IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

BONE CARE INTERNATIONAL, LLC and GENZYME CORPORATION,	)	
Plaintiffs,	)	Case No. 08-cv-1083
v.	)	Judge Robert M. Dow, Jr.
PENTECH PHARMACEUTICALS, INC., and COBREK PHARMACEUTICALS, INC.,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

This matter is before the Court on Defendants' motion for summary judgment for attorneys fees based on frivolous suit [641], Defendants' motion to deem admitted certain of Defendants' statements and counter-statements of material facts [642], and Plaintiffs' cross-motion for summary judgment of no exceptional case [259]. For the reasons set forth below, the Court denies all three motions [259, 641, and 642]. This case is set for further status on May 4, 2012, at 9:00 a.m.

I. Background

A. Defendants' Motion to Deem Admitted Certain Fact Statements

When ruling on summary judgment motions, the Court takes all relevant facts from the parties' local rule ("L.R.") 56.1 statements. L.R. 56.1 requires that statements of fact contain allegations of material fact, and that the factual allegations be supported by admissible record evidence. See L.R. 56.1; *Malec v. Sanford,* 191 F.R.D. 581, 583–85 (N.D. Ill. 2000). The Seventh Circuit teaches that a district court has broad discretion to require strict compliance with L.R. 56.1. See, *e.g., Koszola v. Bd. of Educ. of the City of Chicago,* 385 F.3d 1104, 1109 (7th

Cir.2004); *Curran v. Kwon,* 153 F.3d 481, 486 (7th Cir.1998) (citing *Midwest Imports, Ltd. v. Coval,* 71 F.3d 1311, 1317 (7th Cir.1995) (collecting cases)). Where a party has offered a legal conclusion or a statement of fact without offering proper evidentiary support, the Court will not consider the statement. See, *e.g., Malec,* 191 F.R.D. at 583. Additionally, where a party improperly denies a statement of fact by failing to provide adequate or proper record support for the denial, the Court deems admitted that statement of fact. See L.R. 56.1(a), (b)(3) (B); see also *Malec,* 191 F.R.D. at 584. The requirements for a response under Local Rule 56.1 are "not satisfied by evasive denials that do not fairly meet the substance of the material facts asserted." *Bordelon v. Chicago Sch. Reform Bd. of Trs.,* 233 F.3d 524, 528 (7th Cir. 2000). In addition, the Court disregards any additional statements of fact contained in a party's response brief but not in its L.R. 56.1(b)(3)(B) statement of additional facts. See, *e.g., Malec,* 191 F.R.D. at 584 (citing *Midwest Imports,* 71 F.3d at 1317). Similarly, the Court disregards a denial that, although supported by admissible record evidence, does more than negate its opponent's fact statement—that is, it is improper for a party to smuggle new facts into its response to a party's 56.1 statements of fact. See, *e.g., Ciomber v. Coop. Plus, Inc.,* 527 F.3d 635, 643 (7th Cir. 2008).

With these principles in mind, the Court denies Defendants' motion to deem admitted certain of Defendants' statements and counter-statements of material facts. The Court is well aware of what it may consider on summary judgment. In fact, on the Court's web page (see http://www.ilnd.uscourts.gov/home/JudgeInfo.aspx), the Court included among its Case Management Procedures a link for Summary Judgment Local Rule 56.1 Submissions. That link contains the following statement: "Motions to strike all or portions of an opposing party's Local Rule 56.1 submission are disfavored. Under ordinary circumstances, if a party contends that its opponent has included inadmissible evidence, improper argument, or other objectionable

material in a Rule 56.1 submission, the party's argument that the offending material should not be considered should be included in its response or reply brief, not in a separate motion to strike." Defendants have in essence asked the Court to strike Plaintiffs' responses and deem their facts admitted. As with motions to strike, the relief Defendants that have asked for should have been included in its reply brief. The separate motion is unnecessary.

In any event, the Court is capable of disregarding unfounded assertions of fact found in Defendants' statements or Plaintiffs' denials. Any statements or responses that contain legal conclusions or argument, are evasive, contain hearsay or are not based on personal knowledge, are irrelevant, or are not supported by evidence in the record will not be considered by the Court in ruling on Defendants' motion for summary judgment. Consistent with its obligations under the federal and local rules, the Court will rely only on material statements of fact which are both admissible and supported by the record compiled at the summary judgment stage. See Fed. R. Civ. P. 56(e); L.R. 56.1; see also *Davis v. Elec. Ins. Trs.*, 519 F. Supp. 2d 834, 836 (N.D. Ill. 2007); *Lawrence v. Bd. of Election Com'rs of City of Chicago*, 524 F. Supp. 2d 1011, 1014 (N.D. Ill. 2007). To the extent that Plaintiffs' denials are evasive and Defendants' statements are supported by admissible evidence, those statements will be admitted. And to the extent Defendants have put forth legal conclusions in their statements, the Court will disregard the legal conclusions. Defendants' motion to deem facts admitted [642] is denied.

B. Facts

Although a lengthy history exists between the parties in this litigation, the Court sets forth only the facts relevant to the disposition of the cross motions for summary judgment. This case arises under the Hatch-Waxman Act which governs the Food and Drug Administration's approval of new and generic drugs. Plaintiffs Bone Care International, LLC and Genzyme

Corporation (collectively "Plaintiffs"), hold approved New Drug Application ("NDA") No. 021-027 for Hectorol® injectable, which contains the active ingredient doxercalciferol. Plaintiffs have ownership in United States Patent Nos. 6,903,083 ("'083 patent") and 5,602,116 ("'116 patent"). Defendants Pentech Pharmaceuticals, Inc. and Cobrek Pharmaceuticals, Inc. (collectively "Defendants") sought approval of a generic drug by filing Abbreviated New Drug Application ("ANDA") No. 90-040. The ANDA included Paragraph IV certifications that, in Defendants' opinion, the '083 patent and '116 patent are invalid or will not be infringed by the manufacture, use, or sale of its generic drug. See 21 U.S.C. § 355(j)(2)(A)(vii). The filing of Defendants' Paragraph IV certifications constitutes an act of patent infringement (see 35 U.S.C. § 271(e)(2)(A)), and Plaintiffs subsequently filed the instant action alleging infringement of both patents. Defendants filed an answer and included counterclaims seeking, *inter alia*, a declaratory judgment that they did not infringe the '083 patent and that the '083 patent is invalid.

U.S. Patent No. 6,903,083 (the "'083 patent"), assigned to Plaintiff Bone Care International LLC's (and subsequently sold to Genzyme Corporation), has an effective filing date of July 18, 2000. The parties agree that under 35 U.S.C. § 102(b), the one-year statutory bar date for the '083 patent is July 18, 1999.[1] The '083 patent covers a stabilized form of 1α-hydroxyvitamin D_2 ("vitamin D_2"). One of the named inventors of the '083 patent, Dr. Charles Bishop ("Bishop") was Bone Care's President, CEO, and a director) as of July 18, 1999.

Before March 1999, Bone Care acquired twelve lots[2] of vitamin D_2 from Hauser, Inc. ("Hauser").[3] Dr. Bishop admitted under oath that the Hauser lots embodied the claims of the

[1] Although this is a conclusion of law, the Court includes it in the factual background because the parties agreed to the statement and it helps clarify the issues raised in the current motions.

[2] A "lot" is a batch of product that is made in a single production run.

subsequently-filed '083 patent. Dr. Joyce C. Knutson, a co-inventor of the '083 patent, testified that Hauser synthesized the vitamin D_2 material of Example 2 of the '083 patent. Example 2 of the '083 patent is a compound within the claims of the '083 patented invention. According to Dr. Bishop, Bone Care was "stockpiling lots" of vitamin D_2 made by Hauser "for the purposes of commercialization after FDA approval of Bone Care's first NDA." The last five of those nine lots are designated as Lot Nos. K52-K56. As set forth in invoices for Lot Nos. K52-K56, Hauser charged Bone Care $78,100 per lot. Transfers of all five of those lots occurred between October of 1998 and February of 1999, prior to the July 18, 1999 date at issue. Lot Nos. K52-K56 cumulatively contained 33.395 grams of vitamin D_2. The largest single dose of HECTOROL® contains 2.5 µg (micrograms - i.e., 2.5 millionths of a gram) of vitamin D_2. By way of deduction, this would mean that Lot Nos. K52-K56 cumulatively contained several million doses of vitamin D_2.[4]

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[3] Plaintiffs maintain that Hauser did not "sell" lots of vitamin D_2 to Bone Care. Rather, Plaintiffs contend that "title to the lots was never transferred, but instead vested in and remained with Bone Care, and these transactions therefore do not constitute 'sales' under 35 U.S.C. § 102(b)." In support of this position, Bone Care points to its November 10, 1998 contract with Hauser—aptly named the "Supply Agreement," as it goes on to set forth the terms for the exchange of goods and consideration—which states:

> All of the products, exact copies of laboratory notebook pages and supportive data, ideas, information and the like, resulting from services specified in or performed by Hauser pursuant to this Agreement, or prepared for or submitted to [Bone Care] by Hauser under this Agreement shall belong exclusively to [Bone Care] and shall be deemed to be works made for hire.

As set forth in the Analysis section, the Court concludes that this position—which skirts the fact that the "Supply Agreement" was a contract for stated quantities of vitamin D_2 at stated prices—borders on frivolous (and lacks common sense); however, for purposes of setting forth the relevant facts, the Court takes into account Plaintiffs' characterization of how Bone Care acquired vitamin D_2 from Hauser.

[4] Since the cumulative amount of vitamin D_2 in Lot Nos. K52-K56 was 33.395 grams, and the largest single dose of HECTOROL® contains 2.5µg, these lots cumulatively contained the equivalent of 13,358,000 vitamin D_2 doses.

In a letter dated February 10, 1999, Hauser offered[5] Bone Care five additional lots of vitamin D_2 for $99,000 per lot.[6] The offer was for vitamin D_2 having the same specifications as the vitamin D_2 lots in K52-K56. Andrew Morgan, Plaintiffs' Federal Rule of Civil Procedure 30(b)(6) deposition witness, conceded that the letter (specifically, the offer to transfer additional lots at $99,000 per run) constituted an "agreement in principle." Dr. Bishop was copied on the letter from Hauser offering five additional lots. The February 1999 Hauser release control specifications reads identically to the compositional limits of claim 1 of the '083 patent.[7] Dr. Bishop testified that his recollection was that vitamin D_2 embodying the claims of the '083 patent was reduced to practice during the first half of 1998.

The FDA approved Bone Care's NDA No. 20-862 for an oral dosage form of the vitamin D_2 product on June 9, 1999. In October 1999, Bone Care began commercially selling vitamin D_2 under the name HECTOROL®, which contained the vitamin D_2 manufactured by Hauser and acquired by Bone Care prior to July 18, 1999. Bishop admitted that he knew of Bone Care's payments to Hauser (and Hauser's invoices) at the time they were made. Bishop also testified that he knew the potential ramifications of such "transfers," *i.e.*, that they could bar patentability. He further testified that Bone Care's patent attorneys were made aware of the potential ramifications. The Patent Office was never informed of the Hauser transactions.

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[5] Again, Plaintiffs dispute that the letter constituted an "offer to sell."

[6] That would have made a total of 17 commercial-scale lots of the claimed 1α-hydroxyvitamin D_2 that Hauser sold and/or offered to sell to Bone Care.

[7] Despite the fact that Plaintiffs' dispute this fact, the Court concludes that no other reasonable inference can be drawn from the statements set forth in the February 1999 offer letter.

The '083 patent issued on June 7, 2005. In July 2005, Genzyme Corporation acquired[8] Bone Care International, Inc. (and all of its intellectual property, including the '083 patent) for $600 million.[9] Following the acquisition of Bone Care International, Inc. by Genzyme, Bone Care underwent a change of corporate form to become Bone Care International LLC.

Thomas DesRosier, Genzyme's Senior Vice President and General Counsel, made the decision to sue Defendants on the '083 patent. Prior to the acquisition of Bone Care by Genzyme, DesRosier was part of a team that investigated the validity of the '083 patent. Genzyme received a letter in January 2008 from Pentech Pharmaceuticals, Inc. ("Pentech"), notifying Genzyme of the submission of its abbreviated new drug application ("ANDA") seeking the Food and Drug Administration's approval to make a generic version of Genzyme's Hectorol® (doxercalciferol) and purporting to set forth "a detailed statement of the factual and legal bases of Pentech's patent certification regarding the invalidity, unenforceability and/or non-infringement of the claims of the '116, '980 and '083 patents." Pentech's January 8, 2008 letter to Genzyme Corporation did not include any statements regarding the invalidity of the '083 patent and did not mention the Hauser transactions.[10]

Plaintiffs maintain that prior to the commencement of document review and production in this litigation, no officer or decision-maker at Genzyme or Bone Care who was responsible for

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[8] The parties quibble over whether Genzyme acquired or merged with Bone Care. The publicly available documents reflect that Genzyme created a wholly owned merger subsidiary, Macbeth, which merged with Bone Care and Bone Care became the sole surviving and continuing legal entity after the merger. For present purposes, whether it was a merger or an acquisition does not affect the disposition of the pending motions.

[9] Dr. Bishop resigned as President and CEO of Bone Care in July 2001, but he was an officer of the company—namely, executive vice president and chief scientific officer of research and development—when Bone Care was acquired by Genzyme.

[10] Defendants point out that they could not have known the identity of Bone Care's manufacturer, as that information at that time was not publicly available.

this litigation was aware of any issues under 35 U.S.C. § 102(b) concerning the Hauser transactions. According to Plaintiffs, DesRosier first became aware of the documents concerning the Hauser transactions on or around November 2008, as a result of the document collection and review efforts of Fitzpatrick, Cella, Harper & Scinto, which included a review of approximately two million pages of documents and a production of over half a million pages of documents. Defendants contend that, at a minimum, officers and decision-makers at Genzyme and Bone Care possessed constructive knowledge by virtue of Bishop's knowledge. In any event, the parties agree that Plaintiffs have possessed documents relating to Bone Care's transactions with Hauser since Genzyme's acquisition of Bone Care.

Defendants served Plaintiffs with requests for admissions on March 13, 2009, at which time Plaintiffs denied that the Hauser lots embodied claims of the '083 patent or that the Hauser lots were sold or offered for sale prior to the critical date. Because of those denials, Defendants moved for summary judgment as to the validity of the '083 patent on July 23, 2009. However, prior to Defendants filing for summary judgment, on March 13, 2009, Plaintiffs provided Defendants with a covenant not to sue with respect of the '083 patent. Then, on April 28, 2009, the parties executed a consent judgment with respect to Plaintiffs' claims of infringement of the '083 patent in accordance with Plaintiffs' March 13, 2009 covenant not to sue. The consent judgment read as follows: "The parties stipulate that judgment should be entered for Defendants with respect to Plaintiffs' claim of infringement of U.S. Patent No. 6, 903,083 in accordance with the Plaintiffs' March 13, 2009 Covenant Not To Sue on that patent in relation to Defendants' ANDA 90-040." At that time, Plaintiffs did not disclaim the patent or pay attorneys fees as Defendants requested. The Court entered the consent judgment on May 12, 2009. Plaintiffs then disclaimed the '083 patent on August 3, 2009, two days before the Court entertained argument

on Defendants' July 23, 2009 motion. Plaintiffs' disclaimer came only four years into the patent's enforceable term.[11] According to Plaintiffs, Mr. DesRosier decided that the cost of continuing to assert the '083 patent was unsupportable in view of the introduction of a generic competitor to doxercalciferol beginning no later than 2014, and possibly as early as mid-2011.[12]

II. Legal Standard

Summary judgment is proper if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). On cross-motions for summary judgment, the Court construes all facts and inferences "in favor of the party against whom the motion under consideration is made." *In re United Air Lines, Inc.*, 453 F.3d 463, 468 (7th Cir. 2006) (quoting *Kort v. Diversified Collection Servs.*, Inc., 394 F.3d 530, 536 (7th Cir. 2005)); see also *Gross v. PPG Industries, Inc.*, 636 F.3d 884, 888 (7th Cir. 2011); *Foley v. City of Lafayette, Ind.*, 359 F.3d 925, 928 (7th Cir. 2004). To avoid summary judgment, the opposing party must go beyond the pleadings and "set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (internal quotation marks and citation omitted).

A genuine issue of material fact exists if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248. The party seeking summary judgment has the burden of establishing the lack of any genuine issue of material fact. See

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[11] The '083 patent issued on June 7, 2005.

[12] At the time of filing this lawsuit, Plaintiffs faced generic competition from a drug known as "calcitriol." Furthermore, on November 20, 2008, Abbott Laboratories and the Wisconsin Alumni Research Foundation ("WARF") sued Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries Ltd. (collectively, "Teva") in the Northern District of Illinois based upon Teva's submission of an ANDA seeking to market a generic version of Abbott's Zemplar® (paricalcitol). Zemplar® is a competitor to Hectorol® in the market for secondary hyperparathyroidism treatments. According to the pleadings filed in the matter of *Abbott Labs. v. Teva Pharms. USA, Inc.*, Civ. No. 08-6659 (N.D. Ill.), Abbott's and WARF's patents and exclusivities covering paricalcitol will expire in 2014.

Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Summary judgment is proper against "a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Id.* at 322. The non-moving party "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). "The mere existence of a scintilla of evidence in support of the [non-movant's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [non-movant]." *Anderson*, 477 U.S. at 252. "Summary judgment is as appropriate in a patent case as it is in any other case." *C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc.*, 911 F.2d 670, 672 (Fed. Cir. 1990).

III. Analysis

A patent is invalid if, prior to the critical date, the invention was ready for patenting and was the subject of a commercial sale or offer for sale. Defendants contend that the 1998-1999 transactions involving the Hauser lots described in the factual background constitute commercial sales or offers for sale of the invention claimed in the '083 patent—a vitamin D analog known as doxercalciferol or 1α-hydroxyvitamin D_2 that meets particular purity specifications. Defendants further contend that Plaintiff Bone Care and its officer-inventors knew of these sales yet asserted the '083 patent against Defendants anyway. According to Defendants, this renders Plaintiffs' lawsuit against Defendants for infringement of the '083 patent frivolous, justifying an award of attorneys' fees under 35 U.S.C. § 285.

In response, Plaintiffs dispute that the 1998-1999 transactions involving the Hauser lots constitute commercial sales or offers for sale. Plaintiffs also contend that Defendants lack clear and convincing evidence of Plaintiffs' bad faith or gross negligence in suing Defendants on the

'083 patent and instead that the record contains substantial evidence of Plaintiffs' good-faith belief that the '083 patent was valid. Plaintiffs also contend that it would not be grossly unjust for Defendants to bear their own attorneys' fees; rather, it would be unjust for Plaintiffs to bear those fees. The Court first addresses whether the transactions between Bone Care and Hauser constituted commercial sales or offers for sale and then addresses whether Defendants have met their burden in demonstrating that an award of attorneys' fees is appropriate in these circumstances.

A. The Transactions between Bone Care and Hauser

The "on sale" bar provision of 35 U.S.C. § 102(b) precludes an inventor from commercializing his invention for more than a year before he files his application.[13] *In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985). A patent is invalid under the § 102(b) on-sale bar if, prior to the critical date, the invention was ready for patenting and was the subject of a commercial sale or offer for sale. See *In re Cygnus Telecommunications Technology, LLC, Patent Litigation*, 536 F.3d 1343, 1353 (Fed. Cir. 2008) (citing *Pfaff v. Wells Elec., Inc.,* 525 U.S. 55, 67 (1998)). "An invention can be found to be 'ready for patenting' in at least the following ways: by proof that it was reduced to practice, or by proof that the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." *Cargill, Inc. v. Canbra Foods, Ltd.,* 476 F.3d 1359, 1368 (Fed. Cir. 2007); see also *Plumtree Software, Inc. v. Datamize, LLC,* 473 F.3d 1152, 1161 (Fed. Cir. 2006) (noting that an invention is ready for patenting if, among other

[13] The "on sale" bar has the following underlying policies: (1) a policy against removing inventions from the public domain which the public justifiably comes to believe are freely available due to commercialization; (2) a policy favoring prompt and widespread disclosure of inventions to the public; and (3) a policy of giving the inventor a reasonable amount of time following sales activity to determine whether a patent is worthwhile. See *General Electric Co. v. United States,* 654 F.2d 55, 61 (Ct. Cl. 1981).

things, there is "proof of reduction to practice before the critical date."). Further, the transaction at issue must be a "sale" in a commercial law sense. *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1352 (Fed. Cir. 2002). "[A] sale is a contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold." *In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985); see also Trading *Technologies Intern., Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1361 (Fed. Cir. 2010). "Once a defendant demonstrates a *prima facie* case of on-sale * * * the patent holder must come forward with convincing evidence to counter that showing." *U.S. Environmental Products Inc. v. Westall*, 911 F.2d 713, 716 (Fed. Cir. 1990) (internal quotations omitted).

Plaintiffs dispute that the Hauser transactions were, in fact, "sales" under 35 U.S.C. § 102(b). Plaintiffs contend that, based on ¶ 12.1 of the Supply Agreement, legal title to the vitamin D_2 that Hauser produced for Bone Care vested in Bone Care, not Hauser. As a result, when Hauser delivered vitamin D_2 lots to Bone Care in exchange for hundreds of thousands of dollars, that transaction was not a "sale" under U.C.C. § 2-106(1), because there was no "passing of title from the seller to the buyer for a price."

Plaintiffs' argument fails to get out of the gate.[14] The Supply Agreement between the parties clearly was a "contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold." *In re Caveney*, 761 F.2d at 676. The aptly named "Supply Agreement" was for the sale of vitamin D_2 lots to Bone Care (which did not have the capability to manufacture those lots itself) in exchange for hundreds of thousands of dollars. It was not for services rendered (*cf. Trading*

[14] A fine line exists between "creative" arguments made in the face of a dearth of case law or in light of unique set of facts (neither of which exists here) and those arguments that a party should know defy common sense and lack any merit in light of the relevant legal standards. In the Court's view, Plaintiffs' argument that the Hauser transactions were not sales toes that line.

Technologies Intern., Inc., 595 F.3d at 1361) but explicitly set forth terms related to the sale of goods. The contract was for millions of doses of vitamin D_2, which, as one of the inventors of the '083 patent admitted in his deposition, Bone Care was stockpiling "for the purposes of commercialization after FDA approval of Bone Care's first NDA." The transaction clearly was a "sale" in a commercial law sense.

Plaintiffs admit that the Hauser matters were "transactions," and there is no dispute that the vitamin D_2 lots delivered by Hauser to Bone Care were "goods" within the meaning of U.C.C. § 2-103(k). Plaintiffs' contention that "title to the physical [vitamin D_2] product vested immediately" in Bone Care does not mean that a sale did not take place. To "vest" means "[t]o confer ownership of (property) upon a person." BLACK'S LAW DICTIONARY 1157 (Bryan A. Garner ed., 7th ed., West 1999). Even under Plaintiffs' interpretation of the Supply Agreement, Bone Care did not have vested title to the vitamin D_2 until the Supply Agreement was signed, the goods and invoices were delivered, and Bone Care paid for the goods. If title "vested" in Bone Care, it was only after the sale was consummated.

Plaintiffs' only support for their position is ¶ 12.1 of the Supply Agreement. Paragraph 12.1 is the first paragraph under the heading, "12.0 PROPRIETARY RIGHTS," and is entitled "The Company's [*i.e.*, Bone Care's] Rights in Data." These headings suggest that ¶ 12.1 relates to ownership of intellectual property and data. This interpretation is bolstered by the complete text of ¶ 12.1, which provides:

> All of the products, exact copies of laboratory notebook pages and supportive data, ideas, information, and the like, resulting from services specified in or performed by Hauser pursuant to this Agreement, or prepared for or submitted to [Bone Care] by Hauser under this Agreement, shall belong exclusively to [Bone Care] and shall be deemed to be works made for hire. In the event that such works are deemed not to be works made for hire, Hauser hereby irrevocably assigns to [Bone Care], in perpetuity, all right, title, and interest in such works, including, without limitation, copyrights, without further consideration. [Bone

> Care] shall have sole and exclusive right to obtain and hold in its own name all copyrights, patents, registrations, and similar protection which may be available in or with respect to said Final Products, items, etc., and Hauser agrees to give [Bone Care] or its designees all assistance reasonably required to perfect any such rights (including, if requested, execution or separate instruments of assignments and/or patent applications and the like).

Such provisions are commonly found in supply agreements. Bone Care obviously had an interest in owning data, laboratory notebook copies, and other information generated by Hauser pursuant to Hauser's contractual obligations. Moreover, Bone Care had an interest in being legally unencumbered in its ability to reproduce such data/notebooks/information as necessary. Paragraph 12.1 made Bone Care the owner of copyrights in such data/notebooks/information, thereby ensuring that Bone Care had the right to reproduce and publicly distribute those materials. *See* 17 U.S.C. § 106. This clearly is the intent behind, and effect of, ¶ 12.1. The fact that ¶ 12.1 of the Supply Agreement grants Bone Care ownership rights in "all copyrights, patents, registrations, and similar protection which may be available in or with respect to said Final Products," says nothing about whether there was a sale for purposes of 35 U.S.C. § 102(b).

The official comment to U.C.C. § 2-101 ("Sales") casts further doubt on Plaintiffs' position:

> The arrangement of the present Article is in terms of contract for sale and the various steps of its performance. The legal consequences are stated as following directly from the contract and action taken under it without resorting to the idea of when property or title passed or was to pass as being the determining factor. The purpose is to avoid making practical issues between practical men turn upon the location of an intangible something [i.e. title] , the passing of which no man can prove by evidence and to substitute for such abstractions proof of words and actions of a tangible character.

The "tangible character" of the actions taken by Hauser and Bone Care under their Supply Agreement is that Bone Care "purchased" vitamin D_2 for a price and then stockpiled that vitamin D_2 for the purposes of commercialization after the FDA approved Bone Care's first NDA.

Plaintiffs' questionable attempt to spin the transaction another way (in order to avoid a clear finding of invalidity) is unavailing.

Although not necessary to the disposition of whether the 1998-1999 transactions involving the Hauser lots constitute commercial sales or offers for sale of the invention claimed in the '083 patent—as previously indicated, common sense is really all that is necessary—it is worth noting that years before this litigation commenced, Bone Care admitted that it "purchase[d]" vitamin D_2 from outside manufacturers before the critical date. In Bone Care's Form 10-K S.E.C. filing for the fiscal year ending June 30, 1999 (*i.e.*, before the '083 patent critical date), Bone Care admitted:

> We have no internal manufacturing capabilities. We have contracted and intend to contract with others for the production of active pharmaceutical ingredients and for the subsequent manufacturing and packaging of finished drug products. *We purchase Hectorol*[15] from an FDA-inspected and approved supplier.

(footnote and emphasis added). Incidentally, the choice of the word "purchase" in Bone Care's S.E.C. filing was approved by the '083 patent inventors and Bone Care officers Mazess and Bishop, who signed and attested to the report.

As evidenced by invoices for sales of the last five Hauser lots (Lot Nos. K52-K56), each of which was sold for $78,100, these sales were made between October of 1998 and February of 1999, prior to the July 18, 1999 '083 patent critical date. Each lot was commercial in scale and intended for commercial resale. In fact, at least some of the Hauser lots ultimately were used in Plaintiffs' HECTOROL®, purchased by patients after FDA approval. Accordingly, the sales of Lot Nos. 52-56 were anticipating sales within the meaning of § 102(b). Any one of these sales renders the '083 patent invalid. In short, Defendants have demonstrated a *prima facie* case that the Hauser sales anticipated the '083 patent. The only "evidence" that Plaintiffs offer in rebuttal

[15] "Hectorol" was the trademark adopted by Bone Care for vitamin D_2. (C.F.S. No. 3).

is an implausible interpretation of ¶ 12.1 of the Supply Agreement between Hauser and Bone Care. Plaintiffs submit no other "facts" to support their position that title to the vitamin D_2 vested immediately from Hauser to Bone Care upon signing, such that the transactions were not "sales" under 35 U.S.C. § 102(b). Accordingly, the Court concludes that the Hauser "transactions" were sales invalidating the '083 patent as a matter of law.[16]

Plaintiffs also contend that there are disputed issues of fact regarding Hauser's offer to sell five additional lots of vitamin D_2 to Bone Care, as embodied in a February 10, 1999 letter. In support of their position, Plaintiffs point out that the terms "sell" or "sale" are not used in the offer letter and that the letter does not set forth the purity specifications for the vitamin D_2 that is the subject of the offer letter. Thus, Plaintiffs claim that there could not have been a formal offer for the sale of the later-patented vitamin D_2. This argument also fails. The English language is capable of expressing "sale" in many other ways. Synonymous terms, such as "price" and "supply," are used in the offer letter. The offer letter also sets a price of $99,000 for each of the five additional production lots of vitamin D_2. The relevant question is whether Hauser's offer letter evinces a "manifestation of willingness to enter into a bargain, so made as to justify [Bone Care] in understanding that [its] assent to that bargain is invited and will conclude it." *Linear Technology Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1050 (Fed. Cir. 2001) (quoting *Restatement*

[16] For the sake of completeness, the Court also notes that the Federal Circuit *does not* recognize a "supplier" exception to the on-sale bar "that * * * allow[s] inventors to stockpile commercial embodiments * * * via commercial contracts with suppliers more than a year before they file their patent application." *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1354 (Fed. Cir. 2001). In *Special Devices*, the court explained that "it does not matter who places the invention 'on sale'; it only matters that someone—inventor, supplier or other third party—placed it on sale." *Id*. at 1355 (patent-in-suit invalid because patented invention was subject of three commercial scale sales from a supplier to the patentee before the critical date). Thus, it does not matter that the Hauser sales were between a supplier (Hauser) and the patentee (Bone Care). *Id*.; see also *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 182 F.3d 888 (Fed. Cir. 1999) (invalidating patent-in-suit based on pre-critical date sales from supplier to patentee); *Zacharin v. U.S.*, 213 F.3d 1366 (Fed. Cir. 2000) (same).

(Second) of Contracts § 24 (1981)). Under that standard, the offer letter represents a pre-critical date commercial offer for the sale of vitamin D_2 and Plaintiffs have provided no reasonable inference to the contrary. Thus, Hauser's February 1999 offer to sell Bone Care five additional lots of the claimed vitamin D_2 at $99,000 per lot is an invalidating offer for sale.

B. Attorneys' Fees in Frivolous Suits

A district court has discretion to award reasonable attorney fees to a prevailing party in a patent case if the court determines that the case is "exceptional." 35 U.S.C. § 285. However, this discretion is not unbridled. *MarcTec, LLC v. Johnson & Johnson*, 664 F.3d 907, 915-16 (Fed. Cir. 2012); *Old Reliable Wholesale, Inc. v. Cornell Corp.,* 635 F.3d 539, 543 (Fed. Cir. 2011) (citing *Wedgetail, Ltd. v. Huddleston Deluxe, Inc.,* 576 F.3d 1302, 1304 (Fed. Cir. 2009)). Given the "substantial economic and reputational impact" of an award of attorney fees, an award of attorneys' fees is the exception, not the rule. *Id.* (quoting *Medtronic Navigation, Inc. v. BrainLAB Medizinische Computersysteme GmbH,* 603 F.3d 943, 953 (Fed. Cir. 2010)); see also *Wedgetail,* 576 F.3d at 1304. Deciding whether to award attorney fees under § 285 requires a two-step inquiry. First, the court must determine whether the prevailing party has proved by clear and convincing evidence that the case is exceptional. *Forest Labs., Inc. v. Abbott Labs.,* 339 F.3d 1324, 1327 (Fed. Cir. 2003); see also *Aspex Eyewear Inc. v. Clariti Eyewear, Inc.,* 605 F.3d 1305, 1314 (Fed. Cir. 2010) ("The party seeking attorney fees under § 285 must establish, by clear and convincing evidence, that the case is exceptional."). If a court finds that the case is exceptional, it must then determine whether an award of attorney fees is justified. *Cybor Corp. v. FAS Techs. Inc.,* 138 F.3d 1448, 1460 (Fed. Cir. 1998) (en banc).

A case may be deemed exceptional under § 285 where there has been a frivolous suit or willful infringement, fraud or inequitable conduct in procuring the patent, misconduct during

litigation, vexatious or unjustified litigation, conduct that violates Federal Rule of Civil Procedure 11, or like infractions. *Serio–US Indus., Inc. v. Plastic Recovery Techs. Corp.,* 459 F.3d 1311, 1321–22 (Fed. Cir. 2006); see also *Forest Labs, Inc.*, 339 F.3d at 1329. Where, as here, the alleged infringer prevails in the underlying action (in this instance, by way of a consent judgment), factors relevant to determining whether a case is exceptional include "the closeness of the question, pre-filing investigation and discussions with the defendant, and litigation behavior." *Computer Docking Station Corp. v. Dell, Inc.,* 519 F.3d 1366, 1379 (Fed. Cir. 2008). Where a patentee "prolongs litigation in bad faith, an exceptional finding may be warranted." *Id.*

A frivolous infringement suit is "one which the patentee knew or, on reasonable investigation, should have known, was baseless." *Haynes Intern., Inc. v. Jessop Steel Co.*, 8 F.3d 1573, 1579 (Fed. Cir. 1993). Defendants contend that the '083 patent suit was frivolous because Bone Care knew, and Genzyme at least should have known, of the '083 patent's invalidity. In turn, Plaintiffs allege that they could not have known of the patent's invalidity because (1) the actors involved in the Hauser sales left Bone Care before this law suit; (2) Bone Care's management changed; and (3) Bone Care underwent a "change of corporate form."

Plaintiffs contend that they were entitled to rely upon the statutory presumption under 35 U.S.C. § 282 that the '083 patent was valid, absent any actual knowledge of its invalidity at the time that they sued Defendants. See *Q-Pharma Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1303-04 (Fed. Cir. 2004); *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1372-73 (Fed. Cir. 2003) (in light of patent's presumed validity, and absence of bad faith by the patentee, there was no basis for deeming the infringement action exceptional); *Brooks Furniture Mfg., Inc. v. Dutailier Int'l Inc.,* 393 F.3d 1378, 1382 (Fed. Cir. 2005) (once the PTO has issued a patent, "[t]here is a presumption that the assertion of infringement of a duly granted patent is made in

good faith"). Unfortunately, what was known to Plaintiffs at the time they sued Defendants is murky at best.[17]

What is obvious is that Dr. Bishop understood generally that commercial sales or offers for sale may bar patentability under 35 U.S.C. § 102(b) and that he had concerns about the Hauser transactions. Plaintiffs contend that Dr. Bishop nevertheless believed that the Hauser transactions did not constitute such potentially invalidating commercial sales or offers for sale, but the Court is not persuaded that the record reflects that view. Rather, the Court's review of Dr. Bishop's deposition testimony suggests that he was aware of the problem and alerted Bone Care's attorneys to the potential ramifications. In an effort to distance themselves from Dr. Bishop's concessions, Plaintiffs highlight that Dr. Bishop resigned as President and CEO of Bone Care in July 2001. What Plaintiffs sidestep is that Dr. Bishop was an officer of the company—namely, executive vice president and chief scientific officer of research and development—when Bone Care was acquired by Genzyme.

Plaintiffs also point out that Genzyme Corporation conducted due diligence on the '083 patent and purchased the '083 patent, along with BCI's other intellectual property, for multiple millions of dollars. Plaintiffs suggest that this evidence militates against any finding that Plaintiffs possessed sufficient knowledge to question the validity of the '083 patent. However, the evidence just as easily cuts the other way. The Court has difficulty imagining that a corporation as sophisticated as Genzyme could have documents in its possession that would lead even a novice patent lawyer to question the validity of the '083 patent and yet no cause for concern was raised prior to consummating a $600 million transaction. At a minimum, given the

[17] At a fairly early stage of this case, the parties – with the Court's consent – concentrated this litigation on the issues relating to the '116 patent. The Court's consideration of this long-deferred motion brings back into focus the relatively underdeveloped state of the record concerning the '083 patent, at least as it relates to the matters for decision by the Court.

money at stake, it would have seemed prudent for those charged with Genzyme's due diligence to have read Bone Care's annual reports to the S.E.C., where, among other things, Bone Care admitted that before June 30, 1999, it had been purchasing vitamin D_2 from a manufacturer because Bone Care did not have manufacturing facilities of its own. That same annual report shows a large increase in "inventory" from a year earlier—seemingly another red flag for Genzyme's due diligence team. Even without looking at the internal Bone Care documents that relate to Bone Care's transactions with Hauser—which Plaintiffs have had in their possession since Genzyme's acquisition of Bone Care—these red flags belie Plaintiffs' assertions that they simply had no idea of the invalidating sales.

Mr. DesRosier's explanation for why Plaintiffs wanted to withdraw the '083 patent from this suit also raises concerns. Mr. DesRosier claims that because generic competition from another product would come in 2014 and because the '116 patent in this suit would expire in the same year, it was not financially worthwhile to continue suit on the '083 patent after early 2009. Plaintiffs' justification fails to account for a few variables that existed at the time suit was filed. First, Plaintiffs already faced generic competition from a drug known as calcitriol at the time suit was filed. Plaintiffs also must have known about the 2014 dates prior to filing suit, as those dates were public information. Mr. DesRosier does not explain what changed after suit was filed in February 2008 to lead him to conclude a few months later that asserting the '083 patent was no longer a worthy endeavor. If 2014 were a critical date, then Genzyme could have disclaimed only that portion of the '083 patent that extended beyond that time. The more plausible explanation relates to the Hauser sales, of which Mr. DesRosier claims he first learned in November 2008.

Furthermore, what knowledge Bishop possessed of the Hauser sales, as well as Bone Care's corporate records memorializing those sales, generally can be imputed to Bone Care and its directors. See *In re Hellenic Inc.*, 252 F.3d 391, 395 (5th Cir. 2001) (noting that "courts generally agree that the knowledge of directors or key officers, such as the president and vice president, is imputed to the corporation"); *United States v. One Parcel of Land Located at 7326 Highway 45 N.,* 965 F.2d 311, 316 (7th Cir. 1992) (under Illinois common law, the knowledge of an officer, director, or agent is imputed to the corporation if the person with knowledge is acting within the scope of his employment at the time and "at least in part with the intent to benefit the corporation."); see also *Cement-Lock v. Gas Technology Institute*, 618 F.Supp.2d 856, 891 (N.D. Ill. 2009) (same). Thus, Plaintiffs' claim that Bishop's resignation as President and CEO of Bone Care in 2001 occurred "long before Plaintiffs decided to sue Defendants" not only fails legally, but it also is factually inaccurate because, as noted above, Bishop was an officer of Bone Care in 2005 when Genzyme acquired the company. Furthermore, in addition to Bishop's personal knowledge, the Hauser sales are part of Bone Care's corporate history and are evidenced by company records that did not disappear with Bone Care's alleged management changes or transition from a corporation to an LLC.

The concerns addressed above are only bolstered by Plaintiffs' litigation conduct. Instead of disclaiming the '083 patent immediately and calling a halt to a massive document production, they produced more than 500,000 documents, the vast majority of which related to the '083 patent, and forced Defendants to produce approximately 86,000 documents of their own. Saddling Defendants with so many documents that Plaintiffs knew at the time of document production would become clearly irrelevant when the '083 patent was withdrawn weighs heavily

against a finding of good faith on the part of Plaintiffs. Plaintiffs' counsel has handled many large patent cases and obviously knows how expensive document review can be.

Plaintiffs' attempt to portray themselves as victims of Defendants' refusal to regard the '083 patent as water under the bridge also paints them in a bad light. Notwithstanding Plaintiffs' underwhelming arguments regarding whether the Hauser sales were actually "sales," the Hauser sales clearly were invalidating. Mr. DesRosier knew this upon learning of those sales, allegedly as late as November of 2008, even though he should have known about them (by his own due diligence standards) in 2005. It then took him until August of 2009 to disclaim the '083 patent, only after the avalanche of discovery served on Defendants. If Plaintiffs had come clean in November of 2008, and disclaimed the '083 patent at that time and relieved both parties of an enormous document production and discovery effort, the attorneys' fees issue may have been avoided. Instead, Plaintiffs' kept the '083 patent case alive by delivering more than half-a-million production documents to Defendants and demanding over 86,000 documents while refusing to admit to the invalidity of the '083 patent in light of clear evidence to the contrary. In fact, they still maintain that the '083 patent is not invalid, on the basis of an untenable argument.

At this stage, inference upon inference favors Defendants. However, Defendants also face a steep burden in proving that they are entitled to attorneys' fees in a patent suit. Plaintiffs contend that Bishop's appreciation of the significance of the Hauser sales is an unresolved issue of fact. The Court agrees, but only because the burden on Defendants in demonstrating an exceptional case is so high. Bishop testified that, at the time of the Hauser sales, he was aware of the on-sale bar concept and that he knew that the Hauser sales occurred more than one year before the '083 patent's filing date. He also regarded the Hauser sales as important enough to inform Bone Care's patent counsel about them. At a minimum, Defendants should be given

leave to explore through further discovery exactly what Bishop knew and when and to whom he conveyed the information. Defendants also should be allowed to explore the questions left answered by Mr. DesRosier's affidavit. While his affidavit casts some doubt on Defendants' assertions of bad faith, his reasoning is too convenient—and too simplistic given what was at stake—to accept without further exploration.

Given the sophistication of the parties at issue in this lawsuit and the hundreds of millions of dollars at stake in acquiring and holding on to patents and the additional money at stake in acquiring or merging with other companies, it may well be the case that Plaintiffs either knew that the '083 patent was invalid at the time they filed suit (and certainly shortly after they filed suit but before they disclaimed the patent) or they should have known but for their own gross negligence. Unfortunately, at this time, the Court cannot conclude one way or another whether Defendants have presented *clear and convincing* evidence as to Plaintiffs' knowledge or conduct. Thus, the Court concludes that summary judgment is not appropriate for either side at this juncture in view of (1) the underdeveloped state of the record and (2) the heightened standard of proof that applies to the matter in dispute.

Litigation regarding the '083 patent was pushed to the side so that the parties could focus on the '116 patent. The Court now has resolved the issues related to the '116 patent and had hoped to resolve the remaining issues presented by the '083 patent. Unfortunately, there simply are too many holes to do so. To the extent that the parties desire to attempt to settle the issues related to attorneys fees on the '083 patent, the Court will make its resources available toward that end. Otherwise, the Court believes additional discovery will be necessary—particularly with respect to what Dr. Bishop and Mr. DesRosier knew about the '083 patent and prior invalidating sales and when they knew it, and perhaps with respect to what other officers and directors of

Plaintiffs knew and when. After that information is elicited, the parties may again present (at summary judgment or trial) the issue of whether this is an exceptional case warranting an award of attorneys' fees.

IV. Conclusion

For the reasons set forth above, the Court denies Defendants' motion for summary judgment for attorneys fees based on frivolous suit [641], Defendants' motion to deem admitted certain of Defendants' statements and counter-statements of material facts [642], and Plaintiffs' cross-motion for summary judgment of no exceptional case [259]. This case is set for further status hearing on May 4, 2012 at 9:00 a.m.

Dated: March 29, 2012

Robert M. Dow, Jr.
United States District Judge