evidence is adduced in the district court. It is contrary to statute, Judge Newman noted, when the same deferential review is applied to both civil actions under § 145 and APA direct appeals to the Federal Circuit. "The statutory plan is designed to differ from such a duplicative procedure, not to create it." Newman op. at 2. Judge Newman further explained that "[t]he purpose of the section 145 proceeding is to achieve fresh judicial determination of patentability issues that had been decided by the Patent Office, and to conduct this determination de novo on the evidence before the court, whether or not the same evidence or all of it was before the examiner." *Id.* at 2-3.

In a separate dissenting opinion, which Judge Gajarsa joined, Judge Dyk stated that district court proceedings in § 145 actions should follow the established administrative law standard embodied in § 706 of the APA. Judge Dyk explained that the APA requires judicial review on the agency record and submission of all relevant evidence to the agency. While Judge Dyk agreed that § 145 contemplates the introduction of new evidence, he noted that this should only be allowed when agency procedures are inadequate. With regard to the PTO, Judge Dyk found that the agency procedures are inadequate only insofar as they do not provide for live testimony when it is deemed necessary. Judge Dyk noted that allowing a trial de novo in the district court denigrates the important expertise of the PTO. In addition, Judge Dyk wrote that the majority opinion invites applicants to deliberately withhold evidence from the PTO in favor of a more hospitable district court forum. Judge Dyk also warned that the majority's decision "reflects yet another misguided effort to craft special rules for patent cases that the Supreme Court in other cases has held to be impermissible." Dyk op. at 3.

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Federal Circuit Law Governs Patent Assignment Interpretation and Nunc Pro Tunc Assignments Cannot Retroactively Confer Standing

Mindy L. Ehrenfried

Judges: Newman (dissenting), Gajarsa (author), and Linn
[Appealed from D.N.J., Judge Pisano]

In *Abraxis Bioscience, Inc. v. Navinta LLC*, No. 09-1539 (Fed. Cir. Nov. 9, 2010), the Federal Circuit reversed the district court's denial of Navinta LLC's ("Navinta") motion to dismiss for lack of standing, vacated the judgment, and remanded for the district court to dismiss the complaint with prejudice.

Abraxis Bioscience, Inc. ("Abraxis") markets the anesthetic Naropin®. U.S. Patent No. 4,870,086 ("the '086 patent") discloses Naropin's active ingredient, ropivacaine hydrochloride monohydrate ("ropivacaine"). U.S. Patent Nos. 5,670,524 ("the '524 patent") and 5,834,489 ("the '489 patent") disclose methods of pain treatment using low-concentration ropivacaine.

Abraxis acquired the patents from AstraZeneca ("AZ-UK"). In 2006, Abraxis and AZ-UK executed an Asset Purchase Agreement ("APA"). The APA provided that AZ-UK "shall or shall cause one or more of its Affiliates" to transfer to Abraxis all of AZ-UK's right, title, and interests in the asserted patents. Two months later, pursuant to the APA, Abraxis and AZ-UK executed an IP Assignment Agreement ("the First Agreement"), purportedly transferring title in the asserted patents. The First Agreement contained a "Further Assurances" provision, which ensured AZ-UK would execute all further assignments necessary to vest the transferred IP title in Abraxis. After discovering AZ-UK affiliates never formally assigned the asserted patents to AZ-UK, Abraxis invoked the Further Assurances provision. In March 2007, AZ-UK secured written assignments transferring title from its affiliates to AZ-UK. Later in November 2007, Abraxis and AZ-UK executed a second IP Assignment Agreement ("the Second Agreement"), confirming the asserted patents' sale, assignment, conveyance, and transfer to Abraxis.

On the same day AZ-UK secured the written assignments in March 2007, Abraxis filed suit against Navinta under the Hatch-Waxman Act. Navinta previously filed both an ANDA for a generic Naropin and a Paragraph IV Certification, certifying its generic would not infringe the '086 patent. Accordingly, under 35 U.S.C. § 271(e)(2), Abraxis alleged artificial infringement of the '086 patent—the only patent listed in the Orange Book. Unable to allege § 271(e)(2) infringement of the '524 and '489 patents, Abraxis argued indirect infringement under 35 U.S.C. § 271(b)–(c). Electing to await the expiration of the'086 patent, Navinta filed a "Section viii Statement" and proposed a label carving out uses covered by the '524 and

’489 patents to avoid infringement allegations. Navinta therefore filed a motion to dismiss for lack of subject matter jurisdiction, arguing that Abraxis’s counts alleged speculative future infringement. Abraxis countered by listing the ’524 and ’489 patents in the Orange Book and amending its complaint to allege infringement under § 271(e)(2). Navinta changed tactics, declared Abraxis did not own the asserted patents when Abraxis filed its complaint, and filed a second Rule 12(b)(1) motion to dismiss for lack of standing. Denying Navinta’s motion, the district court acknowledged the March 2007 assignment’s *nunc pro tunc* provisions bestowing retroactive effect to the First Agreement in 2006. Following a bench trial, the district court found direct and indirect infringement of the ’086 patent and indirect infringement of the ’524 and ’489 patents.

On appeal, the Court first restated a bedrock principle—standing is a constitutional requirement pursuant to Article III and a threshold jurisdictional issue reviewed *de novo*. The Court then reiterated that Federal Circuit law—not state law—governs whether a patent assignment clause creates a present assignment of patent rights or an agreement to assign rights in the future (citing *DDB Techs., LLC v. MLB Advanced Media, LP*, 517 F.3d 1284, 1290 (Fed. Cir. 2008)). The Court distinguished contract language expressly conveying rights in future inventions from contract language obligating a future promise to convey. The former needs no further act once an invention comes into being; indeed, the transfer of title occurs by operation of law. By contrast, the latter vests no legal title in the assignee; the contract merely obligates the owner to grant rights at some point in the future. Thus, the Court explained, “agrees to assign” reflects a mere promise to assign rights in the future, not an immediate transfer of expectant interests (citing *Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 583 F.3d 832, 841–42 (Fed. Cir. 2009) (*cert. granted* Nov. 1, 2010)).

“Even if the . . . agreement is considered to be a nunc pro tunc assignment, for purposes of standing, Abraxis was required to have legal title to the patents on the day it filed the complaint and that requirement can not be met retroactively.” Slip op. at 15.

Relying on the APA contractual language, the Court concluded that the parties intended to achieve actual transfer of title by a separate agreement. In other words, the APA established a promise to assign in the future and the consummation of the assignment could only occur by a subsequent written agreement. While Abraxis and AZ-UK executed the First Agreement after the APA, AZ-UK did not yet possess title to the patents. Therefore, when the parties executed the First Agreement, AZ-UK lacked authority to assign the patents to Abraxis.

The Court further explained, although the March 2007 assignments vested title in AZ-UK, the assignments did not automatically consummate an assignment to Abraxis. For title to vest in Abraxis, the Court reasoned, AZ-UK had to execute a further assignment to Abraxis, which it did in the Second Agreement. The Second Agreement, however, postdated Abraxis’s complaint. Thus, the Court held Abraxis did not own the patents when it filed its complaint and lacked standing to file the lawsuit.

In so holding, the Court rejected the district court’s finding of retroactive title. Regardless of the retroactive validity of either the March 2007 assignments to AZ-UK or the Second Agreement, the Court found Abraxis lacked standing. AZ-UK did not assign the patents to Abraxis until the Second Agreement, which occurred *after* Abraxis filed its complaint. *Nunc pro tunc* assignments, the Court clarified, cannot retroactively confer standing (citing *Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998)). One narrow exception to the Court’s holding—a party may sue for past infringement before it

acquires legal title if the written assignment so authorizes—does not apply to Abraxis's case.

The Court also found irrelevant Abraxis's reliance on *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574 (Fed. Cir. 1991). Abraxis contended that the APA was sufficient to transfer equitable title, which thereby conferred standing. But the Court distinguished *Arachnid* as concerning a present agreement to assign future inventions. By contrast, Abraxis's APA and First Agreement with AZ-UK attempted to assign rights to existing patents, but failed. Thus, not yet owning the asserted patents, Abraxis lacked standing on the day it filed its complaint, a defect Abraxis cannot retroactively fix.

In a dissenting opinion, Judge Newman disagreed with the majority's preemption of state law and imposition of Federal Circuit law, "a new and convoluted law unique to the patent aspect of commercial transactions." Newman Dissent at 2. Judge Newman characterized patent conveyances as contracts and supported the district court's application of New York state law. Judge Newman emphasized both parties' clear, unmistakable intent to transfer patent ownership, evidenced by the language in all of the documents—the APA, the First Agreement, the March 2007 assignments, and the Second Agreement. Thus, Judge Newman found ample support in New York state law to uphold the district court's ruling.

Even under the majority's application of Federal Circuit law, Judge Newman further disagreed with the majority's reasoning. Judge Newman distinguished this case from the cases used by the majority, which she described as cases debating rights to *future* inventions. Specifically, Judge Newman distinguished *Enzo*, another case where the Court denied retroactive validity to a patent assignment agreement. In *Enzo*, however, the Court found no evidence of either parties' intention to confer an exclusive license before the licensee filed suit. By contrast, the parties here clearly intended for patent ownership to transfer to Abraxis before Abraxis filed suit, first when they executed the APA and again when they executed the First Agreement.

In Judge Newman's view, the majority vitiated the parties' intent by "engrafting a meaning" to the contracts that neither party reasonably or possibly intended. Newman Dissent at 9. Throughout the dissent, Judge Newman underscored the importance of honoring contractual intent and applying the law that the parties agreed to apply to their contracts.

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Court Clarifies the Prejudice Requirement for Prosecution Laches and the Intent Requirement for Inequitable Conduct

Jeffrey M. Jacobstein

Judges: Newman, Lourie (author), Prost (dissenting)
[Appealed from D. Del., Judge Robinson]

In *Cancer Research Technology Ltd. v. Barr Laboratories, Inc.*, No. 10-1204 (Fed. Cir. Nov. 9, 2010), the Federal Circuit reversed the district court's decision holding U.S. Patent No. 5,260,291 ("the '291 patent") unenforceable for prosecution laches and inequitable conduct.

Cancer Research Technology Limited ("Cancer Research") is the owner of the '291 patent, which claims a genus of tetrazine derivative compounds and methods for treating cancer by administering those compounds. During prosecution of the '291 patent, the examiner rejected the application for lack of utility. The examiner asserted that the utility of a human cancer treatment could only be established by data showing efficacy in humans, but the applicants lacked such data. Rather than respond to the office action, Cancer Research filed a continuation application. The continuation was again rejected for lack of utility, and a further continuation was filed by the applicants. This process was repeated eight more times. On the final application, Cancer Research responded for the first time to the utility rejection, arguing that animal tests were adequate to establish utility in humans. The PTO agreed and the '291 patent subsequently issued.

During prosecution of the '291 patent, Cancer Research continued to study the claimed tetrazine derivatives, revealing that several of the compounds were toxic and had little anti-cancer activity. This data was published in scientific journals but was never submitted to the PTO. Nor did Cancer Research amend their claims in light of the new data.

Several years after the FDA approved an NDA for Temodar®, which contained one of the tetrazine compounds claimed in the '291 patent, Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively "Barr") filed an ANDA with a Paragraph IV certification challenging the validity of the '291 patent. Cancer Research sued Barr for patent infringement and the district court held the '291 patent unenforceable for prosecution laches and inequitable conduct.

On appeal, the Federal Circuit held that prosecution laches requires a finding of prejudice. Furthermore, to establish prejudice, the Court explained that an accused infringer must demonstrate intervening rights,

meaning that "either the accused infringer or others invested in, worked on, or used the claimed technology during the period of delay." Slip op. at 9. The Court rejected Barr's argument that the public was inherently prejudiced by Cancer Research's delay in prosecuting the '291 patent. The Court found that the public was not harmed by the delayed prosecution because Cancer Research did not receive FDA approval to distribute its first cancer drug until several years after the'291 patent issued. Thus, the Court held that the delay did not deprive the public of earlier access to Temodar. Furthermore, the Court held that the harm to the public caused by the extended patent life of the '291 patent was not relevant as it was not a prejudice that emerged during prosecution.

"A court cannot simply infer that an applicant 'should have known' the materiality of withheld information and thus intended to deceive the PTO because the applicant knew of the information and the information is material." Slip op. at 17.

The Court noted that Barr, on the other hand, waited more than seven years after FDA approval of Temodar before filing its ANDA. While entitled to file an ANDA four years after NDA approval, Barr chose to wait an additional three years. Thus, the Court found that Barr was not prejudiced by the delay in issuance of the '291 patent. Furthermore, Barr failed to introduce evidence that any other company was deterred from entering the market for tetrazine derivatives because of the delay in prosecuting the '291 patent. Thus, the Court concluded that Barr failed to establish the prejudice necessary for a finding of laches and reversed the decision of the district court.

After considering prosecution laches, the Federal Circuit turned to the issue of inequitable conduct. The district court had established materiality and inferred intent from the fact that the inventors of the '291 patent published data showing some of their claimed tetrazine compounds lacked cancer utility but failed to report this data to the PTO. The Federal Circuit found that the district court committed clear error in relying solely on evidence of materiality to also infer intent to deceive the PTO.

The Federal Circuit stated that evidence of both materiality and intent are required to render a patent unenforceable for inequitable conduct. A court may not "simply infer that an applicant 'should have known' the materiality of withheld information and thus intended to deceive the PTO because the applicant knew of the information and the information is material." Slip op. at 17. Rather, the Court held that there must be additional evidence from which to deduce intent. In the present case, the Court noted that the district court relied solely on its materiality finding to infer intent to deceive. The Court found that the fact that the articles contradict the disclosure of the '291 patent did not alone establish that the inventors withheld those studies intending to deceive the PTO. The Federal Circuit found this inference unwarranted, as "the prompt publication of data in multiple articles over the entire course of prosecution is inconsistent with finding that intent to deceive is the single most reasonable inference to draw from the evidence in this case." *Id.* at 18 (citing *Research Corp. Techs., Inc. v. Microsoft Corp.*, 536 F.3d 1247, 1252 (Fed. Cir. 2008)). The Court noted that an equally likely inference was that the inventors knew the publication was important for their scientific careers but did not appreciate the importance for patent prosecution purposes. Given this alternative, the Federal Circuit held that it was clear error for the district court to infer intent to deceive from the publication alone. Thus, the Court held that the district court abused its discretion by failing to establish the intent element of inequitable conduct.

In her dissent, Judge Prost stated that she would have affirmed the district court's finding of prosecution laches for two reasons. First, Judge Prost noted that no Supreme Court or Federal Circuit precedent

required a finding of intervening rights to establish prosecution laches. While intervening rights can serve as one route to establish laches, Judge Prost stated that mere delay in prosecution alone can also be adequate. Second, Judge Prost argued that even if prejudice were required, then the majority erred by ignoring the harm to the public from allowing Cancer Research to extend its patent term through delayed prosecution. Judge Prost stated that the majority avoided this issue by confining the relevant harm to the period during which prosecution was pending. However, Judge Prost stated that no legal basis existed for such a limitation.

Judge Prost would also have affirmed the district court's finding of inequitable conduct. Judge Prost felt that the majority created a new evidentiary standard for inequitable conduct when it required separate evidence to prove materiality and intent. Judge Prost noted that while a court must address the two issues separately, there is no legal basis for preventing a court from applying the same evidence to reach both elements. Furthermore, Judge Prost noted that the majority did not afford adequate deference to the district court's credibility findings regarding the intent to deceive the PTO.

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Patent Owner Is a Necessary and Indispensable Party Where Exclusive Licensee Acquired Less Than All Substantial Rights

Krista E. Bianco

Judges: Lourie (author), Bryson, and Dyk

[Appealed from D. Mass, Judge Tauro]

In *A123 Systems, Inc., v. Hydro-Quebec*, No. 10-1059 (Fed. Cir. Nov. 10, 2010), the Federal Circuit affirmed the district court's denial of A123 Systems, Inc.'s ("A123") motion to reopen and dismissal of A123's DJ action against Hydro-Quebec ("HQ"). A123 filed a DJ action in the District of Massachusetts, seeking a declaration of noninfringement and invalidity of two patents, U.S. Patent Nos. 5,910,382 and 6,514,640 (collectively, "the patents-in-suit"), assigned to the Board of Regents, The University of Texas System ("UT") and licensed to HQ. The patents-in-suit are directed to cathode materials for secondary (rechargeable) lithium batteries and claim a genus of lithium-based cathode materials. HQ moved to dismiss A123's suit, arguing that UT was a necessary and indispensable party because, pursuant to UT and HQ's Patent License Agreement, UT had transferred to HQ less than all substantial rights in the patents-in-suit, granting HQ only an exclusive field-of-use license. A month later, HQ and UT jointly initiated an infringement suit against A123, among others, in the Northern District of Texas. After A123 successfully requested a reexamination of both patents, the Texas action was stayed, and the Massachusetts' district court dismissed A123's DJ action without prejudice to either party to reopen within thirty days following the termination of the reexaminations. The district court then subsequently denied A123's timely motion to reopen the case, yielding jurisdiction over A123's DJ suit to the later-filed suit in Texas. The district court concluded that A123's first-filed action, if reopened, would be subject to imminent dismissal for failure to join a necessary party. Moreover, the district court found that A123 could not join UT because UT had not waived its Eleventh Amendment sovereign immunity in the Massachusetts action.

In determining ownership for purposes of standing, labels given by the parties do not control. Rather, the court must determine whether the party alleging effective ownership has in fact received all substantial rights from the patent owner. Slip op. at 7-8.

On appeal, the Federal Circuit first rejected A123's argument that HQ's own actions and representations

proved that HQ had acquired all substantial rights in the patents-in-suit from UT. Specifically, A123 contended that HQ previously held itself out as an exclusive licensee of the patents-in-suit with the right to sublicense the technology and enforce the patents in an earlier lawsuit against a third party and in a letter threatening A123 with suit for infringement. A123 also argued that HQ attempted to enforce the patents-in-suit against the third party without joining UT. Citing the testimony of both HQ's general counsel and UT's Associate Vice Chancellor, the Court held that the district court did not err in finding that HQ was a field-of-use licensee because while UT granted HQ a license to two fields of use, UT retained the right to license other parties in all other patented fields of use. The Court further found that the representations relied upon by A123 were consistent with HQ being a field-of-use-licensee. The court noted that HQ's statements in its first amended complaint in the lawsuit against the third party unmistakably identified HQ's license as less than a complete grant of rights, and while HQ used the label "exclusive licensee" in its letter accusing A123 of infringement, it did not say anything to indicate that its license is exclusive to all fields of use. Moreover, even if HQ had held itself out as having all substantial rights in the patents-in-suit, the Court explained that "[i]n determining ownership for purposes of standing, labels given by the parties do not control. Rather, the court must determine whether the party alleging effective ownership has in fact received all substantial rights from the patent owner." Slip op. at 7-8.

The Court also rejected A123's argument that the district court erred by not examining HQ and UT's Patent License Agreement and further abused its discretion by not granting A123's requested discovery of the Agreement. Concluding that the record did not reflect that A123 did, in fact, request discovery of the Agreement, the Court held that A123 waived its argument. Thus, the Court held that because HQ had acquired less than all substantial rights, UT was a necessary party to A123's DJ action.

Next, undertaking a *de novo* review, the Court considered whether UT had waived its Eleventh Amendment sovereign immunity in the Massachusetts action by filing the Texas action. In *Biomedical Patent Management Corp. v. California, Department of Health Services,* 505 F.3d 1328 (Fed. Cir. 2007) ("*BPMC*"), the Court held that where a waiver of immunity occurs in one suit, the waiver does not extend to an entirely separate lawsuit, even one involving the same subject matter and the same parties. *Id.* at 1339. Accordingly, the Court held that UT's waiver of Eleventh Amendment immunity in the Texas action did not result in a waiver of immunity in the Massachusetts action since it was a separate infringement action.

Finally, applying First Circuit law, the Court found that dismissal of the DJ suit was appropriate under Fed. R. Civ. P. 19(b) when a party is deemed necessary under Fed. R. Civ. P. 19(a), but cannot be joined. The Court rejected A123's argument that the district court erred by not conducting an analysis under Rule 19. The Court held that even though the district court did not undertake a Rule 19(b) analysis, the district court made sufficient factual findings for the Court to determine whether UT is an indispensable party. Further, while remand is the "preferred position" under First Circuit precedent, the Court may rule on Rule 19(b) determinations on appeal de novo.

Guided by Rule 19(b), the Court considered four factors to determine when joinder of a necessary party is not feasible. Analyzing the first factor, the Court found that although HQ and UT undoubtedly share the same overarching goal of defending the patents' validity, neither that goal nor UT's decision to file suit jointly with HQ in Texas demonstrated that UT's interest will be adequately represented by HQ. While HQ and UT's interests in the patents-in-suit were overlapping, they were not identical. Under the second factor, the Court noted that A123 had not suggested any alternative that would reduce the prejudice to UT. Turning to the third factor, the Court agreed with the district court's implicit finding that a judgment rendered without UT would be inadequate. Allowing a field-of-use licensee like HQ to sue or be sued

alone poses a substantial risk of multiple suits and multiple liabilities against an alleged infringer for a single act of infringement. Finally, the Court held that the fourth factor also weighed in favor of holding UT to be an indispensable party. As the district court found, A123 could assert counterclaims for a declaration of noninfringement in the Texas action in view of UT's waiver of immunity and, thus, had a forum to litigate its defenses. Accordingly, the Court held that UT was not only a necessary party but also an indispensable party, making dismissal appropriate.

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Substitute Service of Process Ordered for Defendant from Russian Federation

John A. Kelly

Judges: Rader (author), Newman, Prost
[Appealed from N.D. Cal., Judge White]

In *Nuance Communications, Inc. v. Abbyy Software House*, No. 10-1100 (Fed. Cir. Nov. 12, 2010), the Federal Circuit reversed the district court's dismissal of Abbyy Production LLC ("Abbyy Production") for lack of personal jurisdiction. To allow for additional discovery, the Court also vacated the district court's dismissal of Abbyy Software, Ltd. ("Abbyy Software"). The Court also reversed the dismissal of the case for improper service of process.

Nuance Communications, Inc. ("Nuance") originally sued Abbyy USA Software House ("Abbyy USA") and Lexmark International, Inc. for infringement of its method and system patents directed to optical character recognition, and document recognition and management. Based on responses to interrogatories, Nuance filed an Amended Complaint, adding as defendants Abbyy Software, Abbyy USA's parent, and Abbyy Production, a wholly owned subsidiary of Abbyy Software and the provider of Abbyy USA's software products and support. Abbyy Software and Abbyy Production are corporations organized under the laws of Cyprus and Russia, respectively. A local process server served Abbyy Production in Moscow with the Amended Complaint, Amended Summons, and Standing Orders of the Court. The Abbyy defendants then filed a motion to dismiss Abbyy Production and Abbyy Software for lack of personal jurisdiction, and to dismiss Abbyy Production for improper service of process. The district court concluded that the record did not show that Abbyy Production or Abbyy Software purposefully directed any specific activity at residents of California or within the forum state, or that Nuance's claims arise out of those activities. The district court further concluded that Nuance did not properly serve Abbyy Production in accordance with the Hague Convention. The district court also dismissed the suit against Abbyy Software sua sponte for improper service of process. In its decisions, the district court did not address Nuance's request for jurisdictional discovery.

On appeal, Nuance challenged the district court's determination that it cannot exercise personal jurisdiction over Abbyy Production and Abbyy Software, and that these companies were served in a legally insufficient manner. Nuance first argued that Abbyy Production purposefully directed activities at residents of California, satisfying the first prong of the California test for personal jurisdiction. Nuance focused on the CEO's stated goal of "conquering" the U.S. market, the importation of allegedly infringing products into California, the extraction of royalty payments for the sale of these products, and Abbyy

Production's agreement to provide assistance to Abbyy USA in selling, reproducing, and modifying the accused products in California.

"Rule 4 'was not intended to burden plaintiffs with the [S]isyphean task of attempting service through the Hague Convention procedures when a member state has categorically refused' to effect service." Slip op. at 22 (quoting *Arista Records LLC v. Media Servs. LLC*, No. 06-15319, 2008 WL 563470. at *1 (S.D.N.Y. Feb. 25, 2008)).

The Federal Circuit applied a three-prong test to determine whether specific jurisdiction exists over Abbyy Production and Abbyy Software: "(1) whether the defendant purposefully directed activities at residents of the forum; (2) whether the claim arises out of or relates to those activities; and (3) whether assertion of personal jurisdiction is reasonable and fair." Slip op. at 8 (citing *Akro Corp. v. Luker*, 45 F.3d 1541, 1545-46 (Fed. Cir. 1995)).

The Federal Circuit found that Abbyy Production had purposefully directed activities at the residents of California, availing itself of the privilege of conducting activities there. Specifically, the Court noted that it provided master copies of its software products to its sister company, Abbyy USA, a resident of California, in exchange for royalty payments, and sought to conquer the U.S. market.

The Court also found Nuance's claim arose out of Abbyy Production's importation of its allegedly infringing software into California for sale by Abbyy USA throughout the United States. Abbyy Production's physical absence from California was immaterial to the Court, because Abbyy Production retained ownership over the software, even after importation, under its license agreement with Abbyy USA. Moreover, the Court found that the stream of commerce was not so attenuated as to undermine jurisdiction, because Abbyy Production purposefully shipped its accused software into California directly through an established distribution channel with no intervening links. The Court found the fact that it merely licensed its product, as opposed to physically importing it, was irrelevant for jurisdictional purposes.

The Court further found exercising jurisdiction over Abbyy Production fair and reasonable, because of its established delivery system through a commonly owned subsidiary and intent to deliver its products to the United States. Its litigation burden would be slight due to common management and legal representation with Abbyy USA. For these reasons, the Court found the exercise of personal jurisdiction over Abbyy Production proper.

As to Abbyy Software, the Federal Circuit vacated the district court's dismissal for lack of personal jurisdiction. The Court noted that a global management team directed both Abbyy Software and Abbyy USA, that Abbyy Software's CEO made assertive statements about U.S. entry in a trade magazine, and that Abbyy Software's website, although not offering products for sale in the United States, listed American retailers. The Court, however, could not conclude that Abbyy Software had purposefully availed itself of the privilege of conducting activities in California by intentionally establishing distribution channels terminating there. Rather, the Court found the extent of Abbyy Software's involvement in the sales of allegedly infringing products uncertain, prompting the Court to vacate the district court's dismissal for lack of personal jurisdiction.

Applying Ninth Circuit law, the Federal Circuit also held that the district court abused its discretion by

ignoring Nuance's request for jurisdictional discovery. Finding the district court's failure to address the request in its dismissals a de facto denial, and Nuance's request for jurisdictional discovery based on more than "a mere hunch," the Court granted additional discovery to determine the merits of personal jurisdiction over Abbyy Software. Slip op. at 18 (quoting *Patent Rights Prot. Grp. LLC v. Video Gaming Techs., Inc*., 603 F.3d 1364, 1372 (Fed. Cir. 2010)).

The Federal Circuit then turned to the service of process. After reviewing the requirements of Federal Rule of Civil Procedure 4 and the Hague Convention, the Court concluded that the record indicates that Nuance could not have attempted to serve Abbyy Production through the Hague Convention. Specifically, the Court found evidence that the Russian Federation does not consider the Hague Service Convention in effect between Russia and the United States.

With regard to Nuance's attempts to effect personal service by serving Abbyy Production's manager in Moscow, the Federal Circuit concluded that, on remand, the district court should allow alternate service, including at least substitute service, pursuant to Rule 4(f)(3), of Abbyy Production by substitute service on Abbyy USA.

Finally, the Court reversed the district court's sua sponte dismissal of Abbyy Software for improper service of process, finding that Abbyy Software failed to raise the defense of improper service of process, thereby waiving it.

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Spotlight Info

In *Cancer Research Technology Ltd. v. Barr Laboratories., Inc.*, No. 10-1204 (Fed. Cir. Nov. 9, 2010), the Federal Circuit reversed, *inter alia*, the district court's decision of inequitable conduct. Cancer Research Technology Limited's ("Cancer Research") patent claims a genus of tetrazine derivative compounds and methods for treating cancer by administering those compounds. During a prolonged prosecution, the PTO rejected the application eight times and each time, the applicant responded by filing a continuation before the patent issued. During the intervening period, Cancer Research continued to study tetrazine derivatives, revealing that several of the compounds were toxic and had little anti-cancer activity. Cancer Research published these results in scientific journals, but neither submitted these findings to the PTO nor amended their claims. After Barr Laboratories, Inc. ("Barr") filed an ANDA, Cancer Research sued Barr for patent infringement. In its finding of inequitable conduct, the district court established materiality and inferred intent because the inventors published their findings that some of the compounds lacked cancer utility, but failed to report this data to the PTO. The Federal Circuit, however, held that a court may not rely solely on its materiality finding to infer intent to deceive; rather, additional evidence is necessary from which to deduce intent. See the full summary in this issue.

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Last Month at the Federal Circuit

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Looking Ahead

On August 27, 2010, Microsoft Corporation ("Microsoft") petitioned the Supreme Court for a writ of certiorari from the Federal Circuit's decision in *i4i Limited Partnership v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010). Microsoft's petition asked the Court to reject the Federal Circuit's longstanding rule that invalidity must be proved by clear and convincing evidence even where the prior art on which the invalidity assertion rests was not considered by the PTO. On November 29, 2010, the U.S. Supreme Court granted Microsoft's petition. *Microsoft Corp. v. i4i Limited Partnership*, No. 10-290. The Supreme Court is expected to hear oral arguments in March or April 2011, and a decision is likely sometime before the term ends in June. See future editions for further updates.

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