



## **II. FINDINGS OF FACT**

EUSA and Innocoll are pharmaceutical companies. (Hr'g Tr. 5, 149, Oct. 2, 2008 [hereinafter "10/2 Hr'g Tr."]). EUSA specializes in pain control and cancer management drugs. (10/2 Hr'g Tr. 5.) Innocoll specializes in pharmaceutical products that utilize collagen. (10/2 Hr'g Tr. 149.) This case concerns the CollaRx<sup>®</sup> Bupivacaine Implant ("B-Implant") being developed by Innocoll. EUSA currently has an option to buy the exclusive license to commercialize the B-Implant in the United States. (Pl.'s Ex. 8.) Before it can be commercially profitable, however, the U.S. Food and Drug Administration ("FDA") must approve the B-Implant for use in the U.S. (10/2 Hr'g Tr. 9.)

### **A. The FDA Approval Process**

For a drug to receive FDA approval, the company requesting approval (called a "sponsor") must conduct clinical trials to establish safety and efficacy. (see 10/2 Hr'g Tr. 81-84.) Once clinical trials are complete, the sponsor submits to the FDA a New Drug Application ("NDA") with supporting clinical data. (10/2 Hr'g Tr. 83.) The FDA decides whether to grant approval based on this NDA. (10/2 Hr'g Tr. 83-84.) Thus, the process of developing a drug for the U.S. focuses on putting together a strong NDA with compelling clinical data.

Federal regulations govern how a sponsor may conduct clinical trials. See 21 C.F.R. §§ 312.1 et seq. Before a sponsor may begin a clinical trial on human subjects, two requirements must be satisfied. (10/2 Hr'g Tr. 81.) First, the sponsor must submit to the FDA an Investigational New Drug Application ("IND"). 21 C.F.R. § 312.20(a). Second, an

Investigational Review Board must approve the trial after reviewing its protocol and past clinical trials on animals. (10/2 Hr'g Tr. 81.)

With regard to the clinical trial process, “[t]he clinical investigation of a previously untested drug is generally divided into three phases. Although in general the phases are conducted sequentially, they may overlap.” 21 C.F.R. § 312.21. A Phase I clinical trial involves few patients (usually from 10 to 20) and primarily measures safety. (10/2 Hr'g Tr. 81-82.) A Phase II clinical trial involves more patients (usually from 100 to 200) and primarily measures efficacy.<sup>1</sup> (10/2 Hr'g Tr. 82.) Specifically, a Phase II trial measures how patients respond to a drug at various doses for a given indication (i.e., circumstance in which the drug may be used for treatment). (10/2 Hr'g Tr. 36-37.) In this way, the sponsor tries to determine as closely as possible the optimal dose<sup>2</sup> or range of doses for that indication.<sup>3</sup> Id. A Phase III clinical trial involves many more patients (usually up to several thousand) and aims to produce compelling clinical data for the NDA. (10/2 Hr'g Tr. 36-37, 83.) In Phase III, the sponsor gives enough patients the optimal dose or range of doses determined from Phase II data to establish a high

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<sup>1</sup> Here, “efficacy” means “the ability of a drug to produce the desired therapeutic effect.” Dorland’s Illustrated Medical Dictionary 602 (31st ed. 2007).

<sup>2</sup> Here, “optimal dose” means “the quantity of an agent that will produce the desired effect without other unfavorable effects.” Dorland’s Illustrated Medical Dictionary 571 (31st ed. 2007).

<sup>3</sup> According to federal regulations, “Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug.” 21 C.F.R. § 312.21(b).

likelihood that the drug will be safe and effective when prescribed by doctors.<sup>4</sup> (10/2 Hr’g Tr. 37, 83.)

During this process, a sponsor may request three types of meetings with the FDA. (10/2 Hr’g Tr. 83.) A “Type A” meeting may be requested when a dispute arises between the sponsor and the FDA. (10/2 Hr’g Tr. 85.) A “Type B” meeting may be requested after Phase II to seek guidance from the FDA on how best to proceed with Phase III. Id. Sponsors normally request Type B meetings before designing a Phase III trial. Id. A “Type C” meeting is neither Type A nor B and can be requested at any time. (10/2 Hr’g Tr. 85-86.)

No drug being developed has a 100 percent chance of getting FDA approval and becoming commercially available. (10/2 Hr’g Tr. 27.) According to accepted wisdom in the pharmaceutical industry, however, drugs have an increasingly higher chance of success after each phase of clinical trials. (10/2 Hr’g Tr. 24, 26-27.) During the hearing in this case, a credible witness testified as follows: “[O]bviously in Phase I, the chance of making it are very low, five to ten percent. ... In Phase II, then it’s tens of percent. And at the end of Phase III ... you might get up into the 50 to 70 percent.” (10/2 Hr’g Tr. 26.)

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<sup>4</sup> According to federal regulations, “Phase 3 studies are ... performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.” 21 C.F.R. § 312.21(c).

**B. The B-Implant**

The B-Implant is a novel innovation in post-surgical pain relief. (10/2 Hr’g Tr. 50-53, 152.) It is a collagen<sup>5</sup> sponge impregnated with bupivacaine hydrochloride, a known anesthetic, that a doctor implants inside a patient to provide local anesthesia after surgery. (10/2 Hr’g Tr. 13-14, 150-151.) Once the sponge delivers the medicine, the collagen degrades and becomes indistinguishable from human collagen already inside the body. (10/2 Hr’g Tr. 150.) If the B-Implant becomes commercially available, it could reduce the need for doctors to prescribe opiates such as morphine and OxyContin for post-surgical pain relief. (10/2 Hr’g Tr. 152.)

In a Phase I trial, Innocoll administered the B-Implant to 12 patients who had each undergone a hysterectomy. (10/2 Hr’g Tr. 82.) On February 28, 2007, Innocoll submitted to the FDA an IND for Phase II clinical trials on post-hysterectomy and other post-surgery patients. (Pl.’s Ex. 14.) The document indicates that Phase III trials would occur only after Phase II was completed.<sup>6</sup> (Pl.’s Ex. 14 §§ 4.1.3, 4.1.4.2, 4.1.5.) Currently, Phase II trials for the B-Implant are ongoing. (10/2 Hr’g Tr. 95.)

**C. The Parties’ Negotiations**

In Spring 2007, Bryan Morton (“Morton”), the chief executive officer of EUSA and of EUSA Pharma (Europe) Limited (“EUSA/Europe”), had a meeting with Dr. Michael Myers

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<sup>5</sup> Collagen is a protein found in humans and some animals. (10/2 Hr’g Tr. 149-50.) Innocoll primarily uses bovine collagen. (10/2 Hr’g Tr. 150.)

<sup>6</sup> For instance, the IND stated that for “[t]he Phase 3 clinical program ... [t]he patient population and specific study design will be determined based on the results of the Phase 2 studies.” (Pl.’s Ex. 14 § 4.1.4.2.)

(“Myers”), the chief executive officer of Innocoll. (10/2 Hr’g Tr. 12.) Based on this meeting and on subsequent discussions, EUSA/Europe became interested in purchasing the B-Implant and other products owned by Innocoll. (10/2 Hr’g Tr. 12-13.) Innocoll and EUSA/Europe exchanged proposals that contemplated EUSA/Europe buying, among other things, an option to purchase the exclusive license to commercialize the B-Implant in the U.S. (“Option”). (10/2 Hr’g Tr. 17-18.)

In June 2007, Morton and Myers had several communications in which they negotiated the terms of the Option. (Pl.’s Exs. 1-6.) On June 12, 2007, Morton sent Myers a term sheet that proposed a \$10 million payment upon exercising the Option plus milestone payments upon FDA approval and commercial sales. (Pl.’s Ex. 2.) On June 13, 2007, Myers responded with an email that requested a \$20 million exercise payment and different milestone payments. (Pl.’s Ex. 1.) Myers added: “We will need to put an expiration date on the call option otherwise Innocoll could be hampered in it’s [*sic*] effort to achieve a major funding event.” Id. Later that day, Morton and Myers had a telephone conversation in which Morton stressed EUSA/Europe’s need for clinical data on the B-Implant such that before exercising the Option EUSA/Europe could evaluate the B-Implant and calculate the risks involved. (10/2 Hr’g Tr. 23.) Thus, Morton proposed having the Option expire thirty days after EUSA/Europe received Phase III data. Id. After this conversation, Morton sent an email that proposed a \$15 million exercise payment, accepted the milestone payments that Myers had requested, and stated: “Exercise term expires once PIII data

[Phase III data] analysis has been reviewed by the JSC [Joint Steering Committee] plus one month from that date.”<sup>7</sup> (Pl.’s Ex. 3.)

At this point, the only outstanding issue was the Option’s expiration date. (Pl.’s Ex. 4.)

On June 14, 2007, Myers sent an email to Morton, stating:

There is no support for giving you a free call option on bupivacaine [*sic*] for the US until the end of Phase 3. I can offer it to you free of charge until the end of the first Phase 2 study. Alternatively, it can be extended to the end of Phase 3 as requested for a payment of \$7.5 million ... on signing this deal.

Id. The same day, Morton replied by email: “I cannot live with what you propose. I propose [that] a \$5m total payment at end of Phase 2 keeps the option alive until Phase 3 data are analyzed (plus the month).” (Pl.’s Ex. 5.) On June 16, 2007, Myers responded with the following counteroffer:

If EUSA will support Phase 2 program to the amount of \$1.5 million and, once the option is exercised, contribute 50% of the costs, upto [*sic*] a maximum of \$5 million, to an agreed Phase 3 program, we will agree to your proposal to the [*sic*] extend the option until the first patient is dosed in the Phase 3 study.

(Pl.’s Ex. 6.) Later that day, Morton accepted Myers’s counteroffer by email, thereby concluding negotiations. Id. Throughout this process, both EUSA/Europe and Innocoll expected that clinical studies for the B-Implant would proceed sequentially, meaning that Phase III would not begin until Phase II was completed. (10/2 Hr’g Tr. 30, 159-60.)

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<sup>7</sup> Morton and Myers understood that EUSA/Europe would be represented on the Joint Steering Committee. See infra § II.D.

**D. The Agreement**

On August 22, 2007, EUSA/Europe and Innocoll executed the Commercialization, Development, and License Agreement (“Agreement”). (Pl.’s Ex. 7 [hereinafter “Agr’m.”].) Under the Agreement, EUSA/Europe received the Option and a right of first refusal to the exclusive license to commercialize the B-Implant in the U.S. (“Right of First Refusal”).<sup>8</sup> Agr’m. §§ 2.4-2.5. Around the same time, EUSA/Europe assigned the Option and Right of First Refusal to EUSA.<sup>9</sup> (Pl.’s Ex. 8.)

The Agreement made Innocoll “primarily responsible ... for designing and conducting all Development” needed for the B-Implant to obtain FDA approval. Agr’m. § 4.1.1. In turn, EUSA received authority to oversee this process through a Joint Steering Committee (“JSC”). Agr’m. § 3.2. The JSC’s function was to “review and approve the overall Development strategy” and to “facilitate the management and implementation of the Parties’ Development activities,” among other things. Agr’m. § 3.2.1. In particular, the Agreement provides that “Innocoll shall prepare a Development Plan for Development” of the B-Implant “and shall submit such Development Plan to the ... JSC for its review and approval.” Agr’m. § 4.2.2(a).

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<sup>8</sup> With regard to the Right of First Refusal, the Agreement provides that if Innocoll receives an offer from a third party to commercialize the B-Implant that Innocoll desires to accept, it must advise EUSA in writing; EUSA may then buy the B-Implant according to the terms contained in that offer. Agr’m. § 2.4. The Agreement adds: “For purposes of clarity, if Innocoll shall decide to so Commercialize any Product in the U.S. itself, it shall not be required hereunder to first offer the right to do so to EUSA.” Id.

<sup>9</sup> Given this assignment, this Court will refer to EUSA rather than to EUSA/Europe in describing the Agreement’s provisions relating to the B-Implant.



With regard to the JSC's constitution, its members must include, at minimum, "two (2) senior decision making representatives of each Party."<sup>10</sup> Agr'm. § 3.3.1. Actions are taken "by unanimous vote with each Party having a single vote." Agr'm. § 3.4. When a dispute in the JSC arises, the Agreement provides that, after meeting with EUSA to negotiate in good faith, Innocoll may finally resolve the matter. Agr'm. § 3.4. After EUSA exercises its Option or Right of First Refusal, however, this authority to finally resolve a matter passes to EUSA. Id. Finally, the Agreement provides that "in the event that EUSA fails to exercise its Option by the Successful Completion of Phase II Trials, then ... the Designated JSC for the B-Implant shall no longer have any oversight of Development regarding the B-Implant for the U.S." Agr'm. § 4.2.2(a).

Section 2.5 of the Agreement contains the terms of the Option. It states: "Innocoll hereby grants to EUSA an irrevocable option to obtain an exclusive, fee bearing, license to the Innocoll Know-How and under the Innocoll Patents to Commercialize the B-Implant in the U.S." Agr'm. § 2.5. With regard to expiration, Section 2.5 states: "EUSA shall have the right to exercise the Option at any time on or before the initiation of the JSC approved first visit by the first patient in a U.S. Phase III Trial." Id.

Finally, the Agreement defines certain terms to clarify its substantive provisions, including Section 2.5. First, the definition for "Phase II Trial" states: "any human clinical trial where the principal purpose is to determine preliminary evidence of efficacy and safety and to

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<sup>10</sup> The Agreement also provides that the JSC "shall have a chairperson selected by Innocoll until the exercise by EUSA of the Option or the closing of a Right of First Refusal with EUSA, thereafter EUSA shall select such chairperson." Agr'm. § 3.3.1.

establish a dose or dose range for Phase III clinical trials.” Agr’m. § 1.43. Second, the definition for “Successful Completion of Phase II Trial” states:

(a) the successful completion of all necessary Phase II Trials as determined by the FDA at the end of Phase II meeting for the B-Implant, (b) where the JSC determines that the next step in Development for the B-Implant is a Phase III Trial and (c) where the JSC defines such Phase III Trial for the B-Implant.

Agr’m. § 1.55. Finally, the definition for “Phase III Trial” states in part: “a pivotal trial for seeking or obtaining Regulatory Approval ... or to otherwise establish safety and efficacy ... for purposes of filing a New Drug Application.” Agr’m. § 1.44.

#### **E. Innocoll’s Discussions with Baxter**

On September 5, 2007, shortly after executing the Agreement, Innocoll gave a PowerPoint presentation about the B-Implant to Baxter Healthcare (“Baxter”), another pharmaceutical company. (Pl.’s Ex. 22.) Since then, Innocoll has continued discussions with Baxter regarding the B-Implant. (Hr’g Tr. 58, Oct. 3, 2008 [hereinafter “10/3 Hr’g Tr.”].) In late August 2008, Innocoll gave another PowerPoint presentation to Baxter that was entitled “Product Opportunities” and focused on the B-Implant. (Pl.’s Ex. 24.) Myers testified that Innocoll conducted these discussions to line up a buyer for the B-Implant in the event that EUSA does not exercise its Option or Right of First Refusal. (10/3 Hr’g Tr. 58, 62.)

#### **F. The Open-Label Safety Study**

The instant case stems from Innocoll’s plans to begin an open label safety study (“OLSS”) that Innocoll deems a Phase III trial, even though Phase II has not ended. Crucially,

Innocoll maintains that the OLSS will cause EUSA's Option to expire. (10/2 Hr'g Tr. 157.) Myers acknowledged that "[i]t is somewhat unusual" to begin Phase III before Phase II has ended. (10/2 Hr'g Tr. 174.) He asserted that "the reason the Open Label Safety Study was design[ed] was to accelerate the development of the product so that we could [get] it filed and approved a lot faster," and added: "As a consequence of that ... it does have an impact on the option[,] [b]ut that was not the plan." Id.

In March 2008, Myers and Morton had a meeting at which Myers informed Morton about Innocoll's plans to begin the OLSS in July or August 2008. (10/2 Hr'g Tr. 64, 167.) Myers also told Morton that, because Innocoll deemed the OLSS a Phase III trial, initiating the OLSS's first patient visit would cause the Option to expire. (10/2 Hr'g Tr. 167-68.) EUSA maintained that the OLSS was not actually a Phase III trial and that, without data from Phase II, going forward with a Phase III trial could harm the B-Implant's development. (Hr'g Tr. 48-49.)

At around this time, Innocoll decided to hire Premier Research Group Limited ("Premier") to design and carry out the OLSS. (Pl.'s Ex. 15.) On April 1, 2008, David Prior, an executive at Innocoll, emailed Elliot Bennett-Guerrero, M.D., at the Duke Clinical Research Institute ("DCRI") and stated:

I wanted to let you know sooner rather than later that we have decided to place the open label study with Premier. ... [O]ur decision was ultimately driven by an abnormal consideration. As I mentioned to you, a key factor for us in this trial is when the first patient will be dosed (which is more important to us right now than when the study will be completed).

Id. On June 30, 2008, Premier submitted to Innocoll a final protocol for "A Phase III, Open-Label Study to Investigate the Safety and Tolerability of the CollaRx<sup>®</sup> Bupivacaine Implant." (Pl.'s Ex. 10 at D3432.)

According to the final protocol and Myers's testimony, the OLSS will be conducted in two stages. (10/2 Hr'g Tr. 174-75; Pl.'s Ex. 10 at D3435.) The first stage, planned to begin immediately, will involve 30 or fewer patients. Id. The second stage, planned to begin after results from Phase II are analyzed, will involve 470 or more patients. (10/2 Hr'g Tr. 175; Pl.'s Ex. 10 at D3435.) Myers testified that Innocoll would not begin any Phase III studies testing the B-Implant's efficacy until after successfully completing Phase II and obtaining advice from the FDA. (10/2 Hr'g Tr. 160.)

On August 30, 2008, Premier submitted to the FDA on Innocoll's behalf an IND for the OLSS. (Pl.'s Ex. 9.) This document does not reveal, however, Innocoll's plan to divide the OLSS into two stages and to begin the first stage before Phase II has ended. Id. Innocoll also sent the IND and final protocol for the OLSS to Baxter, although Innocoll never sent them to EUSA or the JSC. (10/3 Hr'g Tr. 61.)

### III. CONCLUSIONS OF LAW

"A primary purpose of a preliminary injunction is maintenance of the status quo until a decision on the merits of a case is rendered." Acierno v. New Castle County, 40 F.3d 645, 647 (3d Cir. 1994). "Status quo" refers to "the last, peaceable, noncontested status of the parties." Kos Pharm., Inc. v. Andrx Corp., 369 F.3d 700, 708 (3d Cir. 2004). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." Winter v. Natural Res. Def. Council, Inc., 129 S.Ct. 365, 374 (2008); see McNeil Nutritionals, LLC v. Heartland Sweeteners, LLC, 511

F.3d 350, 356-57 (3d Cir. 2007). Because I will find that EUSA has established all four elements, I will grant a preliminary injunction. The elements are discussed in turn below.

**A. Likelihood of Success on the Merits**

In the Complaint (Doc. #1), EUSA asks this Court to declare that under the Agreement (1) Innocoll may not commence any Phase III trial until after the successful completion of Phase II trials and (2) the Option cannot expire before the successful completion of Phase II trials.<sup>11</sup> (Compl. 9.) These requests require interpreting the Agreement using Pennsylvania's law of contracts.<sup>12</sup>

In Pennsylvania, “[t]he fundamental rule in interpreting a contract is to ascertain and give effect to the intent of the contracting parties.” Crawford Cent. Sch. Dist. v. Com. of Pa., 888 A.2d 616, 623 (Pa. 2005). “It is well established that the intent of the parties to a written contract is to be regarded as being embodied in the writing itself, and when the words are clear and unambiguous the intent is to be discovered only from the express language of the agreement.” Steuart v. McChesney, 444 A.2d 659, 661 (Pa. 1982). “[W]here language is clear and unambiguous, the focus of interpretation is upon the terms of the agreement as manifestly expressed, rather than as, perhaps, silently intended.” Id. (emphasis omitted). However, “specific, express written language is not necessary for a particular contractual intent to exist in

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<sup>11</sup> EUSA also requests a declaration that the OLSS planned by Innocoll cannot be deemed a Phase III trial under the Agreement. (Compl. 9.) I do not consider this request here because EUSA has conceded that my granting its other two requests would provide full relief. (Hr’g Tr. 6-7, Dec. 19, 2009.)

<sup>12</sup> The Agreement states that it shall be interpreted under Pennsylvania law. Agr’m. § 14.1.

an agreement. Rather, it is common for the intent of contracting parties to be inherent in the totality of their contract.” Murphy v. Duquesne Univ. of the Holy Ghost, 777 A.2d 418, 432 (Pa. 2001).

“Where the contract terms are ambiguous and susceptible of more than one reasonable interpretation, however, the court is free to receive extrinsic evidence, i.e., parol evidence, to resolve the ambiguity.” Krizovensky v. Krizovensky, 624 A.2d 638, 642 (Pa. Super. Ct. 1993). “A contract contains an ambiguity if it is reasonably susceptible of different constructions and capable of being understood in more than one sense.” Murphy, 777 A.2d at 430 (internal quotation omitted). “This question, however, is not resolved in a vacuum. Instead, contractual terms are ambiguous if they are subject to more than one reasonable interpretation when applied to a particular set of facts.” Id. (internal quotation omitted). “The meaning of an unambiguous written instrument presents a question of law for resolution by the court.” Id.

In the instant case, EUSA argues that under the Agreement Phase III may not begin until after Phase II’s successful completion, whereas Innocoll argues that under the Agreement Phase III may begin before Phase II has ended.<sup>13</sup> The Agreement is ambiguous on this issue because no specific provision explains the timing of Phases II and III. Read in its entirety, however, the Agreement implies that Phase III may not begin until after Phase II’s successful completion.

Several provisions imply that Phase III must follow Phase II. First, the Agreement’s definition for “Phase II Trial” states that it must aim “to establish a dose or dose range for Phase III clinical trials.” Agr’m. § 1.43. Second, the Agreement’s definition for “Successful

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<sup>13</sup> The question of when Phase III may begin is central because the Option will expire upon the “first visit by the first patient” in Phase III. Agr’m. § 2.5.

Completion of Phase II Trial” specifies that a Phase III trial must be “the next step in Development for the B-Implant” when Phase II ends. Agr’m. § 1.55. Finally, Section 4.2.2(a) contains the phrase “in the event that EUSA fails to exercise its Option by the Successful Completion of Phase II Trials,” whereas Section 2.5 states that EUSA may exercise the Option “at any time on or before the ... first visit by the first patient in a U.S. Phase III Trial.” Agr’m. §§ 2.5, 4.2.2(a). These phrases can be reconciled only by interpreting the Agreement to provide that Phase III may not begin until after Phase II has ended.

Extrinsic evidence also supports this interpretation. Both sides agree that during their negotiations leading to Section 2.5 Morton and Myers believed that Phase III trials for the B-Implant would not begin until after Phase II trials were completed. (10/2 Hr’g Tr. 30, 159-60.) The way their negotiations unfolded demonstrates that this shared belief was a basic assumption of the ultimate bargain leading to Section 2.5.

In their negotiations, Morton and Myers agreed that EUSA would purchase the Option for \$15 million plus milestone payments, but they disagreed on when the Option should expire. First, Morton proposed an expiration date 30 days after Phase III ended. (Pl.’s Ex. 3.) In response, Myers proposed an expiration date either when the first Phase II trial ended or 30 days after Phase III ended with EUSA paying an extra \$7.5 million upon signing the Agreement. (Pl.’s Ex. 4.) In reply, Morton proposed an expiration date 30 days after Phase III ended with EUSA paying an extra \$5 million after Phase II. (Pl.’s Ex. 5.) Finally, Myers proposed a compromise that Morton accepted: In exchange for EUSA paying an extra \$1.5 million upon signing the Agreement and contributing up to \$5 million toward Phase III upon exercising the

Option, Innocoll would “extend the option until the first patient is dosed in the Phase 3 study.” (Pl.’s Ex. 6.)

Thus, Myers agreed to “extend” the expiration date from 30 days after the first Phase II trial ended to the beginning of Phase III in exchange for \$1.5 million paid up front and up to \$5 million paid later. This bargain would not make sense unless Morton and Myers implicitly agreed that Phase III could not begin until after Phase II.<sup>14</sup>

For the reasons stated above, I interpret the Agreement to provide that Phase III may not begin until after Phase II’s successful completion.<sup>15</sup> Based on Section 2.5, the Option thus cannot expire until after Phase II’s successful completion. For this reason, I find that EUSA has shown a likelihood of success on the merits.

#### **B. Irreparable Harm to the Plaintiff**

EUSA must also show that it will suffer irreparable harm absent a preliminary injunction. Winter, 129 S.Ct. at 374. I have already found that the Option cannot expire until after Phase II’s successful completion. Although Phase II has not ended, Innocoll has declared a plan to begin the OLSS immediately and not to recognize EUSA’s Option once that occurs. (10/2 Hr’g Tr.

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<sup>14</sup> Furthermore, the way the \$5 million figure repeats suggests that, in making his final offer, Myers took into account EUSA/Europe’s willingness to pay \$5 million after Phase II. Thus, his proposal that EUSA/Europe pay up to \$5 million upon exercising the Option suggests a belief that the Option cannot expire until after Phase II has been completed.

<sup>15</sup> Innocoll notes that a federal regulation provides: “Although in general the phases are conducted sequentially, they may overlap.” 21 C.F.R. § 312.21. This case, however, concerns what the Agreement provides, not what federal regulations may provide. Thus, I find Innocoll’s reference to § 312.21 unpersuasive.



167-68.) Thus, EUSA faces losing what the Option guarantees unless this Court issues a preliminary injunction. Now, this Court must determine whether such a loss would constitute irreparable harm.

“In order to demonstrate irreparable harm the plaintiff must demonstrate potential harm which cannot be redressed by a legal or an equitable remedy following a trial.” Campbell Soup Co. v. ConAgra, Inc., 977 F.2d 86, 91 (3d Cir. 1992). Two factors are paramount. First, the harm must be “immediate.” “Establishing a risk of irreparable harm is not enough. A plaintiff has the burden of proving a ‘clear showing of immediate irreparable injury.’” ECRI v. McGraw-Hill, Inc., 809 F.2d 223, 226 (3d Cir. 1987) (quoting Cont’l Group, Inc. v. Amoco Chem. Corp., 614 F.2d 351, 359 (3d Cir.1980)). Second, the harm must be “irreparable.” The Third Circuit has explained:

When the claim is based on a breach of contract, irreparable injury may be found in two situations: (1) where the subject matter of the contract is of such a special nature or peculiar value that damages would be inadequate; or (2) where because of some special and practical features of the contract, it is impossible to ascertain the legal measure of loss so that money damages are impracticable.

ECRI, 809 F.2d at 226. A district court cannot award “an injunction where the claimed injury constituted a loss of money, a loss capable of recoupment in a proper action at law.” Id. Indeed, “[t]he preliminary injunction must be the *only* way of protecting the plaintiff from harm.” Campbell, 977 F.2d at 91.

EUSA has shown a threat of immediate harm because Innocoll clearly intends to begin the OLSS immediately and not to recognize EUSA’s Option once that occurs. Turning to irreparability, I must first clarify what the Option guarantees. The Option gives EUSA (1) a power to buy an exclusive license to commercialize the B-Implant in the U.S., (2) a liberty to

exercise that power at any time before the first Phase III study begins after Phase II's successful completion, (3) a right to review Phase II clinical results for the B-Implant before Phase III can begin, and (4) authority to oversee the B-Implant's development in Phase II.

At minimum, Innocoll's planned course of action would immediately terminate EUSA's authority to oversee the B-Implant's development during Phase II. Once the development occurs without EUSA's participation, no legal action could provide a remedy for the loss. EUSA might still obtain the B-Implant once this case's merits are decided, but EUSA could never recoup the opportunity to guide development during Phase II, and calculating a damage award to compensate EUSA for this loss would be speculative.

Furthermore, EUSA also faces losing either the chance to buy the B-Implant or the right to review Phase II results before the Option expires. Each loss constitutes irreparable harm. In Allegheny Energy, Inc. v. DQE, Inc., 171 F.3d 153 (3d Cir. 1999), two utility companies "Allegheny" and "DQE" reached a merger agreement. Id. at 154. Provided that certain pre-combination transaction did not occur, their stock-for-stock merger could be structured to allow the resulting company to employ the "pooling of interests" accounting method, enabling that company to report higher annual earnings than otherwise. Id. at 156-57 n.4. Because the combination of Allegheny and DQE could not occur until both companies' stockholders had given approval, the agreement provided that neither company could take any action "that would prevent the Merger from qualifying for 'pooling of interests' accounting treatment." Id. at 156. When DQE tried to cancel the merger after receiving unfavorable rulings by regulatory boards, Allegheny sued for specific performance. Id. at 157-58. Allegheny also requested a preliminary injunction to preclude DQE from doing anything to scuttle the merger qualifying for pooling of

interests accounting treatment. Id. at 158. The Third Circuit reversed the district court's denial of this request.

The Third Circuit reasoned that “[i]f the loss of pooling [*sic*] accounting were to block the ultimate consummation of the merger, Allegheny would suffer irreparable harm” because “loss of the opportunity to control DQE ... could not be adequately recompensed through monetary damages.” Id. at 164. This was because “the agreed-upon Allegheny-DQE merger constitute[d] a unique, non-replicable business opportunity for Allegheny.” Id. at 163. The court continued: “If the merger is consummated despite the loss of pooling of interests accounting, Allegheny would suffer irreparable harm because DQE,” once non-existent, “would no longer be able to recompense Allegheny for the difference between the value of the merger under pooling of interests accounting and the value of the merger under purchase accounting.” Id. at 164.

In the same way, Innocoll's refusal to recognize the Option could compromise EUSA's stake in the Agreement. If Innocoll's refusal prevents EUSA from exercising the Option, EUSA will suffer irreparable harm by losing “a unique, non-replicable business opportunity.” Id. at 163. Indeed, the uniqueness of the B-Implant, a novel innovation in post-surgical pain relief still under development, cannot be denied. Moreover, given the uncertainty of FDA approval and future market conditions, the B-Implant's commercial value cannot be calculated without speculation. Also, if Innocoll's threat requires EUSA to exercise the Option immediately, EUSA will suffer irreparable harm by losing the right to review Phase II results before the Option expires. Given that actual Phase II results could become altogether different because EUSA would have final authority in the JSC, one could never know for sure how much that information

might have influenced EUSA. Thus, calculating an award of damages to compensate EUSA would require speculation.

Innocoll argues that EUSA cannot show irreparable harm because of the Right of First Refusal. (Reply Mem. in Supp. of Mot. to Dismiss Pl.'s App'n for Prelim. Inj. for Lack of Threatened Immediate or Irreparable Harm 2-3.) Innocoll reasons that, after the Option expires, another pharmaceutical company will make Innocoll an offer for the B-Implant, whereupon damages will become calculable because EUSA could exercise its Right of First Refusal and sue Innocoll for the difference between that offer and the price of the Option. Id.

The Right of First Refusal does not, however, insulate EUSA from irreparable harm. First, if Innocoll decided itself to commercialize the B-Implant, the Agreement would not require Innocoll to offer this opportunity to EUSA first.<sup>16</sup> Agr'm. § 2.4. Second, Innocoll might receive no competing offer until after Phase III trials for the B-Implant are nearly complete, thus preventing EUSA from participating in the B-Implant's development. Finally, the competing offer may contain terms related to oversight that are less favorable to EUSA than those in the Option. Thus, for the reasons stated above, I find that EUSA has shown that it will suffer irreparable harm without a preliminary injunction.

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<sup>16</sup> Section 2.4 contemplates this, stating: "For purposes of clarity, if Innocoll shall decide to so Commercialize any Product in the U.S. itself, it shall not be required hereunder to first offer the right to do so to EUSA." Agr'm. § 2.4.

**C. Balance of Equities**

With regard to the third element, EUSA must show that the balance of equities tips in its favor. Winter, 129 S.Ct. at 374. Innocoll argues that a preliminary injunction would create greater harm by preventing Innocoll from hastening the B-Implant's development. (Def.'s Proposed Find. of Fact and Concl. of Law With Resp. to Pl.'s App'n for Prel. Inj. 22.) Myers testified that Innocoll intended the OLSS to accelerate the B-Implant's development, but other evidence discredits this testimony. (10/3 Hr'g Tr. 44-45.) In particular, an email dated April 1, 2008, states that Innocoll's decision about which company to hire to carry out the OLSS "was ultimately driven by an abnormal consideration," namely, "when the first patient will be dosed (which is more important to us right now than when the study will be completed)." (Pl.'s Ex. 15.) Based on the entire record, I find that a preliminary injunction will harm Innocoll only by preventing it from violating the Agreement. Thus, I find that EUSA has established that the balance of equities tips in its favor.

**D. Public Interest**

With regard to the final element, EUSA must show that the public interest favors granting a preliminary injunction. Winter, 129 S.Ct. at 374. Here, the public interest favors granting a preliminary injunction because preserving the status quo will protect the integrity of the clinical trial process for the B-Implant. Because EUSA has satisfied all four elements, I will issue the preliminary injunction that it requests.

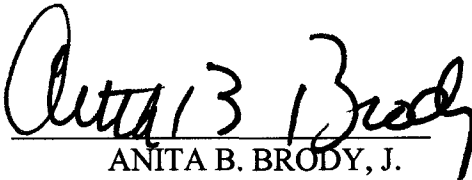
#### **IV. CONCLUSION**

For the reasons stated above, I find that EUSA has shown that all four factors that must be considered favor granting a preliminary injunction. Therefore, I will issue the preliminary injunction requested by EUSA. Furthermore, I will deny the Motion of Defendants Innocoll Pharmaceuticals Limited and Innocoll Technologies Limited to Dismiss Plaintiff's Application for Preliminary Injunction (Doc. #13).

**ORDER**

**AND NOW**, this 26th day of January, 2009, it is **ORDERED** that:

- Plaintiff EUSA Pharma (US), Inc., and Defendants Innocoll Pharmaceuticals Limited and Innocoll Technologies Limited each shall have until **January 30, 2009**, to submit a proposed order consistent with this opinion;
- My Temporary Restraining Order of August 11, 2008, (Doc. #11) shall remain in effect pending an order consistent with this opinion; and
- Motion of Defendants Innocoll Pharmaceuticals Limited and Innocoll Technologies Limited to Dismiss Plaintiff's Application for Preliminary Injunction (Doc. #13) is **DENIED**.

  
ANITA B. BRODY, J.

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