

United States Court of Appeals
for the Federal Circuit

ABRAXIS BIOSCIENCE, INC.,
Plaintiff-Appellee,

v.

NAVINTA LLC,
Defendant-Appellant.

2009-1539

Appeal from the United States District Court for the District of New Jersey in Case No. 07-CV-1251, Judge Joel A. Pisano.

Decided: November 9, 2010

RICHARD DE BODO, Hogan & Hartson, LLP, of Los Angeles, California argued for plaintiff-appellee. With him on the brief were AMY M. GALLEGOS; and SIEGMUND Y. GUTMAN, of Washington, DC.

MEREDITH MARTIN ADDY, Brinks Hofer Gison & Lione, of Chicago, Illinois, argued for defendant-appellant. With her on the brief were MARK H. REMUS, LAURA A. LYDIGSEN, and LUKE A. PARSONS.

Before NEWMAN, GAJARSA, and LINN, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* GAJARSA.
Dissenting opinion filed by *Circuit Judge* NEWMAN.

GAJARSA, *Circuit Judge*.

Appellant Navinta LLC appeals from a final judgment of the United States District Court for the District of New Jersey finding, *inter alia*, that Navinta's Abbreviated New Drug Application ("ANDA") product would directly infringe claims 1-3 of U.S. Patent No. 4,870,086 (the "086 patent") and contribute to and induce infringement of claim 6 of the '086 patent. In addition, the district court found that Navinta's ANDA product would contribute to and induce infringement of claims 1 and 9 of U.S. Patent No. 5,670,524 (the "524 patent") and claim 1 of U.S. Patent No. 5,834,489 (the "489 patent"), both disclosing methods of using low concentrations of ropivacaine hydrochloride to treat pain. *See Abraxis Bioscience, Inc. v. Navinta, LLC*, 640 F. Supp. 2d 553, 569-92 (D.N.J. 2009). Because the district court erred in failing to dismiss Abraxis Bioscience, Inc.'s ("Abraxis's") action for lack of standing, we vacate the judgment below.

BACKGROUND

Abraxis markets the drug Naropin® as a local or regional anesthetic indicated for use in surgery and for acute pain management, such as pain management during labor and delivery. Abraxis sells Naropin® in four concentrations: 1.0%, 0.75%, 0.5%, and 0.2%. The 0.2% concentration is the only FDA-approved strength for use in labor and delivery. The '086 patent discloses the sole active ingredient in Abraxis's Naropin® drug product,

ropivacaine hydrochloride monohydrate (“ropivacaine”).¹ The ’489 patent claims the use of ropivacaine for treating pain at concentrations less than 0.5% administered epidurally. The ’524 patent discloses the use of ropivacaine for treating pain at concentrations less than 0.25%. Asserted claim 9 of the ’524 patent is a composition claim that covers “a pharmaceutical salt of ropivacaine at a concentration [...] lower than 0.25% by weight.”

The sole inventor of the ’086 patent, Rune Sandberg, assigned his rights in the ’086 patent to Astra Lakemedel Aktieboag (“Astra L”) on October 16, 1986. Arne Torsten Eek, as sole inventor, assigned his rights in the ’524 and ’489 patents to AB Astra on June 19, 1994. As a result of a merger between AB Astra and AstraZeneca AB (“AZ-AB”), AB Astra assigned the ’524 and ’489 patents to AZ-AB.

On April 26, 2006, Abraxis entered into an Asset Purchase Agreement (“APA”) with AstraZeneca (“AZ-UK”). The APA provides that AZ-UK “shall or shall cause one or more of its Affiliates to, Transfer to the Purchaser, and the Purchaser shall purchase and accept from the Seller or its Affiliates, as applicable, all of the right, title and interests of the Seller and its Affiliates in” the asserted patents. Following the execution of the APA, AZ-UK and Abraxis executed a written Intellectual Property Assignment Agreement (“IP Assignment Agreement”) on June 28, 2006 purportedly assigning the asserted patents to Abraxis. The “Further Assurances” provision of the IP Assignment Agreement states, in pertinent part, that “Seller will . . . execute . . . any and all further . . . as-

¹ Because the ’086 patent expired on September 24, 2010, Navinta chose not to appeal the district court’s infringement findings regarding that patent.

signments . . . as necessary to . . . vest in Buyer any of the Transferred Intellectual Property.” There was a break in the chain of title, however, because the asserted patents were still owned by Astra L and AZ-AB, neither of which had assigned the rights in the asserted patents to AZ-UK. *See Abraxis Bioscience, Inc. v. Navinta LLC*, No. 07-1251, 2009 WL 904043, at *2 (D.N.J. Mar. 30, 2009) (order denying motion to dismiss for lack of subject matter jurisdiction).

On November 13, 2006, Navinta filed an ANDA for a generic version of Naropin®. Along with the ANDA, Navinta filed a patent certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”), which alleged that none of the claims of the ’086 patent would be infringed by the manufacture, use, or sale of Navinta’s generic ropivacaine hydrochloride product. At the time of the Paragraph IV Certification, the only patent listed by Astra in the Food and Drug Administration’s (“FDA’s”) Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) for Naropin® was the ’086 composition patent. Although the ’524 and ’489 patents issued ten years earlier, on September 23, 1997, and November 10, 1998, respectively, Astra elected not to list those patents in the Orange Book.

On March 15, 2007, Abraxis filed an action against Navinta under the Hatch-Waxman Act, triggering the thirty-month statutory stay on approval of Navinta’s ANDA. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271). The complaint alleged that Navinta’s ANDA with its Paragraph IV Certification artificially infringes the listed ’086 patent under 35 U.S.C. § 271(e)(2). *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990)

(Section 271(e)(2) creates “a highly artificial act of infringement that consists of submitting an ANDA . . . containing a [Paragraph IV Certification] that is in error as to whether commercial, manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent.”); *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004) (“[Section] 271(e)(2) is designed to create an artificial act of infringement for purposes of establishing jurisdiction in the federal courts . . .”). Also, to avoid the listing requirements under § 271(e)(2) with regards to the ’524 and ’489 method patents, the complaint erroneously alleged indirect infringement of the method patents under 35 U.S.C. § 271(b)-(c). Abraxis could not make any such allegation, however, because Navinta has never sold or offered to sell ropivacaine hydrochloride products and an act of actual commercial infringement is required for induced or contributory infringement. See 35 U.S.C. § 271(b)-(c).

On the same day this action was filed, Astra L and AZ-AB each executed nearly identical assignments of their respective patents to AZ-UK. The assignments reference the April 26, 2006 APA and provide that the assignments were executed to allow AZ-UK to “further convey” the patents to Abraxis. On November 12, 2007, almost eight months after filing suit, AZ-UK, in a separate document entitled “Intellectual Property Assignment Agreement,” “confirm[ed] the sale, assignment, conveyance and transfer to Abraxis, for Abraxis’ sole and exclusive use and enjoyment, of all of Astra Zeneca UK’s right, title, and interest, in and to” the asserted patents. The agreement further stated that AZ-UK and Abraxis “consider and have considered Abraxis by way of assignment and pursuant to the [APA], to own all rights, title, and

interest” to the asserted patents, including the right to sue for patent infringement no later than June 28, 2006.

Awaiting the expiration of the ’086 patent on the composition, Navinta submitted a “Section viii Statement” along with a proposed labeling amendment seeking a use for its generic ropivacaine hydrochloride product not covered by the ’524 and ’489 method patents. As a general rule, the label associated with the generic version of a drug must be exactly the same as the label of the branded drug approved in the original New Drug Application (“NDA”). 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G); 21 C.F.R. § 14.94(a)(8)(iv). One exception to the rule under the Hatch-Waxman Act is if a generic manufacturer makes a “Section viii Statement,” 21 U.S.C. § 355(j)(2)(A)(viii), seeking FDA approval for a use not covered by a method patent listed in the Orange Book, along with a proposed label that “carves out” the patented method. Navinta submitted the Section viii Statement to avoid Abraxis’s infringement contentions regarding the unlisted method patents. Specifically, Navinta’s labeling amendment sought to delete the indication for acute pain management and maintained only the indication for surgical anesthesia with a recommended concentration of greater than 0.5%. It is uncontested that the use of ropivacaine for surgical anesthesia at concentrations of at least 0.5% does not infringe the ’524 and ’489 patents because the claims of those patents are limited to methods of treating pain and also require concentrations less than 0.25% and 0.5%, respectively.

Initially, the FDA rejected Navinta’s labeling amendment because the ’524 and ’489 patents were not listed in the Orange Book at the time the complaint was filed, and thus, there was no basis for the Navinta package insert to depart from the approved NDA package insert for

Naropin®. Then, in late 2007, Abraxis finally listed the '524 and '489 patents in the Orange Book. In response, Navinta resubmitted its Section viii Statement and the FDA allowed the labeling amendment after Navinta made significant changes to its package insert to "carve out" all statements that might reasonably relate to the uses claimed in the '524 and '489 patents.

Subsequently, Navinta filed a motion to dismiss the infringement counts with respect to the '524 and '489 patents for lack of subject matter jurisdiction because the counts alleged speculative future infringement of the unlisted method patents under § 271(b)-(c). In response, Abraxis moved to amend the complaint to add a claim of infringement of the '524 and '489 patents under § 271(e)(2). Navinta argued that the district court also lacked jurisdiction under § 271(e)(2) because the '524 and '489 method patents were not listed in the Orange Book and, therefore, Navinta could not make a Paragraph IV Certification as to those patents. The district court granted Abraxis's motion to amend its complaint to allege that Navinta infringed the '524 and '489 patents pursuant to § 271(e)(2). *See Abraxis Bioscience, Inc. v. Navinta LLC*, No. 07-1251 (D.N.J. Oct. 9, 2007) (order granting motion to amend complaint). The district court denied Navinta's Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction and exercised jurisdiction over the method patents based on § 271(e)(2) and the Declaratory Judgment Act. *Id.* (order denying motion to dismiss for lack of subject matter jurisdiction under 35 U.S.C. § 271(e)(2)).

Navinta also filed a second Rule 12(b)(1) motion to dismiss for lack of standing alleging that Abraxis did not own the asserted patents at the time the complaint was filed. *See Abraxis Bioscience*, 2009 WL 904043, at *1.

While acknowledging that there was a break in the chain of title to the patents, the district court held that the “intent” of the various Astra entities was sufficient to imply a *nunc pro tunc* assignment based on the relationship between the corporate entities. *Id.* at *4. The district court found that:

[a]though Defendant is correct that Astra L and AZ-AB were not parties to the APA, neither were they complete strangers to that transaction. They were, respectively, a corporate affiliate and subsidiary of AZ-UK, and each of the March 2007 agreements expressly recognize that they are “affiliate[s] of the Transferee.” So while Astra L and AZ-AB may not have been bound by the terms of the APA, given their relationship to the transaction between Abraxis and AZ-UK, the Court finds that their express recognition of the APA in the March 2007 assignments is significant—it evinces their intent that their transfer of the patents to AZ-UK be in accordance with the terms of that agreement, i.e., retroactive to June 28, 2006.

Id. The district court then gave the March 15, 2007, assignments *nunc pro tunc* effect based on the June 28, 2006 IP Assignment Agreement between AZ-UK and Abraxis in order to cure the defect in ownership as of the date of filing of Abraxis’s complaint. *Id.*

After a seven-day bench trial, the court issued its decision on August 3, 2009, two days before the expiration of the thirty-month stay on Navinta’s ANDA. *Abraxis*, 640 F. Supp. 2d at 558. The district court found direct and indirect infringement of the ’086 patent and indirect infringement of the ’524 and ’489 patents. *Id.* at 569-92. Pursuant to its findings on inducement and contributory

infringement, the district court ordered that the effective date of approval of Navinta’s ANDA product be no earlier than September 14, 2014, the expiration date of the ’524 and ’489 patents.

Navinta timely appealed to this court. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

Standing is a constitutional requirement pursuant to Article III and it is a threshold jurisdictional issue. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). We review standing, a question of law, *de novo*. See *Pennington Seed, Inc. v. Produce Exch. No. 299*, 457 F.3d 1334, 1338 (Fed. Cir. 2006); *Enzo Apa & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1092 (Fed. Cir. 1998). “To the extent [any] jurisdictional facts are in dispute, however, the findings of fact are reviewed for clear error.” *Canadian Lumber Trade Alliance v. United States*, 517 F.3d 1319, 1330-31 (Fed. Cir. 2008); see *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1377 (Fed. Cir. 2007); *Plumtree Software, Inc. v. Datamize, LLC*, 473 F.3d 1152, 1158 (Fed. Cir. 2006).

We have stated that “[a]lthough state law governs the interpretation of contracts generally . . . the question of whether a patent assignment clause creates an automatic assignment or merely an obligation to assign is intimately bound up with the question of standing in patent cases. We have accordingly treated it as a matter of federal law.” *DDB Techs., L.L.C. v. MLB Advanced Media, L.P.*, 517 F.3d 1284, 1290 (Fed. Cir. 2008); see *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1253 (Fed. Cir. 2000) (stating that while the ownership of patent rights is typically a question exclusively for state courts, the question of

whether contractual language effects a present assignment of patent rights, or an agreement to assign rights in the future, is resolved by Federal Circuit law).

A court may exercise jurisdiction only if a plaintiff has standing to sue on the date it files suit. *Keene Corp. v. United States*, 508 U.S. 200, 207 (1993) (There is a “long-standing principle that the ‘jurisdiction of the Court depends upon the state of things at the time of the action brought.’”) (internal citations omitted); *Minneapolis & St. Louis R.R. v. Peoria & Perkin Union Ry. Co.*, 270 U.S. 580, 586 (1926) (“The jurisdiction of the lower court depends upon the state of things existing at the time the suit was brought.”). Based upon this Supreme Court jurisprudence, we have held that in a patent infringement action, “the plaintiff must demonstrate that it held enforceable title to the patent at the inception of the lawsuit” to assert standing. *Paradise Creations, Inc. v. UV Sales, Inc.*, 315 F.3d 1304, 1309-310 (Fed. Cir. 2003); *see also* 35 U.S.C. §§ 100(d), 281 (A “patentee” is entitled to bring a “civil action for infringement of his patent,” and the patentee includes the “successors in title to the patentee.”). Thus, “if the original plaintiff lacked Article III initial standing, the suit must be dismissed, and the jurisdictional defect cannot be cured” after the inception of the lawsuit. *Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*, 402 F.3d 1198, 1203 (Fed. Cir. 2005); *Lans v. Digital Equip. Corp.*, 252 F.3d 1320, 1328 (Fed. Cir. 2001) (affirming dismissal of complaint and denial of motion to amend pleadings to substitute assignee as plaintiff when plaintiff-inventor assigned the patent prior to filing the action).

Whether an assignment of patent rights in an agreement is automatic or merely a promise to assign depends on the contractual language itself. *DDB Techs.*, 517 F.3d

at 1290. If the contract expressly conveys rights in future inventions, no further act is required once an invention comes into being, and the transfer of title occurs by operation of law. *Id.* For example, in *Speedplay*, an employment agreement providing that all inventions made during the term of employment “shall belong” to Speedplay and that the employee “hereby conveys, transfers and assigns . . . all right, title and interest in and to Inventions” operated as an automatic assignment once the invention was created. 211 F.3d at 1253 (holding that a party had standing to assert its patent because the assignment agreement in effect granted it all substantial rights in the patent); *see DDB Techs.*, 517 F.3d at 1290 (holding that an employment agreement reciting that the employee “agrees to and does hereby grant and assign” all rights in future inventions was an automatic assignment to employer by operation of law with no further act required on the part of the employer).

In contrast, contracts that obligate the owner to grant rights in the future do not vest legal title to the patents in the assignee. *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) (finding that “agree to assign” contract language in a university researcher’s patent assignment agreement with the university only provided a promise to assign the invention in the future, and, therefore, was trumped by “will assign and do hereby assign” contract language in a later agreement the researcher signed with a company regarding any invention made while collaborating with the company). Thus, contract language stating that a party “agrees to assign” reflects a mere promise to assign rights in the future, not an immediate transfer of expectant interests. *See IpVenture, Inc. v. Prostar Computer, Inc.*, 503 F.3d 1324, 1327 (Fed. Cir. 2007) (interpreting “agree to assign” as “an

agreement to assign,” requiring a subsequent written instrument); *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1580-81 (Fed. Cir. 1991) (holding that “will be assigned” does not create “a present assignment of an expectant interest”).

Here, the contractual language of the APA indicates that the actual transfer of the asserted patents was to occur in the future. The APA states that AZ-UK “shall, or shall cause one or more of its Affiliates to, Transfer to the Purchaser, and the Purchaser shall purchase and accept from the Seller or its Affiliates, as applicable all of the right, title and interests of the Seller and its Affiliates in” the asserted patents. The actual transfer of the patents was to occur by means of a separate “IP Assignment Agreement” in the form to be mutually agreed upon by the parties prior to a July 31, 2006 closing date. Following the execution of the APA, AZ-UK and Abraxis executed the written June 28, 2006 IP Assignment Agreement. The IP Assignment Agreement purported to assign the asserted patents from AZ-UK to Abraxis. At that time AZ-UK could not assign the patents because it did not possess their titles. AZ-UK had no legal title to assign and, therefore, lacked standing to commence this litigation. *See Gaia Techs., Inc. v. Reconversion Techs., Inc.*, 93 F.3d 774, 778 (Fed. Cir. 1996) (dismissing plaintiff’s patent and trademark infringement claims for lack of standing because of its “inability to prove that it was the owner of the Intellectual Property at the time the suit was filed”), *as amended on reh’g on different grounds*, 104 F.3d 1296 (Fed. Cir. 1996); *see FilmTec Corp. v. Allied-Signal, Inc.*, 939 F.2d 1568, 1572 (Fed. Cir. 1991) (stating that the purported assignment is a nullity if the assignor had nothing to assign). The district court’s ruling to the contrary was legal error.

The dissent contends that our “promise to assign” line of cases is irrelevant. Dissent Op. at 10-11. The dissent’s contention is erroneous. Because the APA is a promise by AZ-UK to assign the relevant patents to Abraxis when AZ-UK obtains legal title, under our “promise to assign” cases, a subsequent written agreement is necessary to consummate the assignment. *See IpVenture*, 503 F.3d at 1327. It is clear from the record that AZ-UK did not have legal title when it executed the June 28, 2006 IP Assignment Agreement and it did not obtain legal title to the patents until March 15, 2007. Whether, as the dissent argues, the March 15, 2007 assignments from Astra L and AZ-AB to AZ-UK contained *nunc pro tunc* provisions is irrelevant. Even if given retroactive effect, the March 15, 2007 assignments do not automatically assign the patents to Abraxis; a subsequent written agreement was necessary. The only subsequent written agreement between AZ-UK and Abraxis is the November 12, 2007 Intellectual Property Assignment Agreement. This document is a clear recognition by Abraxis that AZ-UK did not hold legal title and therefore could not have transferred the patents without a properly executed assignment. It was a futile attempt by the parties to correct a critical error by a *nunc pro tunc* assignment. The effect of this document—executed eight months after the lawsuit was filed—is the critical issue on appeal.

Even if, as the district court found, the March 15, 2007 agreements were considered to be retroactive, title to the asserted patents did not automatically vest in Abraxis upon the March 15, 2007 transfer to AZ-UK because the June 28, 2006 IP Assignment Agreement did not result in an immediate transfer of “expectant interests” to Abraxis. *See Bd. of Trs. of Leland Stanford Junior Univ.*, 583 F.3d at 841-42. For title to vest in Abraxis, a further assignment by AZ-UK was required by

the “Further Assurances” provision of the June 28, 2006 IP Assignment Agreement. Whether Astra L, AZ-AB, and AZ-UK are part of the same corporate structure and are not “complete strangers,” therefore, is irrelevant because there was no valid written assignment to Abraxis. *See* 35 U.S.C. § 261 (assignments of patents must be in writing); *Enzo APA*, 134 F.3d at 1093 (same). Common corporate structure does not overcome the requirement that even between a parent and a subsidiary, an appropriate written assignment is necessary to transfer legal title from one to the other. Without the transfer of legal title of the patents, Abraxis had no standing to bring this infringement action. *Lans*, 252 F.3d at 1328 (holding that a plaintiff-inventor, who assigned his patent to a corporation in which he was the sole shareholder and managing director prior to filing the action, lacked standing to sue).

AZ-UK finally assigned the asserted patents to Abraxis on November 12, 2007, nearly eight months after filing the complaint.² Abraxis contends that the November 12, 2007 assignment confers standing because it was a *nunc pro tunc* assignment, thus, the requirement to have legal title to the patents on the day of suit was met retroactively. But the argument is to no avail because “if the original plaintiff lacked Article III initial standing, the suit must be dismissed, and the jurisdictional defect cannot be cured by . . . the subsequent purchase of an

² On December 5, 2008, Abraxis assigned all rights, title, and interest in the asserted patents to APP Pharmaceuticals LLC and joined APP Pharmaceuticals as a plaintiff in this action. *See Abraxis Bioscience*, 2009 WL 904043, at *5. Because Abraxis did not have standing at the time it filed the complaint, the joinder of APP Pharmaceuticals in 2008 cannot cure the jurisdictional defect after the inception of the action.

interest in the patent in suit.” *Schreiber Foods*, 402 F.3d at 1203. Even if the November 12, 2007 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.³ *Enzo APA*, 134 F.3d at 1093 (vacating judgment of infringement and holding that “*nunc pro tunc* assignments are not sufficient to confer retroactive standing” where no written transfer of rights under patent had been made at the time claims were brought); *Gaia Techs.*, 93 F.3d at 780 (reversing denial of motion to dismiss infringement complaint and vacating verdict that the asserted patents were infringed because alleged *nunc pro tunc* agreement was insufficient to cure the lack of standing existing when the complaint was filed). Thus, despite Abraxis’s delayed attempt to obtain title to the asserted patents, the action must be dismissed because Abraxis lacked standing on the day it filed the action.⁴

³ While Abraxis filed an amended complaint on November 16, 2007, we look to the date of the original Complaint, March 15, 2007, because “the jurisdiction of the Court depends on the state of things at the time of the action brought.” *Keene Corp. v. United States*, 508 U.S. 200, 207 (1993); *see Schreiber Foods*, 402 F.3d at 1203, n.7 (“The initial standing of the original plaintiff is assessed at the time of the original complaint, even if the complaint is later amended.”); FED. R. CIV. P. 15(a) & (c) (requiring an amended pleading to relate back to the date of the original pleading when the amendment asserts a claim that arises out of the conduct, transaction, or occurrence set out in the original pleading).

⁴ The dissent criticizes our reliance on *Enzo*. Dissent Op. at 10. Yet, we are bound by *Enzo* and subsequent cases applying *Enzo*’s clear holding. As we have stated before, “[t]his court’s precedent clearly establishes

The foregoing rule has a narrow exception. A party may sue for past infringement transpiring before it acquired legal title if a written assignment expressly grants the party a right to do so. *Moore v. Marsh*, 74 U.S. 515, 522 (1868) (“[I]t is a great mistake to suppose that the assignment of a patent carries with it a transfer of the right to damages for an infringement committed before such assignment.”); *Arachnid*, 939 F.2d at 1579 n.7, 1580-81 (holding that the right to sue for past infringement “must be express, and cannot be inferred from an assignment of the patent itself”). This exception is irrelevant to this case. Despite what the parties to the November 12, 2007 assignment believed, Abraxis was never granted the right to sue for past infringement that occurred when Navinta filed its ANDA and Paragraph IV Certification on November 13, 2006. The March 15, 2007 assignments to AZ-UK did not assign the right to sue for past in-

that a *nunc pro tunc* assignment executed after filing of a lawsuit cannot retroactively cure standing that was deficient at the time of filing.” *Messagephone, Inc. v. SVI Sys.’s, Inc.*, 243 F.3d 556, at *5 (Fed. Cir. 2000) (Table).

The dissent attempts to distinguish *Enzo* on the grounds that there was no evidence of any intention that the license would be exclusive before the suit was filed. Dissent Op. at 10. The distinction is impuissant. First, the parties in *Enzo* argued that the *nunc pro tunc* assignment agreement “was a memorialization [sic] of the pre-suit oral agreement of the parties,” thereby establishing evidence of an intention that the license would be exclusive before the suit was filed. 134 F.3d at 1092. Second, despite the dissent’s focus on intent, neither *Enzo* nor any subsequent case involving *nunc pro tunc* assignments focused on intent. Instead, *Enzo* and its progeny stand for the clear proposition that irrespective of a party’s intent, “*nunc pro tunc* assignments are not sufficient to confer retroactive standing.” *Id.* at 1093 (formatting added).

fringement, thus AZ-UK could not have assigned those rights to Abraxis on November 12, 2007, even if the November 12, 2007 assignment is “considered” to be retroactive. Therefore, Abraxis’s complaint must be dismissed because Abraxis lacked standing at the time the action was filed and continues to lack standing to sue for past infringement.

Finally, Abraxis improperly relies on *Arachnid* to support its argument that equitable title to the asserted patents through the APA was sufficient to confer standing to sue under the Hatch-Waxman Act. *Arachnid* concerned a present agreement to assign rights to future inventions. 939 F.2d at 1576, 1580. In contrast, the June 2006 IP Assignment Agreement attempted to assign rights to existing patents, but was ineffective, because the assignor, AZ-UK, did not own the patents at the time. Without ownership, AZ-UK had no authority to convey either the patents’ equitable or legal titles to Abraxis. Cf. *Arachnid*, 939 F.2d at 1581. The legal title to the asserted patents remained with Astra L and AZ-AB until March 15, 2007 when it was transferred to AZ-UK, leaving Abraxis with defective legal title to the patents.

Accordingly, we reverse the denial of the motion to dismiss the infringement complaint for lack of standing, vacate the district court’s judgment, and remand with instructions for the district court to dismiss Abraxis’s complaint without prejudice. Because we vacate the judgment of the district court for lack of standing, we need not address Navinta’s alternative jurisdictional ground for dismissal and we cannot review the merits of Navinta’s arguments regarding infringement.

REVERSED, VACATED, AND REMANDED

United States Court of Appeals for the Federal Circuit

ABRAXIS BIOSCIENCE, INC.,
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2009-1539

Appeal from the United States District Court for the District of New Jersey in Case No. 07-CV-1251, Judge Joel A. Pisano.

NEWMAN, *Circuit Judge*, dissenting.

The district court, applying the laws of contract and property transfer, held that the three patents in suit were owned by the plaintiff Abraxis when this suit was filed, and that the plaintiff had standing to bring this suit. The defendant did not seek interlocutory review of that ruling; and there have been over three years of litigation, including full trial of infringement of all three patents, and judicial determination of complex questions of law and fact concerning the Hatch-Waxman Act and its application. This court now finds that the plaintiff did not have standing, after all.

The court thus erases the trial, nullifies the judgment, cancels the appeal, and sends the case back so that the parties and the district court and this court can do it all again. However, the court has not shown reversible error in the district court's ruling on the question of standing, a ruling based on state contract and commercial transaction law. Instead, the panel majority creates a new and convoluted law unique to the patent aspect of commercial transactions. No special public policy is served, and no reason exists for creating a new commercial law, divergent from the governing state law, when the subject of the commercial sale is a patent. I must, respectfully, dissent.

DISCUSSION

New York law applies to these sales and transfer agreements. All of the documents state, and the parties and the district court agree, that the Asset Purchase Agreement and all of the related agreements are governed by New York law. Indeed, the choice of law is fundamental to this court's ruling, for my colleagues do not dispute that when New York law is applied, the district court's decision on standing should be upheld. Instead, the panel majority holds, contrary to New York law, that these commercial contracts cannot be given the effective date of the sales contract, on which these patents were sold and ownership was transferred. Thus although the parties to these contracts do not dispute their effective date, my colleagues now permit third parties to challenge and invalidate this commercial transaction, despite its undisputed validity as between the parties to the transaction.

New York law is otherwise. Indeed, all state and federal law is otherwise.

A

The master agreement between AstraZeneca UK and Abraxis, called the Asset Purchase Agreement (APA) and dated April 26, 2006, provided for the sale and purchase of eight pharmaceutical products and their patents. This master agreement contains a complex series of avowals, warranties, covenants, and considerations provided by each party and states that various aspects will be the subject of “Acquisition Documents,” defining these “Acquisition Documents” as “any and all other agreements, instruments, certificates and other documents executed and delivered in connection with this Agreement.” APA §1.1. Section 3.1 of the APA states that

the effectiveness of the documents, agreements, opinions and certificates delivered in accordance with [the APA], and the consummation of the transactions contemplated hereby shall be deemed to occur at the Effective Time.

The Effective Time is defined as “12:01 a.m., New York time on the Closing Date.” The Closing Date is defined as June 28, 2006.

The Asset Purchase Agreement defines “Transferred Patent Rights” as the patents relating to the products that were sold. For the Transferred Patent Rights, APA §2.1(e) provides that AstraZeneca UK (“the Seller”)

shall, or shall cause one or more of its Affiliates to, Transfer to the Purchaser, and the Purchaser shall purchase and accept from the Seller or its Affiliates, as applicable, all of the right, title and interests of the Seller and its Affiliates in and to . . . all Transferred Patent Rights.

On June 28, 2006 the Intellectual Property Assignment Agreement was executed. This agreement states that the “provisions of this instrument are subject to the terms and conditions of the Purchase Agreement.” The agreement states that the seller “hereby sells, assigns, conveys and transfers to Buyer . . . all of Seller’s right, title and interest” in the patents on the attached Schedule A. Schedule A lists the three patents in suit, and other patents. The Intellectual Property Assignment Agreement includes a “Further Assurances” clause, wherein AstraZeneca UK agrees that it will “do, execute, acknowledge and deliver, or will cause to be done, executed, acknowledged and delivered, any and all further acts, conveyances, transfers, assignments, and assurances as necessary to grant, sell, convey, assign, transfer, set over to or vest in Buyer any of the Transferred Intellectual Property.”

In early 2007 AstraZeneca UK learned that title to some of the patents on Schedule A remained with affiliates of AstraZeneca UK, and had not been formally assigned to Abraxis. Astra Läkemedel Aktieboag (“Astra L”) was still the nominal assignee of U.S. Patent 4,870,086, and AstraZeneca AB was still the nominal assignee of U.S. Patents 5,670,524 and 5,834,489. AstraZeneca UK acted in accordance with the Further Assurances clause, and on March 15, 2007 Astra L and AstraZeneca AB executed additional documents assigning these patents to AstraZeneca UK, the documents stating that “this instrument is being executed by the parties to enable the Transferee to further convey to Buyer that portion of the Transferred Assets” included in the Asset Purchase Agreement, “dated as of April 26, 2006 . . . pursuant to which Transferee agreed to sell to Buyer and Buyer agreed to purchase from Transferee the Transferred Assets, all as more particularly set out in the Purchase Agreement,” with “consummation of the transactions . . . deemed to occur at the Effective Time” on the Closing

Date. APA §3.1. On November 12, 2007 AstraZeneca UK executed an additional document “confirming” that Abraxis has owned all “right, title, and interest” to the patents in suit “since no later than June 28, 2006.”

It is not unusual to transfer a complex set of related assets through a master agreement and additional contracts and assurances. Here the specified patent rights were identified, and sold to Abraxis, in the Asset Purchase Agreement dated April 26, 2006. The patents were listed on Schedule A of the Intellectual Property Assignment Agreement dated June 28, 2006, and then, pursuant to the Further Assurances clause, on March 15, 2007 three of the patents that had been sold were subject to the Further Assurances of formal assignment and delivery, as required by the Asset Purchase Agreement and implemented in the Intellectual Property Assignment Agreement. Nonetheless, my colleagues dismiss the suit for lack of standing, deeming the transfer a “nullity” on inapt authority. Maj. Op. at 12.

The district court reached a different conclusion, upon correct analysis of the transaction documents and on the entire record.

B.

The district court, applying New York law of contracts and property transfers, held that the March 15, 2007 assignment documents were “delivered in accordance with” the terms of the Asset Purchase Agreement and were effective as of June 28, 2006, as stated therein. The district court determined that the June 28, 2006 Closing Date applied to all of the listed patents. The court stated: “Given this retroactive effect, the [Intellectual Property Assignment Agreement] would then operate to transfer title from [AstraZeneca UK] to Abraxis as of that date as well,” and held

that the transfer was effective as of June 28, 2006. *Abraxis Bioscience, Inc. v. Navinta LLC*, Civ. Action No. 07-1251, 2009 WL 904043, at *4 (D.N.J. Mar. 30, 2009). No error of law or fact has been shown in this ruling.

The district court applied the New York law of contracts, which recognizes provision of an effective date before or after the date of signing of a contract. *See Viacom Int'l Inc. v. Tandem Prods., Inc.*, 368 F. Supp. 1264, 1270 (S.D.N.Y. 1974) (“When a written contract provides that it shall be effective ‘as of’ an earlier date, it generally is retroactive to the earlier date.”); *Faculty Ass’n of Suffolk Cnty. Coll. v. Public Emp’t Relations Bd.*, 508 N.Y.S.2d 591, 592 (App. Div. 1986) (recognizing retroactive effect of a successor agreement going back to the expiration date of the predecessor contract); *Local Union 1567, Int’l Bhd. of Electrical Workers, AFL-CIO v. Orange and Rockland Utils., Inc.*, 478 N.Y.S.2d 937, 938 (App. Div. 1984) (retroactive effective date provided by collective bargaining agreement was binding, and applied to grievances that arose before the agreement was executed); *Matthews v. Jeremiah Burns, Inc.*, 129 N.Y.S.2d 841, 847 (Sup. Ct. 1954) (amended agreement was retroactive to the date of the original amendment to which it referred, rather than taking effect only from the amendment’s date of execution); *see also Mutual Life Ins. Co. of N.Y. v. Hurni Packing Co.*, 263 U.S. 167, 175–76 (1923) (applying New York law, “It was competent for the parties to agree that the effective date of the policy should be one prior to its actual execution or issue; and this, in our opinion, is what they did.”). Retroactivity also can serve to fill an unintended omission in an earlier agreement. *See Local Union 1567*, 478 N.Y.S.2d at 938; *Matthews*, 129 N.Y.S.2d at 847; *Buffalo Police Benevolent Ass’n v. City of Buffalo*, 453 N.Y.S.2d 314, 317 (Sup. Ct. 1982) (collective bargaining agreement was made retroac-

tive to cover the period between the lapse of the previous contract and the execution of the new contract).

It is beyond cavil that parties to a contract can set the effective date of their agreement. The district court found, in accordance with New York law, that the June 28, 2006 Closing Date applied to all of the documents that referred to that Closing Date, and that the March 15, 2007 assignments were effective on the Effective Date stated therein.

My colleagues hold that despite the explicit language of the contract documents and the intent of the parties as stated in the contracts, the patents were not transferred on any of the transfer dates stated in the contracts. This court rejects the district court's ruling that the March 15, 2007 reparative assignments were effective as of the Closing Date of June 28, 2006, although those patents were listed and sold in the closing documents. They even reject that the March 15, 2007 reparative assignments were effective on March 15, 2007. And they do not mention that even if there were some imperfection in ownership, it was corrected by the time the suit was filed.

C

The panel majority relies on assorted cases debating rights to future inventions. The question in this case is not whether or to whom an inventor assigned rights in possible unidentified future inventions, as in the "agree to assign" cases typified by *Bd. Of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 583 F.3d 832, 841 (Fed. Cir. 2009). This case relates to the law governing the commercial sale of existing patents, not the law of future rights to unknown inventions.

Patent conveyances are contracts, and the interpretation of sales contracts is a matter of state law. New York law permits contracts to take effect on a specified date, when such is the parties' intent. *Viacom*, 368 F. Supp. at 1270; *Faculty Ass'n of Suffolk Cnty. Coll.*, 508 N.Y.S.2d at 592; *Local Union 1567*, 478 N.Y.S.2d at 938; *Matthews*, 129 N.Y.S.2d at 847; *see also Mutual Life*, 263 U.S. at 175–76. It is incorrect for this court to refuse to apply the law that the parties have agreed to apply to these contracts. Indeed, my colleagues misdescribe New York contract law, ignoring the district court's citation of authority. The district court correctly applied New York law in holding that the listed patents had been transferred as of June 28, 2006, the Closing Date of the transaction, and that Abraxis had title to the patents when suit was filed. No contrary meaning has been suggested for any of these contracts, and no conflicting law has been cited.

New York law recognizes that correct contract interpretation implements the intent of the contracting parties. *E.g., Greenfield v. Philles Records, Inc.*, 780 N.E.2d 166, 170 (N.Y. 2002) (“The fundamental, neutral precept of contract interpretation is that agreements are construed in accord with the parties’ intent.”). For the contracts before us, there is no uncertainty or indefiniteness or ambiguity. *See id.* (“Extrinsic evidence of the parties’ intent may be considered only if the agreement is ambiguous, which is an issue of law for the courts to decide.”). The district court relied on all of the contract documents, and gave effect to the parties’ intent as stated in the Asset Purchase Agreement and all of the documents. *E.g., Snug Harbor Square Venture v. Never Home Laundry, Inc.*, 675 N.Y.S.2d 365, 366 (App. Div. 1998) (“In construing a contract, the document must be read as a whole to determine the parties’ purpose and intent, giving a practical interpretation to the language employed so that the parties’ reasonable expectations are realized.”).

No evidence of a different intent was offered, nor any plausible theory that the parties intended anything other than transfer of the patents on the Closing Date. The March 15, 2007 documents state that they are effective as of June 28, 2006, “to enable the Transferee to further convey to Buyer that portion of the Transferred Assets” included in the Asset Purchase Agreement, “pursuant to which Transferee agreed to sell to Buyer and Buyer agreed to purchase from Transferee the Transferred Assets, all as more particularly set out in the Purchase Agreement.” The Asset Purchase Agreement states that the “Closing Date,” June 28, 2006, is the effective date for the transaction. As the district court correctly held, this date applies no less to the reparative assignments than it does to the other aspects of this commercial transaction. *See Sunrise Med. HHG, Inc. v. AirSep Corp.*, 95 F. Supp. 2d 348, 436–37 (W.D. Pa. 2000) (“[A] *nunc pro tunc* assignment filed before the filing date of the action with an effective assignment date before the action does effect a valid transfer of rights sufficient to confer standing.”) (citing *Gaia Techs., Inc. v. Reconversion Techs., Inc.*, 93 F.3d 774, 779-80 (Fed. Cir.), amended on reh’g on different grounds, 104 F.3d 1296 (Fed. Cir. 1996)).

By ignoring this clear expression of the parties’ intent, the majority has not given a “practical interpretation” to the agreements, and has failed to realize the parties’ intentions. *Snug Harbor, supra*. The majority has done quite the opposite, engraving a meaning that no party could reasonably or possibly have intended, and holding that despite all of these documents, ownership of these three patents was not transferred until the November 12, 2007 “confirmation” of ownership “since no later than June 28, 2006.”

D

The panel majority states that this court has its own law, derived not from state law but from federal patent policy, in order to prevent litigants from filing suit before they have achieved ownership of the assets they seek to litigate, citing *Enzo APA & Son, Inc. v. Geapag A.G.*, 134 F.3d 1090, 1093 (Fed. Cir. 1998). In *Enzo* the court held that an exclusive license executed after a non-exclusive licensee filed suit did not establish standing at the time of filing, even if the exclusive license is stated to be retroactive. In *Enzo* the court found that there was no indication or evidence of any intention that the license would be exclusive before the suit was filed, despite an alleged oral agreement; thus the court held that the proposed retroactivity of exclusivity did not track an actual intent at the earlier time. *Id.* at 1093 (noting that no written license agreement existed at the time suit was filed). In sharp contrast, for the case at bar the Asset Purchase Agreement and the Intellectual Property Assignment Agreement state the sale of all rights to these patents. The parties intended that these patents would be included in the sale, and they were sold on the Closing Date of June 28, 2006. The reparative assignment documents on March 15, 2007 reflected that which was intended. See *Mas-Hamilton Grp. v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed. Cir. 1998) (distinguishing patentee's *nunc pro tunc* agreement correcting an earlier writing as of the earlier date, from *Enzo*, where a post-filing assignment could not retroactively cure the absence of any written pre-suit agreement). *Enzo* does not affect the district court's ruling under New York law, for here there were explicit written pre-suit sales and transfer agreements.

As mentioned *ante*, the panel majority relies on cases interpreting "promise to assign" disputes, stating that these cases mean that the district court erred in implementing the

Further Assurances provision of the June 28, 2006 Intellectual Property Assignment Agreement. Maj. Op. at 11-12. However, the “promise to assign” cases do not invalidate, and indeed have no relation to this Further Assurances provision, for they relate to the special situation of ownership of future inventions not made at the time of the “promise to assign.” *See, e.g., Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1576 (Fed. Cir. 1991) (disputing rights to an invention that may have been conceived during a consulting project). Issues arising from employment contracts have arisen on a variety of facts, but do not relate even remotely to this case. The majority’s reliance on this class of cases is obscure.

The issue here is not an expectant interest in a future invention, but the effect under New York law of the explicit transfer of existing patents, as in the Intellectual Property Assignment Agreement. Indeed, the cases on which the majority relies do not support its thesis. For example, in *Stanford v. Roche, supra*, the court held that the language “do hereby assign” effected a present assignment, 583 F.3d at 842, although the invention and patent did not exist when the contract was made. Here, in contrast, all of the patents at issue were listed in the Asset Purchase Agreement. And even if this court were to conclude that the transfer required separate remedial assignment documents, these documents were obtained when this suit was filed. Thus standing is established even on the majority’s position.

In addition, as a matter of contract interpretation, Federal Circuit precedent is contrary to the position of the panel majority. For example, in *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1250 (Fed. Cir. 2000) the court explained that the “substance of what was granted” governs the interpretation of contracts, quoting *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 874 (Fed. Cir.

1991). The court in *Speedplay* authorized correcting an error in the patent number in view of the clear intent of the parties, whereby the correction was held retroactive to the date of the contract. As another example, in *Viskase Corp. v. American National Can Co.*, 261 F.3d 1316, 1328–29 (Fed. Cir. 2001), this court held that a patent’s incorrect naming of inventors did not impair the patent owner’s rights and thus did not undermine standing to sue. These rulings, like New York law and all contract law, implement contractual intent.

No evidence of any conflicting intent or purpose has been offered as to the Asset Purchase Agreement and any of the related contracts. All parties to the transaction agree that the patents were sold and transferred to Abraxis as of the Effective Date stated in the agreements. This court’s ruling that the transaction was legally void is negated by all precedent, is contrary to New York law, and is not within any federal exception to state law. The district court correctly ruled that Abraxis had standing to sue when this case was filed. With all respect to my colleagues on this panel, I must dissent from their ruling and their reasoning.¹

¹ Although the court dismisses the case for lack of standing, my colleagues nonetheless also offer remarks that appear to be directed to the merits. However, if there was no standing in the district court, the merits decision is not before this panel for review.