UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 07-12389-RGS

BIO-MIMETICS, INC.

v.

COLUMBIA LABORATORIES, INC.

MEMORANDUM AND ORDER ON
CROSS-MOTIONS FOR SUMMARY JUDGMENT

March 31, 2010

STEARNS, D.J.

On December 28, 2007, Bio-Mimetics, Inc., filed this action for breach of contract against Columbia Laboratories, Inc. (Columbia). The Third Amended Complaint, in addition to breach of contract, asserts claims for correction of inventorship (see 35 U.S.C. § 256), and unfair and deceptive trade practices.[1] Bio-Mimetics has moved for partial summary judgment on the breach of contract claim. Columbia has cross-moved for summary judgment on all claims. The court heard oral argument on the motions on February 1, 2010.

[1]In the original Complaint, Bio-Mimetics asserted claims for unjust enrichment and breach of the covenant of good faith and fair dealing. After a hearing on September 5, 2008, the court dismissed those two claims. On September 19, 2008, Bio-Mimetics filed a Second Amended Complaint in which it added a claim pursuant to 35 U.S.C. § 256 for correction of the inventorship of two of the patents at issue. After Columbia moved to strike the Second Amended Complaint, the court issued an Order allowing Bio-Mimetics to proceed on an unfair trade practices claim pursuant to Mass. Gen. Laws ch. 93A, but only insofar as the claim depended on the new claim for correction of inventorship. However, the court ruled that Bio-Mimetics had failed to adequately plead ownership (or assignee) rights in the subject matter claimed in the two patents. Consequently, on October 27, 2008, the court dismissed the claim for correction of inventorship and the dependent Chapter 93A claim. The court additionally granted Bio-Mimetics leave to file the pending Third Amended Complaint, which it did on November 4, 2008.

BACKGROUND

Bio-Mimetics was founded in 1983 by George Stevens and Professor Joseph R. Robinson, who is now deceased. Professor Robinson pioneered a drug delivery system (BDS technology) that uses cross-linked polymers (principally, polycarbophil) as bioadhesive delivery agents. Robinson's first BDS technology patent issued in 1986 as U.S. Patent No. 4,615,697 (the '697 patent), entitled "Bioadhesive Compositions and Methods of Treatment Therewith."[2]

The BDS technology was the subject of a November 22, 1989 "Asset Purchase, License and Option Agreement" (Agreement), under which Columbia gave Bio-Mimetics $2.2 million worth of debentures in exchange for: (1) all of the assets identified on Schedule 1 of the Agreement;[3] and (2) an undivided one-third interest in certain intellectual property rights identified on Schedule 2 of the Agreement (collectively, the Purchased Assets).[4] Bio-Mimetics additionally granted to Columbia an exclusive license for all of Bio-

[2]In November of 1984, Robinson assigned the application for the '697 patent to Bio-Mimetics. The assignment conveyed to Bio-Mimetics "the entire right, title and interest in the invention or improvements in . . . Bioadhesive Compositions and Methods of Treatment Therewith." The '697 patent discloses BDS technology in which polymers swell in the presence of water, but do not dissolve. Compositions are designed to stick to living tissue (bioadhere) and gradually release a treating agent into the targeted area of the body. The '697 patent, which lists Robinson as the sole inventor, issued on October 7, 1986, and expired on October 7, 2003. The last foreign equivalent of the patent expired on September 26, 2006.

[3]Schedule 1 contained seven Agreements and/or License Agreements entered into by Bio-Mimetics and various for-profit drug companies.

[4]Among other items of intellectual property, Schedule 2 included the '697 patent and another U.S. patent application, filed October 31, 1989, entitled, "Method of Moisturizing Tissue and Composition." The patent application was ultimately issued as U.S. Patent No. 5,474,768 (the '768 patent), entitled "Vaginal Tissue Moisturizing Composition and

Mimetics' assets, "including without limitation, any related technology, know-how and business." Agreement ¶ 2.[5] The Agreement finally granted to Columbia a license covering any "improvements made on, or developments made by Seller with respect to, the patents or any related technology and know-how included in the Two-Thirds Interest." Id.

In addition to the $2.2 million in debentures, the Agreement provided for payment by Columbia of a one-percent royalty on the total net sales of products that were "based on" the Purchased Assets or the Two-Thirds Interest. The Agreement included a "Purchase Royalty Maximum," which related to the Purchased Assets. The Purchase Royalty Maximum was set at $2.45 million. See id. ¶ 3(b). The Agreement additionally provided for a License Royalty Maximum of $5.05 million. See id. The combined amount of the two Royalty Maximums was $7.5 million. Finally, the parties agreed that Bio-Mimetics could terminate the License at-will, subject to Columbia's exercise of an Option to purchase the Two-Thirds Interest for $100,000. (Columbia paid $300,000 at the closing to purchase the Option). The Agreement provided that

> [i]f the Option is exercised, there shall remain due and owing to [Bio-Mimetics], in the form of installment purchase payments in consideration of the transfer of the Two-Thirds Interest, amounts exactly equal to and payable on the same conditions and in the same manner as the License Royalty Maximum provided for in subparagraph 3(b).

Method." The '768 patent issued on December 12, 1995, and it will expire on February 9, 2013. Schedule 2 additionally included "[a]ll technology and know-how presently owned by [Bio-Mimetics], whether patentable or not, which relates to the patents and patent applications set forth above."

[5]The Agreement referred to this licensed material as the "Two-Thirds Interest."

Id. ¶ 6. Paragraph 3(b) provided, in pertinent part,

> [i]f the Option is exercised, [Columbia] shall continue to pay royalty equivalents to [Bio-Mimetics] with respect to the Two-Thirds Interest, subject to the License Royalty Maximum, as further set forth in Paragraph 6.

Id. ¶ 3(b).

Columbia exercised the Option in April of 1991, thereby acquiring the remaining Two-Thirds Interest. In 1993, the parties amended the Agreement to adjust the royalty rate from one percent to two percent of total net sales. The amendment also clarified that "Columbia will be required to pay royalties to Bio-Mimetics of up to a total of $7.5 million (i.e., the sum of the Purchase Royalty Maximum and the License Royalty Maximum), reduced by any payments made by Columbia to Bio-Mimetics under the Original Agreement to date."

Columbia currently markets two products, CRINONE and STRIANT, which according to Bio-Mimetics, use the BDS technology covered by the '697 patent.[6] Columbia paid royalties to Bio-Mimetics on both products until 2006, when the last of the '697 patent's foreign patent equivalents expired. This action followed.

DISCUSSION

[6]CRINONE, a prescription vaginal gel that provides progesterone to women, practices Columbia's U.S. Patent No. 5,543,150 (the '150 patent). STRIANT, a prescription tablet that administers testosterone to men, practices Columbia's U.S. Patent No. 6,248,358 (the '358 patent). The '150 patent claims a method of targeting progesterone to the uterus without it passing through the bloodstream. This is accomplished by vaginal administration. The '358 patent claims a "progressive hydration bioadhesive tablet," protecting an active ingredient (like testosterone) that is sensitive to moisture during the manufacturing process until such time as the tablet is inserted in the cheek. The active ingredient is released as the tablet slowly hydrates over the course of several hours.

Summary judgment is appropriate where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). "A 'genuine' issue is one that could be resolved in favor of either party, and a 'material fact' is one that has the potential of affecting the outcome of the case." Calero-Cerezo v. U.S. Dep't of Justice, 355 F.3d 6, 19 (1st Cir. 2004), citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-250 (1986).

It is undisputed that the Agreement is governed by Delaware law. Under the Delaware rules of contract interpretation, "[u]nambiguous written agreements should be enforced according to their terms, without using extrinsic evidence 'to interpret the intent of the parties, to vary the terms of the contract or to create an ambiguity.'" MBIA Ins. Corp. v. Royal Indem. Co., 426 F.3d 204, 210 (3d Cir. 2005), quoting Eagle Indus., Inc. v. DeVilbiss Health Care, Inc., 702 A.2d 1228, 1232 (Del. Supr. 1997). See also In re Olympic Mills Corp., 333 B.R. 540, 554 (1st Cir. BAP 2005), citing O'Brien v. Progressive N. Ins. Co., 785 A.2d 281, 289 (Del. Super. Ct. 2001) (same).

1. Breach of Contract

The issue with respect to this claim is whether Columbia remained obligated to pay royalties on sales of CRINONE and STRIANT after 2006, when the last of the foreign patents related to the '697 patent expired. While Columbia argues that its obligations were then extinguished, Bio-Mimetics contends that Columbia is obligated to continue to make payments until the cumulative total of $7.5 million is exhausted. Neither party is totally right.

Term of the Agreement

The Agreement provides that it

> shall terminate upon the **earlier of** (a) the payment by [Columbia] to [Bio-Mimetics] of the Purchase Royalty Maximum and License Royalty Maximum [$7.5 million] or (b)[i] the expiration or declared invalidity of all Patents covered by this Agreement, or [ii] fifteen (15) years, whichever is later.

Agreement ¶ 7 (emphasis added). As the plain language of Paragraph 7 states, Columbia is not unconditionally obligated to make payments until the $7.5 million amount is reached. If, before that happens, all of the patents covered by the Agreement are found invalid or have expired, Columbia's payment obligations cease.[7]

Columbia argues that Paragraph 7 of the Agreement is superseded by Paragraph 2, which provides that "[t]he term of the License and/or the obligation to pay royalties with respect to products covered by the License shall be coterminous with the life of the patent(s) which are specific to each such product, or fifteen (15) years, whichever is longer." Id. ¶ 2. Columbia reasons that because the '697 patent has expired, no further "royalties" are due. The court, however, agrees with Bio-Mimetics that Paragraph 7 applies only to the *License*, which became obsolete in 1991, when Columbia exercised the Option to purchase the Two-Thirds Interest. As the only issue here is the Asset Purchase

[7]The fifteen-year term specified in Paragraph 2 is no longer relevant, as the fifteen years expired in 2004.

Agreement, Paragraph 7 controls. This determination, however, does not resolve the issue whether CRINONE and STRIANT fall under the Agreement.[8]

What Are Improvements?

Bio-Mimetics claims that the '150 and '358 patents are "improvements" on the '697 patent and that Columbia is therefore obligated to continue to make payments on sales of CRINONE and STRIANT, notwithstanding the fact that the '697 patent has expired.[9] The Agreement provides that certain future inventions by either party are to be automatically added to Schedule 2. Paragraph 2 states:

> [Bio-Mimetics] and [Columbia] agree that any improvements, whether patented or not, made by either party independently, or jointly between them, related to the technology and know-how of [Bio-Mimetics] forming the basis of this Agreement shall automatically become an addition to Schedule 2. Thus, any patents and any unpatented technology or know-how resulting from such improvements shall provide an ongoing basis for the payment of

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[8]The determination does not offend the principle stated in Brulotte v. Thys Co., 379 U.S. 30, 32 (1964), that a patent owner cannot by private contract extend the statutory life of a patent. In this case, the payments owed by Columbia are not royalties in any conventional sense, given that Columbia exercised the Option to purchase all of Bio-Mimetics' remaining assets. Instead, the payments are more appropriately characterized as "installment purchase payments." As Judge Saris has explained, "royalties in an assignment agreement are properly conceived as deferred consideration for the original conveyance of rights, with the amount of consideration pegged to the commercial success of the product." Baladevon, Inc. v. Abbott Labs., Inc., 871 F. Supp. 89, 96 (D. Mass. 1994).

[9]According to Columbia, the invention disclosed in the '150 patent (marketed as CRINONE) was unrelated to any refinement of Robinson's BDS technology. Rather, Columbia argues, the invention described in the '150 patent addresses a problem faced by women in need of hormone replacement therapy (HRT). Traditional methods that deliver high levels of progesterone through the blood can lead to serious side effects. Columbia (through William Bologna and Howard Levine) discovered that by administering low levels of progesterone to the vagina, the drug travels directly from the vagina to the uterus without entering the bloodstream. The inventors called this the "first uterine pass effect."

> royalties called for under Paragraph 3 of this Agreement. For the purpose of this Agreement, an "improvement" shall mean any modification which does not take the resulting product from outside the intellectual property rights listed on Schedule 2.

The court has previously held that the term "improvement must have . . . a foundation in the originally scheduled intellectual property, whether or not the improvement is separately patentable." Order of Sept. 9, 2009.

Bio-Mimetics argues that CRINONE and STRIANT are both based on the transferred BDS technology. It relies on the affidavit of Professor Edith Mathiowitz of Brown University, who opines that the Schedule 2 technology provided the basis for the '150 and '358 patents because it provides an essential element of each of the later inventions. Professor Mathiowitz notes that both the '150 and '358 patents involve the use of a cross-linked polymer for sustained release bioadhesive drug delivery, and that the '697 patent discloses both vaginal administration (used in the '150 patent) and buccal (cheek) administration (used in the '358 patent). Professor Mathiowitz also opines that the '358 patent has a foundation in Robinson's '768 patent (which is listed on Schedule 2), as it teaches a combination of water-soluble and water-insoluble polymers.

Moreover, the specification of the '150 patent references the '697 patent. It states that "[t]he drug delivery system of the present invention is described in U.S. Pat. No. 4,615,697 to Robinson . . . which is incorporated herein." '150 patent, Col. 5, ll. 24-26. The '358 patent is not so explicit. The '358 patent did, however, claim the benefit of the teaching of a provisional patent application, Ser. No. 60/097,843, filed in August of 1998. The provisional application specifically incorporated the '697 patent.

Bio-Mimetics also points to Columbia's website, which refers to Professor Robinson's BDS technology as the "platform" for Columbia's developments of CRINONE and STRIANT. Even more telling, in referring to CRINONE and STRIANT in its 2002 Annual Report, Columbia stated that

> BDS technology also provides the **technological foundation** for new delivery advantages, including a "first uterine pass effect," which delivers medications directly to the uterus, and a progressive hydration approach, in which a product can deliver medications quickly or gradually, depending on the formulation.

(Emphasis added).

In mounting its defense, Columbia argues that the '697 patent does not mention the first uterine pass effect, which is the main subject of the '150 patent. Nor does the '697 patent mention progesterone. The focus of the '358 patent, Columbia argues, was the development of a system to administer steady doses of testosterone to men as they sleep, when their testosterone levels are low.[10] The '358 patent discloses a process of "progressive hydration," in which the inner core of a tablet is protected from degradation, allowing the treating agent to be released over time as the tablet becomes hydrated. While Columbia concedes that the '358 patent utilizes polycarbophil, it argues that it only does so as part of a novel tablet formulation. Columbia points to the fact that the '697 patent does not discuss the concept of progressively hydrating a tablet, nor does it mention testosterone.

[10]The '358 patent addressed a need to treat, among other conditions, hypogonadism in men, which is characterized by a deficiency or absence of testosterone production.

Turning to the language of the Agreement, Columbia contends that it posits an explicit distinction between innovations constituting improvements, and new inventions. Columbia argues that an "improvement" requires the existence of a direct nexus between the Schedule 2 assets and the inventions claimed by the '150 and '358 patents. Columbia gives an example of what it believes would constitute an improvement: had Columbia modified Robinson's use of the polymers in a drug delivery system to make it a better bioadhesive, or to extend the release of the treating agent over a longer period of time, the resulting invention would have a foundation in Schedule 2. As the court indicated at the hearing, the determination of whether or not CRINONE and STRIANT are founded on the BDS technology is a matter for the jury to resolve.

2. Correction of Inventorship/Unfair Trade Practices

Bio-Mimetics additionally asserts claims for unfair and deceptive trade practices (Count II) and correction of inventorship (Count III).[11] Under 35 U.S.C. § 256,

> Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.
>
> The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be

[11]After Columbia moved to strike Bio-Mimetics' Second Amended Complaint, the court dismissed the correction of inventorship claim because "Bio-Mimetics has failed to adequately plead that it had rights as an owner or assignee in the subject matter claimed in the '150 patent and the '358 patent." Order of Oct. 27, 2008, at 3, citing Kucharczyk v. Regents of Univ. of Cal., 48 F. Supp. 2d 964, 973 (N.D. Cal. 1999). The court additionally held that Bio-Mimetics' claim under Mass. Gen. Laws ch. 93A was limited to the claim for correction of inventorship. Id.

> corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

The Federal Circuit instructs that

> an expectation of ownership of a patent is not a prerequisite for a putative inventor to possess standing to sue to correct inventorship under § 256. The statute imposes no requirement of potential ownership in the patent on those seeking to invoke it. We have previously interpreted § 256 broadly as a "savings provision" to prevent patent rights from being extinguished simply because the inventors are not correctly listed. Pannu v. Iolab Corp., 155 F.3d 1344, 1349 (Fed. Cir. 1998). The same considerations apply here. [Plaintiff] should have the right to assert her interest, both for her own benefit and in the public interest of assuring correct inventorship designations on patents. The interest of both inventors and the public are thus served by a broad interpretation of the statute. [Plaintiff] argues that a reputational interest alone is enough to satisfy the requirements of Article III standing. That assertion is not implausible. After all, being considered an inventor of important subject matter is a mark of success in one's field, comparable to being an author of an important scientific paper.

Chou v. Univ. of Chicago, 254 F.3d 1347, 1358-1359 (Fed. Cir. 2001). Here, Bio-Mimetics has not established that it would have an interest in the '150 and '358 patents, even if it were true that Robinson was the inventor. At oral argument, counsel for Bio-Mimetics raised the possibility of Robinson's estate being substituted to bring a belated claim for correction of inventorship. The clock on further amendments of the Complaint, however, has run.

In any event, Bio-Mimetics has failed to present any facts to defend against Columbia's motion for summary judgment on this issue. Bio-Mimetics' sole theory, wholly unsubstantiated, is the speculation that when Robinson worked at Columbia, he might have been involved in the discovery of the inventions described in the '150 and '358

patents.[12] Bio-Mimetics argues that Columbia has produced none of the usual indicia of inventorship (e.g., laboratory notebooks, research memoranda, or invention disclosure forms) in support of the contention that William Bologna and Howard Levine were the actual inventors. This argument misses the mark. It is not Columbia's burden to prove ownership – that is a burden that rests solely on Bio-Mimetics.

It is too late for Bio-Mimetics to go searching for the missing facts. Fact discovery closed on July 2, 2009, and expert discovery closed on October 6, 2009. Whatever the private understanding that counsel for Bio-Mimetics believes that he has with opposing counsel, no request to extend the discovery deadlines was ever made to the court.[13]

CONCLUSION

For the foregoing reasons, Bio-Mimetics' motion for partial summary judgment is DENIED. The determination of whether Columbia breached the parties' Agreement is

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[12]Bio-Mimetics notes that Robinson co-authored an article with William Bologna (listed as the inventor on the '150 patent) entitled "Vaginal and Reproductive System Treatments Using a Bioadhesive Polymer," which appeared in the Journal of Controlled Release in 1994. Bio-Mimetics argues that Robinson should therefore be named as at least a co-inventor on the '150 and '358 patents.

[13]Bio-Mimetics has filed a motion to preclude the testimony of one of Columbia's proffered experts, Gerald J. Mossinghoff, who served as Commissioner of Patents and Trademarks from 1981 to 1985. The majority of Mossinghoff's report deals with the correction of inventorship issue, a claim that the court will dismiss. With regard to the improvement issue, Mossinghoff states that he reviewed the classifications and searches conducted by Patent Examiners for the '697, '150, and '358 patents (along with 12 other patents issued to Robinson). According to Mossinghoff, there is "practically no overlap" in the classifications by the examiners – an indication that the patent examiners did not consider the subject matter of the '697 patent "to relate to the same general type of products and/or methods as the inventions claimed in Columbia's patents." Mossinghoff Report ¶ 45. Because the jury will decide whether or not to credit Mossinghoff's testimony, the motion is DENIED.

dependent upon the jury's finding whether or not the accused technologies constitute improvements of the BDS technology. Columbia's motion is ALLOWED with respect to Bio-Mimetics' claims for violations of Chapter 93A and correction of inventorship. The motion is DENIED with respect to the claim of breach of contract. A jury trial will commence on Monday, July 12, 2010, at 9:00 a.m. The Clerk will issue a Pretrial Order in due course.

SO ORDERED.

/s/ Richard G. Stearns

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UNITED STATES DISTRICT JUDGE