UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA TAMPA DIVISION

MAYO CLINIC JACKSONVILLE, et al.,

Plaintiffs,

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CASE NO.: 8:05-cv-00639-T-23TBM 8:05-cv-01049-T-23TBM

ALZHEIMER'S INSTITUTE OF AMERICA, INC.,

Defendant.

<u>ORDER</u>

The plaintiffs move to dismiss (Doc. 133) counts two and three of the defendant's second amended counterclaim (Doc. 130). Additionally, the defendant moves for leave to join Dr. Todd Golde as a counterclaim defendant (Doc. 117).

Background

On September 13, 1996, the defendant, Alzheimer's Institute of America ("AIA"), granted the plaintiff, Mayo Foundation for Medical Education and Research ("Mayo"), a license in patents owned by AIA.¹ On December 13, 2003, AIA sued in the United States District Court for the District of Kansas and claimed that Mayo infringed AIA's patents. (Doc. 23 in Case No. 8:05-cv-01049) Subsequently, when Mayo sued in

¹ AIA owns U.S. Patent No. 5,455,169 (the '169 patent), which discloses and claims a nucleic acid sequence encoding a mutated form of human amyloid precursor protein or a fragment of the human amyloid precursor protein and a mammalian cell line incorporating the sequence (the "Swedish Mutation cell lines"). In addition, AIA owns U.S. Patent No. 5,795,963 (the '963 patent), which discloses and claims a mutated form of human amyloid precursor protein. (Doc. 145)

Florida state court to compel arbitration, AIA removed the action (Doc. 1).² After removal, Mayo requested (Doc. 25) a stay of AIA's patent infringement action pending arbitration. An October 12, 2005, order (Doc. 40) consolidated the Kansas and Florida actions and stayed the litigation pending arbitration.

The arbitration addressed (1) whether the license includes Mayo's use of "'cell lines' of the patented technology" (Doc. 60-2) and (2) whether Mayo owed AIA compensation under the license agreement for benefits received by Mayo through third-party agreements. The arbitrator found that Mayo's use of cell lines fell outside the scope of the license and that Mayo owed no compensation under the license agreement to AIA for any benefit received by Mayo (Doc. 60-2). After the arbitrator's decision and after resumption of the litigation, AIA filed a counterclaim that included a claim for patent infringement, a claim for breach, a claim for an "equitable interest," and a claim for unjust enrichment (Doc. 71-1). After Mayo moved to dismiss (Doc. 81), the third and fourth counts of AIA's counterclaim were dismissed (Doc. 116) because federal patent law preempts a state law claim premised upon patent infringement.

Count one of AIA's second amended counterclaim (Doc. 130) alleges patent infringement, and count two alleges that, if Mayo infringed AIA's patents, Mayo also breached the license agreement. Count three alleges that Mayo breached the license agreement's "no-challenge" clause, in which Mayo contracted to not "initiate or

² In section 8.03 of the license the parties agreed that "all disputes between them concerning this Agreement, excluding any dispute relating to patent validity or infringement, whether arising before or after Termination, will be settled only according to the mediation and arbitration process described in Exhibit A, attached to and incorporated into this Agreement, and not through any action at law or in equity, except as otherwise provided under Exhibit A." (Doc. 134-2)

voluntarily participate in[] any action" to undermine, invalidate, or declare unenforceable claims of AIA's patents.

Discussion

1. Enforceability of the No-Challenge Clause

Mayo argues that Lear, Inc. v. Adkins, 395 U.S. 653 (1969), bars enforcement of the no-challenge clause because, implementing the "important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain," Lear abrogates licensee estoppel, which bars a patent licensee's challenging the licensed patent. 395 U.S. at 669-71. Observing that the prospective economic gain sufficiently motivates only a licensee to challenge a patent, Lear determines that "federal patent policy prevails over 'the technical requirements of contract doctrine.'" Ransburg Electro-Coating Corp. v. Spiller & Spiller, Inc., 489 F.2d 974, 978 (7th Cir. 1973) (quoting Lear, 395 U.S. at 670); see also Hemstreet v. Spiegel, Inc., 851 F.2d 348, 351 (Fed. Cir. 1988); Pope Mfg. Co. v. Gormully, 144 U.S. 224, 234 (1892) (finding unenforceable a licensee's promise not to challenge the validity of a patent and noting that "[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly ").

A patent by its very nature is affected with a public interest. As recognized by the Constitution, it is a special privilege designed to serve the public purpose of promoting the 'Progress of Science and useful Arts.'... The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope. Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co., 324 U.S. 806, 816 (U.S. 1945). Accordingly, Lear has been interpreted as "establish[ing] that remov[al] [of] restraints on commerce caused by improperly held patents should be considered more important than enforcing promises between contracting parties." <u>Warner-Jenkinson Co. v. Allied Chem. Corp.</u>, 567 F.2d 184, 188 (2nd Cir. 1977); <u>Idaho Potato Comm'n v. M & M Produce Farm & Sales</u>, 335 F.3d 130, 137 (2nd Cir. 2003) ("[C]ourts should weigh the federal policy embodied in the law of intellectual property against even explicit contractual provisions and render unenforceable those provisions that would undermine the public interest.").³ <u>See also Panther Pumps & Equip. Co. v. Hydrocraft, Inc.</u>, 468 F.2d 225, 230-31 & n.15 (7th Cir. 1972) (Stevens, J.) (finding a no-challenge clause in a patent license agreement unenforceable under Lear); <u>Plastic Contact Lens Co. v.</u> <u>W.R.S. Contact Lens Lab., Inc.</u>, 330 F. Supp. 441, 443 (S.D.N.Y. 1970) (finding that a no-challenge clause in a license agreement presented no bar to the defendants' challenging the patent's validity).⁴

³ Critics argue that invalidation of a no-challenge clause erodes a patent holder's liberty to contract, decreases economic efficiency, hurts the patent law's goal of innovation, and renders more difficult the negotiation of a license agreement. <u>See</u> Richard W. Goldstucker, <u>Stop the Bleeding:</u> <u>MedImmune Ends the Unjustified Erosion of Patent Holders' Rights in Patent Licensing Agreements</u>, 16 J. INTELL. PROP. L. 137 (2008); David M. Treadway, Comment, <u>Has the Supreme Court Forgotten the</u> <u>Patentee? Recent Patent Licensing Decisions Contradict Patent Policy, Harm Licensors, and Alter</u> <u>Negotiation</u>, 33 U. DAYTON L. REV. 303 (2008).

⁴ See also Lear, 395 U.S. at 673 (noting that, concerning whether the licensee must pay royalties until the patent is held invalid, "[t]he parties' contract . . . is no more controlling . . . than is the State's doctrine of estoppel, which is also rooted in contract principles."); Pope, 144 U.S. at 235 ("'[N]o man can bind himself by estoppel not to assert a right which the law gives him on reasons of public policy.'") (quoting Crane v. French, 1860 WL 4822 (Miss. Err. App. 1860). But see Sun Studs, Inc. v. ATA Equip. Leasing, Inc., 872 F.2d 978, 991-93 (Fed. Cir. 1989), overruled on other grounds by A.C. Aukerman Co. v. R.L. Chaides Const. Co., 960 F.2d 1020 (Fed. Cir. 1992) (finding no public policy bar under Lear to a contractual promise to "protect, preserve and defend any patents resulting from the consulting contract."); Diamond Scientific Co. v. Ambico, Inc., 848 F.2d 1220, 1224 (Fed. Cir. 1988) (finding no abrogation of (continued...))

Lear, however, "does not grant every licensee in every circumstance the right to challenge the validity of the licensed patent." <u>Gen-Probe Inc. v. Vysis, Inc.</u>, 359 F.3d 1376, 1381 (Fed. Cir. 2004).⁵ For example, <u>Lear</u> permits enforcement of a no-challenge clause in a license agreement entered in settlement of litigation. <u>See</u> HERBERT F. SCHWARTZ, PATENT LAW AND PRACTICE, § 3.I.B n.21 (6th ed. 2008); <u>see also Hemstreet</u>, 851 F.2d at 350-51 (finding that the law favors the settlement of litigation more strongly than the furtherance of federal patent policy); <u>Foster v. Hallco Mfg. Co., Inc.</u>, 947 F.2d 469, 476-77 (Fed. Cir. 1991) (finding no justification in <u>Lear</u> for allowing a challenge to validity if "under normal principles of <u>res judicata</u> applicable to a consent judgment, such challenge would be precluded."); <u>Flex-Foot, Inc. v. CRP, Inc.</u>, 238 F.3d 1362, 1369 (Fed. Cir. 2001) (finding no change after Lear to the rule that a consent decree gives rise to res judicata).

In <u>Flex-Foot</u>, the licensee procured a dismissal with prejudice of the licensor's patent infringement action in exchange for the licensee's covenant not to challenge the validity of the licensor's patent. The settlement agreement, coupled with the dismissal, precluded the licensee from challenging the validity of the patent. 238 F.3d at 1367-68. No bar to licensee estoppel was found under the public policy established in <u>Lear</u> because <u>Lear</u> was distinguishable. For example, the license agreement in <u>Lear</u> resulted

⁴(...continued)

assignor estoppel as a result of <u>Lear</u>); <u>but c.f Beer Nuts, Inc. v. King Nut Co.</u>, 477 F.2d 326, 328-29 (6th Cir. 1973) (distinguishing the public policy of trademarks from the public policy of patents and upholding, under <u>Lear</u>, a written agreement not to challenge the validity of a trademark.).

⁵ Abrogated by <u>MedImmune, Inc. v. Genentech, Inc.</u>, 549 U.S. 118, 128-32 (2007), which held that a licensee need not terminate or breach the license agreement before seeking a declaratory judgment in federal court that the licensed patent is invalid.

neither from a litigation settlement nor a consent decree and contained no express waiver. Furthermore, absent from <u>Lear</u> was a discussion of res judicata and the public interest in settling patent litigation.⁶ 238 F.3d at 1368-69.

Lear stands for the proposition that the law will not infer from a license a bar to a licensee's challenging a patent. However, Lear fails to discuss whether (or under what circumstances) informed persons, acting from positions of substantial parity and benefitting from the advice of counsel, may negotiate a contract that, consequent upon the exchange of a valuable consideration, knowingly, intelligently, explicitly, and voluntarily waives the right to challenge a patent's validity.⁷

⁷ The law frequently permits an individual to waive either a constitutional or a statutory right notwithstanding the strong public interest in preserving the right. See, e.g., United States v. Mezzanatto, 513 U.S. 196, 200-01 (1995) (noting the presumptive ability to waive "a broad array of constitutional and statutory provisions" such as the protection against double jeopardy, compulsory self-incrimination, and the rights to counsel, to a jury trial, to confront an accuser, and to obtain attorney's fees in a civil rights action.); 513 U.S. at 201 ("[A]bsent some affirmative indication of Congress' intent to preclude waiver statutory provisions are subject to waiver by voluntary agreement of the parties."); D.H. Overmyer, Inc. v. Frick, 405 U.S. 174, 185 (1972) ("The due process rights to notice and hearing prior to a civil judgment are subject to waiver."); In re Reed, 161 F.3d 1311, 1316-17 (11th Cir. 1998) ("The most basic rights of criminal defendants are subject to waiver."); In re Garfinkle, 672 F.2d 1340, 1347 (11th Cir. 1982) ("A party may waive any right which it is legally entitled to"); Xerox Corp. v. Media Sciences, Inc., 609 F. Supp. 2d 319, 326 (S.D. N.Y. 2009) ('"Although there is an unquestioned public interest in the 'vigilant enforcement of the antitrust laws through the instrumentality of the private treble-damage action.' this public interest does not prevent the injured party from releasing his claim and foregoing the burden of litigation.'"); Employees Committed for Justice v. Eastman Kodak, 407 F. Supp. 2d 423, 435-36 ("[A]n employee may validly waive a Title VII discrimination claim so long as the waiver is made knowingly and voluntarily."). But see Zedner v. United States, 126 S. Ct. 1976 (2006) (Alito, J.) (holding that the parties lack power to waive the public's interest in a speedy criminal trial).

Lear holds, at most, that the mere existence of a license agreement is insufficient to estop a licensee's challenge to a patent. Lear asserts that the mischief attendant to a party's deploying an invalid patent in the marketplace or enforcing an invalid patent in a court supersedes the typical inference of licensee estoppel. The recognized exception to Lear, the settlement or judicial disposition of litigation, suggests that resort to the court reverses Lear's assessment of the comparative weight of patent policy (continued...)

⁶ "Settlement agreements must be enforced if they are to remain effective as a means for resolving legal disagreements. Upholding the terms of settlement agreements encourages patent owners to agree to settlements and promotes judicial economy." <u>Flex-Foot</u>, 238 F.3d at 1370. <u>See also Foster</u>, 947 F.2d at 477.

In this case, a no-challenge clause in the license agreement purports to prohibit Mayo's challenging the validity of the licensor's patent. The no-challenge clause states that, "MAYO hereby agrees not to initiate or voluntarily participate in, or knowingly permit its Affilliates to initiate or voluntarily participate in, any action directed at undermining, invalidating or declaring unenforceable any claims under the Patent Rights as and if information regarding such Patent Rights is provided by AIA to MAYO in writing." (Doc. 134-2, ¶ 7.02(a)) Because the no-challenge clause is neither part of an agreement reached in settlement of litigation nor the result of a consent decree, federal patent policy may invalidate the clause and permit Mayo to challenge the validity of AIA's patent. However, resolution of that question is unnecessary.

⁷(...continued)

⁽constitutional in origin) and the preservation of contracts (also, constitutional in origin). The pertinent decisions disclose that another policy-the settlement of litigation-decisively vindicates a litigation settlement agreement or "consent decree" that includes an agreement not to challenge the licensed patent. But, neither Lear nor any case decided in consequence of Lear suggests a sound basis in law, fact, or policy to distinguish between, on the one hand, a licensee's waiver in a settlement agreement formalized by the parties a day before litigation otherwise would have occurred (which waiver Lear may reject) and, on the other hand, a licensee's waiver in a settlement agreement formalized a day after litigation began and which agreement is memorialized in a mere moment by court order (and which waiver Lear may accept). A less problematic result follows from focusing the governing distinction not on the occurrence of litigation but on whether the potentially estopped party knew the basis of the alleged invalidity before entering the waiver and whether the parties exchanged a consideration discretely attributable to the prospect of invalidity and waiver (i.e., by focusing on the resolution of a bona fide dispute and not merely on the resolution of a dispute in litigation). In the resolution of a bona fide dispute, both a licensor extending a distinct consideration to avoid an identified risk and a licensee accepting that consideration (e.g., a reduced royalty) should remain bound by the contract-the licensor with a more secure patent but receiving less money and the licensee paying less but unable to challenge. This distinction preserves the public interest in dispute resolution but discourages duplicity and deception. In the present case, both the grounds, if any, to challenge the validity of AIA's patent and the provenance of the waiver remain unspecified. However, in determining the validity of the waiver, this history, unavailable during the determination of a motion to dismiss, might prove most influential.

Even assuming for a moment that federal patent policy permits enforcement of the no-challenge clause, the no-challenge clause, which gravitates against patent policy in a manner reminiscent of Lear, receives the strict construction warranted by a provision that constrains a constitutional, statutory, or other legal right. Applying a strict construction to the no-challenge clause and confining the reach of the clause to that defined by its terms, count three fails to state a claim because the facts of this case present no event of breach of the no-challenge clause. In amended count three of AIA's counterclaims, AIA asserts (Doc. 130, ¶ 31) that Mayo breaches the no-challenge clause by counterclaiming—in Mayo's answer to AIA's counterclaim—for patent invalidity and thereby "initiating" an "action" in violation of the no-challenge clause. AIA's claim fails for several reasons. AIA—not Mayo— "initiated" the claim of patent invalidity by suing Mayo for patent infringement. Mayo has initiated nothing; Mayo merely defends itself. Neither is Mayo "voluntarily participating" in this action. In response to AIA's claim, Mayo asserts both an affirmative defense of invalidity and a defensive counterclaim seeking a declaration of patent invalidity. A counterclaim is a claim within an action, but not itself an action. Also, despite the meaning of the "no-challenge" clause, Mayo undoubtedly remains at liberty to challenge validity by the assertion of an affirmative defense (the traditional method of raising an assertion of invalidity). If intended to bar a challenge to AIA's patent validity, the no-challenge clause is clumsily and ineffectively constructed, omits to preclude even the typical challenge of invalidity by affirmative defense, and overlooks the potential for a

counterclaim. If intended to prevent Mayo's aggressive attack on patent validity, the nochallenge clause perhaps persists, although subject to the vagaries of <u>Lear</u>.⁸

2. Res Judicata

Mayo argues that res judicata bars count two. Res judicata operates when the plaintiff shows that an earlier decision "(1) was rendered by a court of competent jurisdiction; (2) was final; (3) involved the same parties or their privies; and (4) involved the same causes of action." <u>Trustmark Ins. Co. v. ELSU, Inc.</u>, 299 F.3d 1265, 1269 (11th Cir. 2002). "Claims are part of the same 'cause of action' when they 'arise out of the same transaction or series of transactions.'" 299 F.3d at 1269-70 (quoting <u>In re</u> <u>Piper Aircraft Corp.</u>, 244 F.3d 1289, 1296 (11th Cir. 2001)). If the claims derive from the same factual predicate, the claims are the same for the purposes of res judicata. The substance and not the form of the proceedings matters. 299 F.3d at 1270. Thus, the issue is whether the claims arise out of the same transaction or series of transactions and whether the plaintiff ought to have brought the second claim in the plaintiff's first lawsuit. <u>Ragsdale v. Rubbermaid, Inc.</u>, 193 F.3d 1235, 1239 (11th Cir. 1999). "Res judicata acts as a bar not only to the precise legal theory presented in previous

⁸ The notion that a defensive assertion is permissible even if an aggressive assertion is not permissible is exemplified by the treatment of a time-barred compulsory counterclaim. A compulsory counterclaim that is "in the nature of a defense arising out of some feature of the transaction upon which the plaintiff's action is grounded . . . is never barred by the statute of limitations so long as the main action itself is timely." <u>Bull v. United States</u>, 295 U.S. 247, 262 (1935); <u>see also Burlington Indus. v. Milliken & Co.</u>, 690 F.2d 380, 389 (4th Cir. 1982) (finding that "'the institution of plaintiff's suit tolls or suspends the running of the statute of limitations governing a compulsory counterclaim.'"); <u>Builders Supply Co. v. Old World Artisans, Inc.</u>, 702 F. Supp. 1561, 1569 (N.D. Ga. 1988) (noting the distinction between "an affirmative independent cause of action" that must comply with the statute of limitations and a claim that is "in the nature of a defens[e]" and relates back to the date of the original complaint). Thus, notwithstanding the statute of limitations, a defendant is permitted to assert a compulsory counterclaim as long as the counterclaim is equivalent to a defense to the plaintiff's action and is not an independent cause of action seeking affirmative relief. A claim barred by a contract is entitled to no less consideration than a claim barred by a statute.

litigation, but to all legal theories and claims arising out of the same operative nucleus of fact" <u>Pleming v. Universal-Rundel Corp.</u>, 142 F.3d 1354, 1356-57 (11th Cir. 1998).

In the present dispute, count two satisfies the first three elements of res judicata.⁹ As for the fourth element, Mayo contends that res judicata bars count two because AIA failed to raise count two during arbitration along with AIA's other breach of contract claims. In response, AIA argues that arbitration specifically excluded patent infringement and because count two depends on the outcome of AIA's patent infringement claim no opportunity to bring count two existed during arbitration. AIA bases count two's breach of contract claim on a theory of "implied negative covenant."¹⁰ Specifically, the theory is that by granting Mayo a limited privilege to use AIA's patents, Mayo had an implied duty not to exceed the limit of the privilege.

Even though arbitration excluded patent infringement, arbitration specifically addressed whether Mayo's conduct exceeded the scope of the license. Count two of AIA's second amended counterclaim derives from the same nucleus of fact; specifically, whether Mayo's conduct amounts to a breach of the license and entitles AIA to

⁹ <u>See</u> Doc. 133. A January 16, 2009, final order (Doc. 65) confirming the arbitration award involved the same parties as the present case. For purposes of res judicata, if an arbitration proceeding provides the basic elements of adjudicatory procedure, the arbitration order generally receives conclusive treatment in later proceedings. <u>Greenblatt v. Drexel Burnham Lambert, Inc.</u>, 763 F.2d 1352, 1360 (11th Cir. 1985).

¹⁰ Although some jurisdictions recognize an implied negative covenant in a contract, no such duty appears to exist under Florida law. <u>See e.g. Eli Lilly and Co. v. Emisphere Tech., Inc.</u>, 408 F. Supp. 2d 668, 689-90 (S.D. Ind. 2006) (finding breach of license agreement and reasoning that "'[w]hen permission is granted to operate in a restricted area, the acceptance of the privilege implies a condition that the area reserved will not be invaded.'") (quoting <u>Shaw v. E.I. DuPont DeNewmours & Co.</u>, 226 A.2d 903, 909 (1967)).

compensation. By basing count two on patent infringement, AIA attempts to circumvent the arbitration clause and the arbitration order, which explicitly exclude patent infringement. At its core, however, count two is another breach of contract claim arising from the same facts at issue in arbitration. Count two simply presents a different theory of breach. Accordingly, AIA should have included count two in AIA's initial breach of contract claim against Mayo. <u>See Trustmark</u>, 299 F.3d at 1270.

3. Joinder of Dr. Todd Golde

Personal liability for direct infringement may exist for a corporate officer if the facts warrant disregarding the corporate form, or "piercing the corporate veil." See Manville Sales Corp. v. Paramount Sys. Inc., 917 F.2d 544, 552 (Fed. Cir. 1990); but c.f. Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1578-79 (Fed. Cir. 1986) (finding that it is not necessary to pierce the corporate veil before holding a corporate officer personally liable). In addition, personal liability for a corporate officer may arise in other situations. See Hoover Group, Inc. v. Custom Metalcraft, Inc., 84 F.3d 1408, 1411-12 (Fed. Cir. 1996) (a corporate officer is personally liable for the officer's tortious acts just as an individual is liable for a civil wrong); Water Tech. Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988) (an officer that possesses the specific intent to aid and abet another's direct infringement is personally liable for infringement). For example, an officer is personally liable for wrongful conduct on behalf of the corporation if "personal wrongdoing is not supported by legitimate corporate activity." Hoover, 84 F.3d at 1411 (noting the distinction between torts committed in the course of an officer's employment and other culpable wrongful acts).

On the other hand, no authority exists for holding an employee who is not an officer, director, or shareholder of a corporation liable for the corporation's patent infringement. Here, AIA fails to allege that Dr. Golde is an officer, director, or shareholder of Mayo. Furthermore, AIA's motion for leave to join Dr. Golde alleges that Dr. Golde's conduct occurred in Dr. Golde's capacity as a scientist for Mayo. Therefore, there is no basis for holding Dr. Golde personally liable for Mayo's alleged patent infringement.

Conclusion

Accordingly, Mayo's motion to dismiss (Doc. 133) counts two and three of AIA's second amended counterclaim is **GRANTED**. Counts two and three are **DISMISSED WITH PREJUDICE**. In addition, AIA's motion for leave to join a party to AIA's counterclaims (Doc. 117) is **DENIED**.

ORDERED in Tampa, Florida, on November 24, 2009.

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STEVEN D. MERRYDAY UNITED STATES DISTRICT JUDGE