

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,  
and MYLAN INC.,

Defendants.

Civil Action No. 11-cv-717  
(RMB/KW)

SEALED OPINION

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**BUMB**, United States District Judge:

After holding an eight-day trial in this patent infringement case, the Court issued an Opinion and Order on January 28, 2014, finding in favor of Plaintiff Endo Pharmaceuticals, Inc. (the "Plaintiff" or "Endo"). (Dkt. Ents. 226, 227.) Less than an hour later, Defendants Mylan

Pharmaceuticals, Inc. and Mylan Inc. (the "Defendants" or "Mylan") filed a letter informing the Court that the parties had reached a settlement in principle prior to receiving the Court's Opinion. (Dkt. Ent. 228.) Later that day, Endo filed a responding letter that claimed the parties "did not reach an agreement to settle, and are not working on drafting settlement papers." (Dkt. Ent. 229.) Thereafter, Defendants sought the Court's intervention and moved to enforce the purported settlement agreement. (Dkt. Ent. 231.) On March 18, 2014, the Court conducted a hearing on Defendants' motion.

In the meantime, Defendants separately moved under Federal Rule of Civil Procedure 60(b) for relief from this Court's Opinion and Order, arguing such relief was justified in light of the parties' purported settlement. (Dkt. Ent. 253.) For its part, Plaintiff moved for entry of final judgment, essentially requesting the Court modify its prior Order by directing the effective date of Defendants' ANDA drug pursuant to 35 U.S.C. § 271(e)(4)(A), and enjoining Defendants pursuant to 35 U.S.C. § 271(e)(4)(B). (See Dkt. Ent. 230.) For the reasons set forth below, Defendants' motions are GRANTED and Plaintiff's motion is DENIED as moot.<sup>1</sup>

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<sup>1</sup> This Opinion constitutes the Court's findings of facts and conclusions of law as required by Federal Rule of Civil Procedure 52(a)(1).

I. FACTUAL BACKGROUND

At the conclusion of the patent infringement trial, the Court directed the parties to meet and confer regarding settlement. Pursuant to this Order, Minaksi Bhatt, Assistant Global General Counsel for Patent Litigation at Mylan, Inc. and Guy Donatiello, Senior Vice President of Intellectual Property, at Endo, scheduled an in-person meeting to take place on December 4, 2013 at the Airport Marriott in Philadelphia, Pennsylvania (the "December 4th Meeting"). (Bhatt Tr.<sup>2</sup> 126:15-22.) In advance of that meeting, Bhatt conveyed Mylan's initial settlement offer to Donatiello by phone. Bhatt testified that the offer consisted of the following terms:

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<sup>2</sup> "Tr." refers to the transcript of the hearing held on March 18, 2014, and is preceded by the name of the testifying witness.

<sup>3</sup> U.S. Patent No. 5,464,864 (filed Nov. 7, 1995) (the "'864 Patent").

Donatiello testified on direct examination that, during the December 4th Meeting, Endo made a counteroffer:

Bhatt confirmed Donatiello's direct testimony. (Bhatt Tr. 127:8-15.) (On cross-examination, Donatiello's recollection as to these terms differed somewhat. (Donatiello Tr. 175:22-176:5 (explaining counteroffer also included a

but that he "did not discuss whether we'd be permitted

...)) Specifically, Bhatt testified that the parties "talked about the concept of a but that Donatiello did not include this term as part of his counteroffer and they "didn't reach agreement on that term that day." (Bhatt Tr. 127:17-19.) Donatiello acknowledged that Endo could accept the concept of a (Donatiello Tr. 141:11-18 (Endo agreed to this term "in principle" at that meeting, although no specifics were discussed).)

On the following day, December 5, 2013, Bhatt and Donatiello spoke again, by phone. Bhatt and Donatiello testified consistently that, during this call, Mylan countered with:

Both Bhatt and Donatiello on his direct examination agreed that they did not discuss the [redacted] on December 5. (Bhatt Tr. 128:5-7; Donatiello Tr. 142:5-8.) (On cross-examination, however, Donatiello testified that “[t]he [redacted] was discussed during that call [redacted].” Donatiello Tr. 176:20-23.) By this point, though, Mylan had determined the [redacted] was not important to it in this case for several reasons:

(Bhatt Tr. 128:8-21.)<sup>4</sup> For

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<sup>4</sup> See also Tiglio Tr. 58:22-60:3 (“My understanding was, is that Endo was fine with the concept of a [redacted] but as the negotiations went forward Mylan realized that this provision really didn’t have that much relevancy . . .”).

these reasons, Mylan ceased pushing this term almost immediately.<sup>5</sup>

During the following weeks, Bhatt and Donatiello spoke several more times and always about the same three terms. (Bhatt Tr. 129:1-4.) During one of those calls, which Donatiello thought may have occurred sometime in mid-December, Donatiello testified that he offered the following terms:

Donatiello testified that Bhatt specifically raised the \_\_\_\_\_ during this call, and asked if it remained a part of Endo's offer. Donatiello replied that Endo had agreed to the \_\_\_\_\_ in principle and Bhatt could assume for the purposes of negotiations that it was still part of the offer. (Donatiello Tr. 142:17-143:3.) Bhatt, however, firmly stated that she did not mention the \_\_\_\_\_ again after the December 4th Meeting. (Bhatt Tr. 129:5-7, 138:9-20.)

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<sup>5</sup> Bhatt Tr. 137:3-7 ("The \_\_\_\_\_ in this case was something it would be nice to have, it wasn't a requirement for settlement on behalf of Mylan and it was not a material term for settlement.").

On December 19, Bhatt and Donatiello spoke again. Donatiello testified on direct examination that this time Mylan offered:

Andrea D. Tiglio, Patent Litigation Counsel for Mylan Inc., confirmed that this was her understanding of the terms as of this time. (Tiglio Tr. 43:1-24.) (On cross-examination, however, Donatiello testified that the offer included a

. Donatiello Tr. 177:11-18.)

On December 20, Donatiello met with Tiglio. (See Tiglio Tr. 42:15-19; DX-328.) Both Donatiello and Tiglio testified consistently that, at this time, the parties had already agreed to . (Tiglio Tr. 44:2-5; see also Donatiello Tr. 145:12-13.) They both testified, also consistently, that Endo proposed:

Donatiello testified that he intended his offer to include the possibility of a but he acknowledged that he did not discuss the ; with Tiglio. (Donatiello Tr.



144:22-25.) Tiglio confirmed that the \_\_\_\_\_ was not discussed.  
(Tiglio Tr. 46:6-8.) Thus, by this date, both parties are in agreement as to the status of the negotiations.

During this same meeting or shortly thereafter,<sup>6</sup> both Donatiello on direct examination and Tiglio testified that Mylan counter proposed:

(On cross-examination, however, Donatiello suggested that this counter-offer included a

\_\_\_\_\_ (Donatiello Tr. 178:1-9.)

Donatiello agreed to discuss the counterproposal regarding the \_\_\_\_\_ with his business people. (Donatiello Tr. 145:24-146:2; see also DX-352.) Tiglio testified that the focus of this meeting was the \_\_\_\_\_ term and there were no other settlement terms that

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<sup>6</sup> Tiglio testified that she made this offer during the December 20 meeting, but Donatiello's testimony as to the timing of this offer is less certain and he seems to suggest the offer was made during a phone call after the December 20 meeting. However, Donatiello emailed Tiglio on December 20, informing her that he would "test the waters on your proposal, but as we were set a \_\_\_\_\_ I do not anticipate favorable consideration." (DX-352.) Thus, it seems more likely that this exchange occurred as part of the December 20 meeting.

had been raised or were being discussed at that time. (Tiglio Tr. 44:19-22, 45:1-5, 46:6-22.)

After the New Year, discussions resumed between Bhatt and Donatiello. On or around January 7, 2014,<sup>7</sup> Donatiello offered:

From at least this point forward, the parties were in agreement as to

(See id. at 146:12-18.)

Mylan countered with:

Endo responded with:

Then, on January 10, Bhatt and Donatiello had a phone call during which Mylan again offered the same term:

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<sup>7</sup> Donatiello testified on direct examination that he reengaged in discussions with Bhatt around January 8. (Donatiello Tr. 146:9-11.)

<sup>8</sup> It does not seem logical that Mylan would have countered with a \_\_\_\_\_ in light of the prior negotiator

Donatiello responded with \_\_\_\_\_ by which he meant that Endo would be permitted \_\_\_\_\_

(Id. at 150:20-151:6.) Specifically, Donatiello testified that:

(Donatiello Tr. 150:25-151:4.) In other words, the only term discussed at that point was Endo's \_\_\_\_\_ which is consistent with the course of negotiations up to this point. Thus, Endo's "final" settlement offer (the "January 10 Offer") consisted of:

Neither party raised the . . . during the January 10 call and, as Bhatt persuasively testified, this issue was no longer relevant to Mylan as of at least December 5, 2013.

Between January 10 and 24, the parties exchanged one or two communications in which Mylan advised Endo that it was still waiting on internal approval of Endo's January 10 Offer.

(Donatiello Tr. 151:11-22.) On January 24, Tiglio emailed a draft settlement agreement to Donatiello (the "January 24 Draft"). (DX-368; DX-369.) The cover email states, "We are still awaiting final management approval, but in the meantime, in order to keep the ball rolling, we have put together a draft settlement and license agreement for your review." (DX-368 (emphasis added).) The email also notes that Mylan is still "tweaking" provisions in the draft and that Bhatt had not reviewed the draft because she had been out of the office that week. (Id.) Significantly, neither party viewed this draft agreement as a counteroffer.<sup>10</sup> In fact, Donatiello testified that

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<sup>9</sup> See also Tiglio Tr. 49:10-22.

<sup>10</sup> Tiglio Tr. 56:24-57:5 ("Q. Did you intend for this document to be a counteroffer to the three terms that Endo had offered in settlement? A. No. . . . It's just a - just a model or draft starting point ultimately after we had received approval that we could memorialize the offer in writing."); Donatiello Tr. 151:23-152:1 (agreeing that, prior to January 28, Endo had not withdrawn January 10 Offer); id. at 152:18-23 ("Q. Okay. Did you consider the draft from Dr. Tiglio to be a

he did not review the draft thoroughly because the parties had not yet agreed to any terms. (Donatiello Tr. 152:12-17.) The draft included a number of miscellaneous terms that had never been discussed by the parties, and also set forth the specifics of a \_\_\_\_\_ DX-369.) In Mylan's view, these other terms were either boilerplate or "belt and suspenders [] provisions that we like to have in" but none were material. (Tiglio Tr. 57:16-18.)

In the meantime, the Court held a teleconference with the parties on January 23 to discuss the status of settlement negotiations. During that call, Jeffrey Lewis, Esq., advised the Court that Endo had made an offer that had been outstanding for nearly two weeks, and that he understood this "was probably the final [offer] or extremely close to it."<sup>11</sup> (Jan. 23, 2014 H'rg Tr. 3:22-25.) Douglas Carsten, Esq., advised that the offer had been elevated to Mylan's senior management and they were still awaiting final approval or disapproval. (Id. at 4:22-24.)

Bhatt testified that final approval of the January 10 Offer was obtained from senior management on January 27, although she did not learn of this approval until the morning of January 28.

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counteroffer? A. You know, I don't know that I thought about it in those terms. So I can't say that I did or I didn't, I didn't really think about it that way."); id. at 154:6-8.

<sup>11</sup> The parties agree that Mr. Lewis was referring to the January 10 Offer.

(Bhatt Tr. 132:8-17.) At that time, she told Tiglio to contact Donatiello and accept Endo's offer. (Id. at 132:18-20.) Tiglio called Donatiello's office on January 28 around 11:35 a.m. and was told by Donatiello's assistant that Donatiello was out of the office for a week but could be reached via email. (Tiglio Tr. 63:1-5, 106:24-107:2.) Tiglio then sent Donatiello an email at 11:40 a.m., asking that he call her so she could "update [him] concerning our Frova settlement." (DX-303.) Within moments, she received an automatic reply indicating that Donatiello would "have limited access to e-mails." (DX-304.) Upon realizing that she had his cellphone number, Tiglio immediately called Donatiello who answered the phone. At that time, Tiglio informed Donatiello that Mylan accepted Endo's final January 10 Offer. (Tiglio Tr. 63:17-64:9.) It is undisputed that Tiglio then recited the three terms of that offer:

(Id.) Donatiello responded, "That's great."

(Donatiello Tr. 157:15-18.)

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<sup>12</sup> Donatiello testified, "I don't recall whether she recited those precise terms or not." (Donatiello Tr. 154:15-18; id. at 156:1-3.)

According to Tiglio, her precise recitation of the terms of Mylan's acceptance was "intentional":

A. I told him that Mylan accepted the terms of their offer.

Q. And did you then go through each of the three material terms that form Endo's settlement offer?

A. I did.

Q. Do you believe there was any confusion in your choice of words when you recited the terms as to what the terms of the agreement were?

A. No. My recitation was intentional.

Q. And, in fact, what were the words that Mr. Donatiello used when he dictated to you the content of the letter that should go to the Court?

A. He said that two sentences, the parties had reached an agreement on the material terms, and the parties were now working on finalizing the papers.

(Tiglio Tr. 109:5-18.) Tiglio also credibly explained that it was critical she accept Endo's final offer as quickly as possible on January 28 because she knew the Court was preparing to rule. (Tiglio Tr. 74:18-75:4 ("I was excited that I thought we'd finally gotten signoff because we had been waiting for it. I wanted to communicate it to [Donatiello] as soon as possible. And also I knew that your Honor was going to issue her decision soon. You had canceled the Monday the 27<sup>th</sup> conference on the -- on Friday the 24<sup>th</sup>, that gave me every indication that you were ready to issue your decision at any time. And also that you had promised that you would have your decision by the end of

January. So I knew that your decision was going to come out any time, so I wanted to communicate as fast as possible, as soon as I had the information and authority available to me, to do so.").

During their brief call, Donatiello and Tiglio also discussed the January 24 Draft, which Donatiello indicated appeared to include other previously-undiscussed terms that represented to him "significant issues to be resolved," including the terms of the (Donatiello Tr. 157:21-25; see also Tiglio Tr. 66:19-24.) In response, Tiglio told Donatiello to "mark it [the January 24 Draft] up." (Donatiello Tr. 167:25-168:2; Tiglio Tr. 93:7-9.)

Tiglio also asked Donatiello whether the parties should notify the Court that an agreement in principle had been reached, and Donatiello agreed. (Tiglio Tr. 65:1-12; Donatiello Tr. 158:25-159:2.) Tiglio testified that Donatiello wanted the letter to be short and that he actually dictated two sentences: one, the parties have reached an agreement on the material terms; and two, the parties are working on finalizing the settlement documents. (Tiglio Tr. 65:13-20.) Donatiello also testified that he said the letter should be short. Although he did not recall exactly what he said ("I don't remember exactly what I said," Donatiello Tr. 160:11-12), he denied telling Tiglio that the letter should say the parties had reached an



agreement on all "material" terms. (Donatiello Tr. 159:12-25.)  
When Tiglio asked, however, whether the parties should request that the Court hold its decision in abeyance, Donatiello said no, explaining:

THE COURT: Do you recall Dr. Tiglio saying to you should we ask the Court to hold her decision in abeyance, do you recall her asking you that?

THE WITNESS: Yes, I do.

THE COURT: And was your response back to her something along the lines . . . that it's not for you to tell the Judge what to do?

THE WITNESS: I didn't think it was necessary, that the Court would know what to do.

THE COURT: You didn't think it was necessary what?

THE WITNESS: I didn't think it was necessary to tell the Court what to do.

THE COURT: And is that because you knew that if I were to get a letter from the parties saying that an agreement had been reached in principle, I would know not to issue an opinion.

THE WITNESS: That's - yes, that's correct.

(Donatiello Tr. 161:18-25 (emphasis added); see also Tiglio Tr. 65:7-11.) Indeed, Donatiello testified, "We'd reached agreement on the threshold items, the rest of them were things to be worked out but that doesn't mean that they were unimportant."  
(Donatiello Tr. 162:22-24.)

Approximately 20 minutes after Tiglio's and Donatiello's phone call, the Court issued its Opinion finding in favor of Endo on the patent infringement claims. Upon learning of the

Opinion, Bhatt and Tiglio attempted to contact Donatiello to confirm whether he would stand behind the settlement agreement. (Tiglio Tr. 68:8-14; Bhatt Tr. 133:5-10.) He returned their call around 2:00 p.m. Donatiello told Tiglio and Bhatt that the parties did not have a settlement agreement, that nothing had been reduced to writing, and, in his view, they did not have an enforceable agreement. (Bhatt Tr. 133:23-134:2; Tiglio Tr. 69:8-13; Donatiello Tr. 164:18-19.) Bhatt endeavored to convince Donatiello to stand by their agreement, but Donatiello told Bhatt and Tiglio that "circumstances have changed." (Tiglio Tr. 69:16-70:2.) However, he agreed that it made sense for the parties to continue discussing settlement as a motion to enforce the settlement or an appeal of the Court's decision was likely. (Bhatt Tr. 134:3-14; Donatiello Tr. 164:19-24.)

On February 3, 2014, Mylan filed the instant motion to enforce the settlement.

## **II. LEGAL ANALYSIS**

As an initial matter, although Mylan filed a separate motion for relief pursuant to Rule 60(b)(5) and (6), that motion seeks relief from this Court's Opinion and Order based upon an oral settlement agreement purportedly reached by the parties- unbeknownst to this Court-prior to entry of final judgment in favor of Endo on the issue of patent infringement. Accordingly, the outcome of Mylan's Rule 60(b) motion depends on whether the

Court finds that the parties entered into a settlement agreement. Mylan also seeks to enforce that oral settlement agreement.

Under Rule 60(b)(6), "the court may relieve a party or its legal representative from a final judgment, order, or proceeding" for "any other reason that justifies relief." Fed. R. Civ. P. 60(b)(6). This provision is a "catchall" provision that "'provides for extraordinary relief and may only be invoked upon a showing of exceptional circumstances.'" Coltec Indus., Inc. v. Hobgood, 280 F.3d 262, 273 (3d Cir. 2002) (quoting In re Fine Paper Antitrust Litig., 840 F.2d 188 (3d Cir. 1988)). "Rule 60(b)(6) exists so that courts may 'vacate judgments whenever such action is appropriate to accomplish justice,' Klapprott v. United States, 335 U.S. 601, 614, 69 S.Ct. 384, 93 L.Ed. 266 (1949), in situations that are not addressed by the other five clauses of Rule 60(b)." Budget Blinds, Inc. v. White, 536 F.3d 244, 254 (3d Cir. 2008). Mylan contends that applying the Opinion and Order is inequitable in light of the parties' settlement agreement and "depriving the parties of their pre-judgment bargained-for agreement would be an extreme and unexpected result." (Mylan's Mot., Dkt. Ent. 253, at 2.) Endo responds that, even assuming a settlement was reached, Mylan's delay in responding to Endo's settlement offer precludes finding of "extreme and unexpected hardship" sufficient to relieve Mylan

from this Court's judgment. The Court disagrees with Endo. Because, as discussed in-depth below, the Court finds that the parties entered into an oral settlement agreement prior to entry of the Court's judgment, Mylan has established extraordinary circumstances justifying relief from final judgment pursuant to Rule 60(b)(6).<sup>13</sup>

**A. Mylan's Motion to Enforce the Settlement Agreement**

Turning now to Mylan's motion to enforce the settlement agreement, it is well-settled, and the parties do not dispute, that this Court has the "inherent authority to enforce agreements settling litigation before it." McClure v. Twp. of Exeter, No. 05-5846, 2006 U.S. Dist. LEXIS 69414, at \*2 (E.D. Pa. Sept. 27, 2006); Maya Swimwear Corp. v. Maya Swimwear L.L.C., 855 F. Supp. 2d 229, 233 (D. Del. 2012); New Castle Cnty. v. U.S. Fire Ins. Co., 728 F. Supp. 318, 319 (D. Del. 1989) ("Additionally, by entering into a settlement agreement, the parties implicitly consent to the Court's assertion of its jurisdiction to compel compliance with that agreement." (citing Cooper-Jarrett, Inc. v. Central Transport, Inc., 726 F.2d 93, 96 (3d Cir. 1984))). In analyzing this motion, the Court must apply principles of contract law, which govern settlement agreements.

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<sup>13</sup> Because the Court finds that relief should be granted under Rule 60(b)(6), it need not address Mylan's arguments under Rule 60(b)(5).

See Sanofi-Aventis U.S. LLC v. Sandoz, Inc., No. 07-2762, 2009 U.S. Dist. LEXIS 91923, at \*6 (D.N.J. Oct. 2, 2009); Parker-Hannifin Corp. v. Schlegel Elec. Materials, Inc., 589 F. Supp. 2d 457, 461 (D. Del. 2008).

Under applicable choice of law rules, Mylan argues that Pennsylvania or Delaware contract law should govern, although New Jersey may also have an interest in the dispute. (Mot., Dkt. Ent. 232, at 6.) However, Mylan concedes that it is immaterial which of these states' laws is applied because they are substantially similar. (See id.) Endo "agrees" that Pennsylvania contract law governs whether there was an enforceable agreement among the parties because Pennsylvania has the most significant interest in the dispute. (Opp., Dkt. Ent. 245 at 7 n.5.) In particular, both Endo and Mylan are located in Pennsylvania, and the in-person settlement negotiations as well as most of the phone conversations occurred in Pennsylvania. (See Declaration of Guy Donatiello ("Donatiello Decl."), Dkt. Ent. 246 ¶¶ 1, 7; see also Declaration of Andrea D. Tiglio ("Tiglio Decl."), Dkt. Ent. 233 ¶ 3.)

The Court need only conduct a choice-of-law analysis where the proposed states' laws actually conflict. See In re Teleglobe Commc'ns Corp., 493 F.3d 345, 358 (3d Cir. 2007); Sanofi-Aventis, 2009 U.S. Dist. LEXIS 91923, at \*7 ("The court, however, need not engage in any choice of law analysis because

it appears that both states apply similar principles with regard to the issues at hand and, therefore, the choice of law will have no effect on the Court's ultimate disposition of this motion."). Because the Court does not find that Delaware and Pennsylvania law conflict, it need not analyze which law should apply but will apply the law of the forum state, Delaware. See Maya Swimwear, 855 F. Supp. 2d 229 ("Under Delaware law[, ] a contract comes into existence if a reasonable person would conclude, based on the objective manifestations of assent and the surrounding circumstances, that the parties intended to be bound by their agreement on all essential terms." (quoting Rohm and Haas Elec. Materials, LLC v. Honeywell Int'l, Inc., No. 06-297, 2009 WL 1033651, at \*5 (D. Del. April 16, 2009))); Quandry Solutions, Inc. v. VeriFone, Inc., No. 07-097, 2009 U.S. Dist. LEXIS 31459, at \*25 (E.D. Pa. April 13, 2009) ("Enforceable agreements, under Pennsylvania law, must satisfy three requirements: (1) both parties must manifest an intent to be bound by the terms of the agreement; (2) the terms must be sufficiently definite to be enforceable; and (3) the agreement must be supported by consideration.").<sup>14</sup>

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<sup>14</sup> Endo argues that, under Pennsylvania law, the appropriate burden of proof for establishing an oral contract is not clearly established, but that some courts apply the "clear and precise" standard while others apply the "preponderance of the evidence" standard. (Opp. at 7-8 (citing Legendary Art, LLC v. Godard, 888 F. Supp. 2d 577, 584-85 (E.D. Pa. 2012)).) Mylan responds that

As the party seeking to enforce the settlement agreement, Mylan bears the burden of proving the existence of the agreement by a preponderance of the evidence. See Williams v. Chancellor Care Ctr. Of Delmar, No. 06C-05-146, 2009 Del. Super. LEXIS 166, \*8-9 (Sup. Ct. Del. April 22, 2009). Mylan contends that on January 28, 2014, Mylan orally accepted Endo's January 10 Offer, which consisted of three terms that Tiglio recited during the January 28 call with Donatiello. In response, Endo argues that the oral agreement is unenforceable because (1) there was no meeting of the minds; (2) the parties intended for any settlement to be in writing; and (3) the oral agreement did not address all essential settlement terms including the

that Mylan initially raised during negotiations.

The Court addresses each of these arguments in turn.

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the clear and precise standard only applies in certain circumstances not present here, such as "an oral modification to a written contract, an oral contract to make a will, and an oral contract enforced against a decedent's estate." (Mylan's Rep., Dkt. Ent. 251, at 3 (quoting Quandry, 2009 U.S. Dist. LEXIS 31459, at \*19).) The Court agrees with Mylan and "concludes that it would be error to impose a burden of proof other than preponderance of the evidence in this case." Quandry, 2009 U.S. Dist. LEXIS 31459, at \*19 ("[I]n cases involving garden variety oral contracts, Pennsylvania courts have applied the preponderance of the evidence burden of proof."). Therefore, the standard of proof applicable under both Delaware and Pennsylvania is the same. In any event, Mylan has established the existence of an oral contract under either standard.

## 1. Offer and Acceptance

"A contract is created upon the valid acceptance of an offer." Williams, 2009 Del. Super. LEXIS 166, at \*9; Quandry, 2009 U.S. Dist. LEXIS 31459, at \*26 ("In general, the first element of contract formation is established through evidence of offer and acceptance." (citations omitted)). It is undisputed that, on January 10, Endo made its "final" offer to Mylan, which proposed (1) a Launch Date of four weeks prior to Patent expiration, (2) an AG no earlier than ten days prior to Patent expiration, and (3) \$1.5 million in attorneys' fees. At no point prior to January 28 did Endo withdraw or amend the January 10 Offer. Significantly, there is no dispute that on January 28, Tiglio called Donatiello and accepted the January 10 Offer, and specifically recited those three terms.<sup>15</sup> Donatiello, in turn, stated "That's great." Endo suggests this response should be construed as reflecting "optimism . . . that some issues are now resolved and others can be addressed." (Endo's Sur., Dkt. Ent. 270, at 6.) However, a reasonable person would view Donatiello's response as indicating an intent to be bound as it reflects his

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<sup>15</sup> Donatiello could not recall whether Tiglio listed the three terms after accepting the January 10 Offer, but he acknowledged it was his understanding that she was agreeing to those three terms. (Donatiello Tr. 157:4-9 "THE COURT: But just dealing with the issues in the first sentence, you don't recall her explicitly setting those forth but you do recall her telling you that Mylan agreed to those three,

THE WITNESS: Yes.").



understanding that an agreement had been reached as to the three terms recited by Tiglio.<sup>16</sup> Moreover, to the extent Donatiello indicated other issues remained unresolved, this statement was made in response to Tiglio's query whether he had reviewed the January 24 Draft (Tiglio Tr. 66:19-24; Donatiello Tr. 156:23-157:3), and thus when viewed in context does not indicate an intent not to be bound by the three terms.<sup>17</sup>

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<sup>16</sup> As discussed infra, as long as an agreement had been reached with respect to the essential terms, the settlement agreement is enforceable even where a finalized settlement may have involved negotiations concerning non-essential terms.

<sup>17</sup> Endo also argues that Mylan's failure to email confirmation of the settlement agreement in the wake of the 11:45 a.m. call and its failure to notify the Government of the oral settlement in accordance with its obligations under the Medicare Modernization Act demonstrate that Mylan did not consider itself bound by the terms of the agreement. (See Dkt. Ent. 301 at 5.) These arguments are meritless. Not only is there no requirement that a party confirm an oral settlement in writing but, more significantly, only twenty minutes after the settlement had been reached, the Court issued its Opinion. Mylan can hardly be faulted for failing to confirm the settlement in the interim. The urgency that prompted Mylan to reach out to Endo was eliminated upon Mylan's acceptance of Endo's offer.

The Court draws no conclusions from Mylan's purported failure to comply with the Medicare Modernization Act, which requires that any settlement between a generic drug applicant and a brand name drug company be reported to the Government within ten days of the agreement's execution. See §§ 1112-13. It became immediately apparent to Mylan that Endo contested the existence of any such settlement agreement. This dispute put Mylan in an impossible position: by refraining from notifying the Government of the disputed settlement agreement, Mylan is vulnerable to the challenge asserted here; but by notifying the Government, Mylan would have opened itself to an argument that it acted in bad faith because the parties had a dispute as to whether a settlement was reached.

Endo first argues that the parties did not agree as to the . Endo points to Tiglio's Declaration in support of Mylan's motion to enforce the settlement in which Tiglio describes the agreed-upon (Tiglio Decl. ¶ 4.) According to Endo,

parties' understandings.<sup>19</sup> (Opp. at 11.) During the hearing, however, Tiglio clarified that the parties had agreed to a to Patent expiration, but that she had simply . (Tiglio Tr. 50:18-53:22; see also Donatiello Tr. 181:21-182:2.) The Court finds this explanation to be credible. In fact, Donatiello admitted that it had occurred to him

.<sup>20</sup> (Donatiello Tr. 197:21-198: ("THE COURT: So either way you look[ed] at it as potentially being an error? THE WITNESS: Yes . . . ."). Thus, the parties clearly agreed prior to Patent expiration.

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<sup>18</sup> The January 24 Draft also reflects a (DX-369 ¶ 8(a).)

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<sup>20</sup> See also Donatiello Tr. 197:8-13 ("I would think, yes, one could calculate with certainty.").

As to the proper expiration date, Endo now claims that the date provided in the filewrapper of the '864 Patent specifies an expiration date of November 8, 2015 (see DTX-1077 at 13-14), thereby making . However, prior to trial—and any relevant settlement negotiations—the parties submitted their joint Stipulated Facts, which stipulated to an expiration date of November 7, 2015. (Stipulated Facts, Dkt. Ent. 170 ¶ 39.) Indeed, the Court itself relied upon this Stipulation in its Opinion. (See Opinion 14.) Endo cannot now manufacture a dispute as to the expiration date sufficient to defeat enforcement of the settlement agreement when it previously agreed to the November 7, 2015 date and presented this date to the Court.

Endo next argues that the oral settlement is unenforceable because the parties ultimately intended that the agreement be embodied in a formal, written settlement contract. However, an oral contract need not be reduced to writing in order to be enforceable. Moreover, “[t]he fact that the parties intend to execute a formal agreement . . . is not dispositive. The question is whether the parties positively agree that there will be no binding contract until the formal document is executed.” Maya Swimwear, 855 F. Supp. 2d at 234 (quoting Anchor Motor Freight v. Ciabattoni, 716 A.2d 154, 156 (Del. Supr. 1998)) (finding no evidence that agreement was “contingent upon

memorialization" although parties clearly contemplated written agreement); see also Loppert v. WindsorTech, Inc., 865 A.2d 1282, 1287-88 (Del. Ch. 2004).<sup>21</sup>

Although both parties clearly intended that a written contract would ultimately be drafted (see DX-368; DX-369), the record contains no evidence indicating that the parties made a settlement contingent upon the execution of a written agreement. Rather, Endo refers to its (unwritten) practice of entering written settlement agreements, especially in Hatch-Waxman litigations such as this one. (Donatiello Tr. 173:6-12.) However, Endo failed to advise Mylan of this practice or Endo's view that any verbal agreement would not be final and enforceable until it was formalized in writing.<sup>22</sup> At most, Donatiello suggested this during the telephone call with Mylan on the afternoon of January 28 - after Mylan had accepted Endo's offer and after Endo had learned of this Court's Opinion. Thus, the lack of a formal, written settlement agreement does not preclude enforcement of the parties' oral settlement. See Maya

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<sup>21</sup> Quandry, 2009 U.S. Dist. LEXIS 31459, at \*27-28 ("Nevertheless, 'where the parties have settled on the terms of an agreement, the intent to later formalize that agreement by writing does not prevent the formation of a contract.'" (citation omitted)).

<sup>22</sup> Indeed, the parties' discussion about notifying the Court of their settlement agreement confirms that a settlement was reached in the absence of a formal written agreement.

Swimwear, 855 F. Supp. 2d at 234; see also Loppert, 865 A.2d at 1287 ("Here, there is no evidence that the parties 'positively' agreed to be bound only by a formal document. . . . Defendant's argument is really nothing more tha[n] an observation that the parties manifested an intention that the settlement agreement would be memorialized in writing-an observation that I share with defendant.").

Throughout the hearing, Endo consistently referred to the settlement terms the parties discussed as "threshold" terms, i.e., three or four terms that had to be addressed before a full agreement could be reached. (See Donatiello Tr. 162:6-17.) According to Endo, these "threshold" terms were simply a starting point and "there's so many other issues that have to go into a settlement agreement." (Id.) However, nowhere did Donatiello testify that the parties agreed these four terms were simply the starting point of settlement negotiations. Indeed, Tiglio testified that Mylan would not have undertaken the effort to have management review a partial offer.<sup>23</sup> (Tiglio Tr. 55:18-22.) Further, the law is clear that "A settlement agreement is enforceable if it contains all essential terms, even though it expressly leaves other matters for future negotiation." See

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<sup>23</sup> Donatiello was aware that the delay in responding to his final offer was due to Mylan's efforts to secure the necessary approval from upper management. (See Donatiello Tr. 183:3-10.)

Loppert, 865 A.2d at 1289. And, the objective evidence shows that the terms discussed by the parties—the Launch Date, the attorneys' fees, and the conditions of an AG launch—were the “heart of the agreement” and not simply a starting point for further discussion. See Parker-Hannifin, 589 F. Supp. 2d at 463.

The Court finds it quite significant that, during the January 28 call, Donatiello and Tiglio specifically discussed notifying the Court that an agreement in principle had been reached. They were both in agreement that a letter should be sent to the Court. The only point of contention was how the letter should be phrased, i.e., should the letter tell the Court to stop the issuance of its Opinion. Donatiello did not feel that it was the parties' role to ask the Court to hold its decision in abeyance. Rather, “[he] knew that if [the Court] were to get a letter from the parties saying that an agreement had been reached in principle, [the Court] would know not to issue an opinion.” It is clear from this conversation that both parties believed an agreement had been reached as of that time and the litigation had settled in principle.<sup>24</sup> Accordingly, the

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<sup>24</sup> Although the Court does not rely on evidence of the January 23 call with counsel in rendering its decision, it is worth noting that outside counsel were operating under the belief that Endo had made an offer and was simply waiting for Mylan to accept that offer. In fact, counsel indicated to this Court that they had hoped to report the matter as settled during that call.

Court finds that it is undisputed that Endo's January 10 Offer consisted of three terms, and it is undisputed that on January 28 Mylan orally accepted that offer.<sup>25</sup> What remained, as the parties testified, were "additional boilerplate and conventional settlement language." See Maya Swimwear, 855 F. Supp. 2d at 236-37 ("In short, a reasonable person would not conclude, based upon the 'other fine points' language and the state of the settlement proposal, that essential terms were outstanding. Instead, on the whole, a reasonable person would conclude that all essential terms had been either explicitly or implicitly resolved through negotiations as of June 20, 2011.").<sup>26</sup>

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<sup>25</sup> Donatiello Tr. 158:1-7 ("Q. Let me ask this, sir, on the morning of January 28th when you woke up and got ready to go to work, there was an outstanding settlement offer from Endo to Mylan, correct? A. That's right. Q. And later that morning Andrea Tiglio called you and told you she accepted on behalf of Mylan that offer, correct? A. That's correct.").

<sup>26</sup> Endo's letter to the Court later in the day on January 28, disputing that a settlement had been reached and stating that the parties "are not working on drafting settlement papers" (Dkt. Ent. 229) is disconcerting. The letter actually contradicts Donatiello's testimony that the parties did indeed agree to put together a settlement agreement. Donatiello testified that, in discussing a letter to the Court, the parties wanted to communicate that they "believe[d] we [could] put together a settlement agreement." (Donatiello Tr. 160:10-11.) Thus, the only logical explanation for why the parties were "not working on drafting settlement papers" that afternoon is that the Court had issued its Opinion.

## 2. The Essential Terms

Whether or not the parties have a valid and enforceable settlement agreement in large part depends on what the essential terms of a settlement agreement are. If the parties reached an agreement on all essential terms, then a valid contract exists. See Intellisource Grp., Inc. v. Williams, No. 98-57-SLR, 1999 U.S. Dist. LEXIS 12446, at \*12 (D. Del. Aug. 11, 1999). In determining whether a term is essential to the agreement, "[t]he court must look to the parties' antecedent expressions, their past action and custom, and other circumstances." Intellisource Grp., 1999 U.S. Dist. LEXIS 12446, \*12-13 (quoting 1 Corbin on Contracts § 29, at 88 (1963)). "A contract contains all essential terms and is therefore enforceable when 'it establishes the heart of the agreement;' it need not, however, contain all terms as some matters may be left for future negotiation." Maya Swimwear, 855 F. Supp. 2d at 234 (quoting Parker-Hannifin, 589 F. Supp. 2d at 463).<sup>27</sup> "In other words, '[u]ntil it is reasonable to conclude, in light of all of these surrounding circumstances, that all of the points that the parties themselves regard as essential have been expressly or

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<sup>27</sup> See also Quandry, 2009 U.S. Dist. LEXIS 31459, at \*37 ("Although an agreement need not contain all of the terms necessary for the execution of the agreement, it must 'represent a meeting of the parties' minds on the essential terms of their agreement.'" (citations omitted)).



. . . implicitly resolved, the parties have not finished their negotiations and have not formed a contract.'" Maya Swimwear, 855 F. Supp. 2d at 234 (citation omitted). But, a settlement may be reached even where parties have agreed to continue negotiation on "'other fine points.'" Maya Swimwear, 855 F. Supp. 2d at 236.

As an initial matter, Endo argues that the parties must have reached an agreement on all terms because they ultimately intended to reduce the settlement to writing. But Endo misconstrues the caselaw. Rather, it is clear, even under Endo's own cases, that "[o]ral settlement agreements are enforceable, but only if the parties have agreed upon the **essential terms** of the bargain." Lannett Co. v. Celgene Corp., No. 08-3920, 2011 U.S. Dist. LEXIS 32915, at \*6 (E.D. Pa. Mar. 29, 2011) (emphasis added); cf. Intellisource, 1999 U.S. Dist. LEXIS 12446, at \*15 (finding no enforceable agreement where essential terms were left unresolved); Behrend v. Comcast Corp., No. 03-6604, 2012 U.S. Dist. LEXIS 137451, at \*26-27 (finding no meeting of the minds "[g]iven the material terms left unresolved in the Term Sheet"). Thus, because the Court finds the essential terms were agreed to, the oral settlement is enforceable even in the absence of a finalized written agreement.

Endo also insists that the parties did not agree on the terms of a settlement agreement because they did not reach an

agreement on the \_\_\_\_\_ or other key terms that were included in the January 24 Draft. However, the parties' course of dealings and the objective manifestations of the parties' intent show that these other terms, and specifically the \_\_\_\_\_, were not "essential" to the formation of a settlement agreement.

With respect to the \_\_\_\_\_, Endo relies heavily on the fact that Mylan initially raised this term. It is undisputed that Mylan raised the concept of a \_\_\_\_\_

\_\_\_\_\_ just prior to, and during, the parties' December 4th Meeting, and that Endo indicated it was not opposed to the concept. At this point, the parties were still in the preliminary phase of negotiations. Although Mylan \_\_\_\_\_

\_\_\_\_\_ it is clear that Mylan determined upon reflection that the risks in this matter did not necessitate inclusion of a \_\_\_\_\_ to protect Mylan's interests. As Bhatt explained, not only had \_\_\_\_\_

Accordingly, Mylan did not insist upon this term and ceased \_\_\_\_\_

pushing it altogether almost immediately.<sup>28</sup> (See Bhatt Tr. 138:18-20 ("THE COURT: [] Is your testimony it never came up after [December 4]? THE WITNESS: That's correct.")). While neither Bhatt nor Tiglio informed Donatiello that it considered the non-essential to settlement, their failure to raise or insist upon the term in any of the offers or counteroffers is consistent with their subjective belief as to its non-importance. Furthermore, Donatiello testified that Endo would not have objected to eliminating the term altogether, signifying that Endo also did not believe the term was essential to resolution of the matter. (Donatiello Tr. 166:4-13 ("Q. . . . If Mylan wanted to give up [the] if they concluded it's not that important to us, would Endo have objected to that? A. No, I don't think so. . . .").)

The Court finds it significant that, as the negotiations progressed

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<sup>28</sup> Donatiello testified that, on one other occasion, Bhatt specifically asked him whether Endo's offer included a to which Donatiello replied that it did. He had difficulty identifying the date of this conversation but surmised that it occurred around mid-December. However, on several other occasions, Donatiello's recollection of the date or terms of the counteroffers was less clear. In light of this, and Bhatt's clear recollection that she did not raise the trigger after December 4, the Court finds that it is more likely that Donatiello is conflating his recollection with the earlier conversation that occurred on December 4.

Mylan ceased including the term in its negotiations. Yet, it seems to this Court that, as the

: dropped from the course of negotiations is consistent with Mylan's contention that they had determined internally this term was not essential to any settlement agreement. While Bhatt and Tiglio acknowledge they did not explicitly convey this thought to Donatiello, the fact that Mylan did not push this term (and in fact ceased raising it at all) demonstrates their lack of concern over a

This conclusion is further buoyed by Tiglio's and Donatiello's conversation on January 28. Not only did Tiglio accept the January 10 Offer, which Donatiello acknowledges did not explicitly include the , but also Tiglio did not include the when she recited the terms of Mylan's acceptance. Rather, it was Donatiello who raised the after Mylan accepted Endo's offer, noting Endo's objection to the

as set forth in the January 24 Draft. Tiglio responded that Donatiello should "mark it up," indicating her belief that the remainder of the terms in the draft could be worked out or

were non-essential. The parties did not discuss any further particulars but rather proceeded to discuss informing the Court of their agreement.

For similar reasons, the Court does not find it significant that the January 24 Draft contained other terms that had not been part of the parties' negotiations. While in Donatiello's view these terms, as drafted, were not "unimportant," that does not by default render them essential terms.<sup>29</sup> (See Donatiello Tr. 162:22-24 ("[T]he rest of them [other potential terms] were things to be worked out but that doesn't mean that they were unimportant.")) "[A] written settlement document will necessarily contain additional, boilerplate and conventional settlement language, not specifically addressed by the parties." Maya Swimwear, 855 F. Supp. 2d at 236 (citing Loppert, 865 A.2d at 1289). Consistent with Delaware law, as long as the parties agreed to the essential terms, or the "heart" of the settlement, the settlement agreement is enforceable. Id. Here, the essential terms of the settlement were the Launch Date, Endo's ability to market an AG, and the attorneys' fees to be paid by Endo to Mylan. Because the undisputed evidence reflects that the parties

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<sup>29</sup> Nor does his statement that the January 24 Draft raised significant issues that needed to be resolved indicate that he did not intend to be bound by the terms of the January 10 Offer. To the contrary, as discussed above, the undisputed evidence shows his clear intent to be bound by the terms of that offer.

agreed to these terms and intended to be bound by them, the Court finds that a reasonable person would conclude that a settlement agreement was reached. See id. at 234 (“Under Delaware law[,], a contract comes into existence if a reasonable person would conclude, based on the objective manifestations of assent and the surrounding circumstances, that the parties intended to be bound by their agreement on all essential terms.”).

#### **B. Endo’s Motion for Entry of Final Judgment**

Endo seeks entry of final judgment in accordance with the Court’s Opinion and Order. It also requests a modification of the Court’s Order to include a provision setting forth the effective date of any approval of Mylan’s ANDA product as well as a provision enjoining certain acts of infringement. However, in light of the Court’s finding that the parties entered into a valid and enforceable settlement agreement prior to the Court’s issuance of its Opinion and Order, and its related decision to grant Mylan relief from that Opinion and Order, Endo’s motion must be denied as moot.

### **III. CONCLUSION**

For the reasons set forth above, the Court grants Defendants’ Rule 60(b) motion as well as its motion to enforce their settlement agreement with Plaintiff, consistent with the terms set forth in the January 10 Offer and recited by Tiglio

during the January 28 call. An order vacating this Court's prior Opinion and Order, and enforcing the settlement in accord with this Opinion, will be entered separately.

Date: April 8, 2014

s/Renée Marie Bumb  
RENÉE MARIE BUMB  
UNITED STATES DISTRICT JUDGE