

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ABBOTT LABORATORIES and	:
ABBOTT RESPIRATORY LLC,	:
	:
Plaintiffs,	:
	:
v.	: Civil Action No. 09-152-LPS
	:
LUPIN LIMITED and LUPIN	:
PHARMACEUTICALS, INC.,	:
	:
Defendants.	:
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**MEMORANDUM OPINION**

May 19, 2011  
Wilmington, Delaware.

  
Stark, U.S. District Judge:

Presently before the Court are (1) the Motion to Preclude Defenses Not Disclosed in Defendants' Interrogatory Responses and to Strike Defenses Not Contained in Defendants' Paragraph IV Letter and Dismiss Related Counterclaims (D.I. 111) filed by Plaintiffs Abbott Laboratories and Abbott Respiratory LLC (together, "Abbott"); (2) the Motion for Leave to File a Surreply Brief in Opposition to Abbott's Motion to Exclude Expert Evidence (D.I. 133) filed by Defendants Lupin Limited and Lupin Pharmaceuticals Inc. (together, "Lupin"); (3) the request made by Abbott to supplement its motion to preclude, which Abbott makes in its opposition brief to Lupin's motion for leave (D.I. 134); (4) the Motion for Summary Judgment of Invalidity of the '428 Patent (D.I. 147) filed by Lupin; and (5) the Motion for Summary Judgment of No Invalidity of U.S. Patent No. 6,080,428 for Double Patenting (D.I. 151) filed by Abbott.

For the reasons discussed, the Court will grant Lupin's motion for leave and Abbott's motion for summary judgment, but will deny the other three motions.

## **I. BACKGROUND**

This is a Hatch-Waxman patent infringement action which Abbott initiated against Lupin on March 6, 2009, asserting infringement of U.S. Patent Nos. 6,129,930 ("the '930 patent"), 6,406,715 ("the '715 patent"), 6,676,967 ("the '967 patent"), 6,746,691 ("the '691 patent"), 7,011,848 ("the '848 patent"), and 6,080,428 ("the '428 patent") (together, the "patents-in-suit"). (See D.I. 1) Plaintiffs had received, on January 22, 2009, a Paragraph IV notice letter informing them of Lupin's ANDA Nos. 90-446, 90-860, and 90-892, in which Lupin seeks FDA approval to market generic niacin extended-release tablets. (*Id.* at ¶¶ 30-31) Lupin's notice letter asserted only that the patents-in-suit were not infringed; no invalidity claims were made in the notice

letter. (*Id.* at ¶ 32) Abbott Laboratories holds NDA No. 20-381 and has listed the patents-in-suit in the Orange Book as covering NIASPAN® niacin extended-release tablets in 500 mg, 750 mg, and 1000 mg. (*Id.* at ¶ 29)

Lupin filed its Answer (D.I. 7) on March 26, 2009, asserting defenses of non-infringement, invalidity, lack of personal jurisdiction, and improper venue. Subsequently, on September 24, 2009, Lupin amended its Answer to include two counterclaims for declarations of non-infringement and invalidity. (D.I. 39) Abbott answered the counterclaims. (D.I. 36)

Meanwhile, on May 29, 2009, the Court issued a Scheduling Order (D.I. 26) requiring the parties to file amended pleadings by September 18, 2009, fact discovery to end on July 9, 2010, and expert discovery to end on September 10, 2010. The Court subsequently amended the Scheduling Order (*see* D.I. 119; D.I. 122) to extend the deadline for expert discovery to March 7, 2011.

On September 27, 2010, Abbott filed its Motion to Preclude Defenses Not Disclosed in Defendants' Interrogatory Responses and to Strike Defenses Not Contained in Defendants' Paragraph IV Letter and Dismiss Related Counterclaims. (D.I. 111) Lupin filed its Motion for Leave to File a Surreply Brief in Opposition to Abbott's Motion to Exclude Expert Evidence on January 6, 2011. (D.I. 133) In its opposition to this motion for leave, filed on January 14, 2011, Abbott requested leave to supplement its motion to preclude. (D.I. 134) On March 25, 2011, the parties filed cross-motions for summary judgment as to the validity of the '428 patent for obvious-type double-patenting. (D.I. 147, D.I. 151)

The Court held a pretrial conference on May 17, 2011. A bench trial in this matter is scheduled to begin on May 31, 2011.

## II. LEGAL STANDARDS

### A. Motion for Summary Judgment

“The court shall grant summary judgment 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). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 415 U.S. 574, 586 n.10 (1986). An assertion that a fact cannot be – or, alternatively, is – genuinely disputed must be supported either by citing to “particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for the purposes of the motions only), admissions, interrogatory answers, or other materials,” or by “showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then “come forward with specific facts showing that there is a genuine issue for trial.” *Matsushita*, 415 U.S. at 587 (internal quotation marks omitted). The Court will “draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.” *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the non-moving party must “do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita*, 475 U.S. at 586-87; *see also Podoknik v. U.S. Postal Service*, 409 F.3d 584, 594 (3d Cir. 2005) (stating party opposing summary judgment “must present more than just bare assertions,

conclusory allegations or suspicions to show the existence of a genuine issue”) (internal quotation marks omitted). However, the “mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;” a factual dispute is genuine only where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 411 U.S. 242, 247-48 (1986). “If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 411 U.S. 317, 322 (1986) (stating entry of summary judgment is mandated “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”).

**B. Motion to Exclude**

Federal Rule of Civil Procedure 26(a)(2)(B)(i) requires that an expert’s report contain “a complete statement of all opinions the witness will express and the basis and reasons for them.” Further, Rule 26(a)(2)(c) provides that “a party must make these [expert] disclosures at the time and in the sequence that the court orders.” Parties are always under an obligation to supplement their contentions, including supplementing expert reports, when it becomes necessary to do so. *See Fed. R. Civ. Proc. 26(e)(1)(A)* (“[A]ny party who has . . . responded to an interrogatory . . . must supplement or correct its disclosure or response . . . in a timely manner if the party learns that in some material respect the disclosure or response is incomplete.”). However, parties may not use their obligation to supplement as an excuse to violate the clear terms of a Scheduling Order, unilaterally buying themselves additional time to make disclosures, thereby unduly prejudicing other parties and potentially delaying the progress of a case.

Pursuant to Rule 37(c)(1), the Court has the power to exclude evidence as a sanction for a party's failure to comply with its obligations under the rules, including the specific deadlines and obligations imposed by a scheduling order. In pertinent part, Rule 37(c)(1) provides that "[i]f a party fails to provide information . . . as required by Rule 26(a) or (e), the party is not allowed to use that information . . . to support evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." In determining whether a failure to disclose is harmless courts consider such factors as: (1) the importance of the information withheld; (2) the prejudice or surprise to the party against whom the evidence is offered; (3) the likelihood of disruption of the trial; (4) the possibility of curing the prejudice; (5) the explanation for the failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence (the "Pennypack factors"). See *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997).

It bears emphasis that exclusion of "critical evidence," such as an expert report on infringement, is an "extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence ." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994) (internal quotation marks omitted); see also *Dow Chem. Co. v. Nova Chems. Corp.*, 2010 WL 2044931, at \*1 (D. Del. May 20, 2010). The determination of whether to exclude evidence is committed to the discretion of the Court. See *In re Paoli*, 35 F.3d at 749.

### **III. DISCUSSION**

#### **A. Lupin's Motion to File a Sur-Reply Brief**

Lupin moves for leave to file a sur-reply brief in opposition of Abbott's motion to

exclude. Lupin asserts that new facts have arisen – to wit, the matters covered in Abbott’s rebuttal expert reports – which the sur-reply brief addresses. Abbott responds by expressing no opposition to the filing of a sur-reply brief if Abbott is allowed to supplement its motion to exclude (to include arguments allegedly raised for the first time in Lupin’s rebuttal expert report<sup>1</sup>) and is given the opportunity to respond to the prejudice argument raised in the sur-reply brief. Lupin replies that the allegedly new arguments are all responses to Abbott’s infringement position as presented in Abbott’s opening expert reports. Lupin adds that Abbott should have filed a second motion to exclude to allow full treatment of the issue it raised in its opposition to Lupin’s motion for leave to file a sur-reply.

The Court will grant Lupin’s motion since it merely informs the Court, in a concise manner, about the content of Abbott’s rebuttal expert reports, which goes directly to the issue of prejudice, which is important to the Court’s analysis of Abbott’s motion to exclude.

**B. Abbott’s Motion to Exclude Defenses Not Disclosed in Lupin’s Interrogatory Responses**

Abbott asks the Court to preclude Lupin from asserting invalidity defenses based on certain prior art references pursuant to Rule 37(c)(1). The purported prior art at issue is EP ’965, the ’930 patent, and about a dozen publications that were not disclosed until Lupin’s opening expert report on invalidity (“the non-disclosed publications”). Abbott asserts that Lupin failed to disclose with specificity its invalidity arguments in accordance with the Scheduling Order, and this failure is unjustified. Abbott further contends that its awareness of the references is irrelevant and it was prejudiced by the late disclosure, since it was left with one month (until the

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<sup>1</sup>The Court will treat this as a separate motion to supplement.

deadline for rebuttal expert reports) to respond to the new arguments.

Lupin responds that Abbott's reliance on Rule 37(c)(1) is misplaced, arguing that under Rule 26(e)(1)(A), no supplementation was required since the information "otherwise had been made known . . . during the discovery process." Fed. R. Civ. P. 26(e)(1)(A). Namely, Lupin's arguments had been made known through the written expert report. Lupin also contends that, even applying Rule 37(c)(1), its invalidity contentions based on EP '965 and the '930 patent should not be excluded. Lupin's late disclosure is justified, it contends, because it first became aware of the potential invalidity arguments when Abbott disclosed third-party notice letters on June 22, 2010. Lupin insists that had Abbott disclosed the letters earlier, Lupin could then have asserted the defenses sooner. Lupin further argues that the *Pennypack* factors favor admissibility, arguing that the delay was caused by Abbott's delay in disclosing the third-party notice letters, Abbott will not be prejudiced, the trial date will not be disrupted, the evidence is critical to Lupin's case, and Lupin has not acted in bad faith.

Abbott replies that Rule 37(c)(1) applies and Lupin's attempt to circumvent it through its alleged compliance with Rule 26(e)(1)(A) would create a gaping loophole through which parties could always delay disclosure of defenses until expert discovery. Abbott also argues that Lupin's purported explanation for its delay in disclosing the invalidity defenses is not credible, since it ignores Lupin's duty to assess the issues in the litigation and the public nature of the documents on which Lupin relies. Last, Abbott emphasizes that it is prejudiced by Lupin's delay since it can address Lupin's arguments only in expert discovery and the additional time until trial provides no relief since Abbott is already busy familiarizing new experts with the dispute. Abbott also emphasizes that, although it was aware the asserted prior art existed, it was unaware that Lupin



was mounting defenses based on these references, and it is that lack of knowledge which is critical to the exclusion inquiry.

Finally, in its sur-reply, Lupin contends that the rebuttal expert reports served by Abbott in December 2010 address the prior art references and invalidity arguments Abbott seeks to exclude, showing that Abbott has not suffered prejudice from the delayed disclosure.

Having considered the record and the pertinent factors, the Court concludes that the “extreme sanction” of precluding Lupin from relying on the disputed invalidity defenses is not warranted. As an initial matter, the Court observes that Lupin’s disclosure of additional invalidity contentions more than sixteen weeks after the close of fact discovery was not a disclosure in “a timely manner” as mandated by Rule 26(e). Turning to Rule 37(c)(1), however, the Court finds Lupin’s failure to supplement its contention interrogatories, in the circumstances of this case, was not unduly prejudicial to Abbott. Abbott had more than three months to respond to Lupin’s opening expert reports. While the Court is sympathetic to the difficulties Abbott encountered following the death of one of its experts, Abbott concedes that it was able to address Lupin’s tardy invalidity arguments in its rebuttal report. (D.I. 129 at 2)

The balance of the *Pennypack* factors also weighs in favor of allowing Lupin to present its invalidity defenses at trial. First, and weighing heavily here, the invalidity contentions are critical to Lupin’s defense in this action. Courts favor the resolution of disputes on their merits. *See Prof'l Cleaning & Innovation Building Servs., Inc., v. Kennedy Funding, Inc.*, 245 Fed. App’x 161, 165 (3d Cir. 2007) (stating “one of the basic objectives of the federal rules . . . [is] the determination of cases on their merits”). This is particularly true with respect to the validity of patents. *See U.S. v. Glaxo Group Ltd.*, 410 U.S. 52, 69 (1973) (“[T]here is a public interest

favoring the judicial testing of patent validity . . . . For when a patent is invalid, the public parts with the monopoly grant for no return, the public has been imposed upon and the patent clause subverted.”).

The other *Pennypack* factors also largely favor admissibility of Lupin’s defenses. Abbott, although it was prejudiced and surprised by Lupin’s untimely disclosure (including by loss of the opportunity to consider deposing the authors of purported prior art references), was able to address Lupin’s contentions, and thereby largely cured the prejudice to it. There is, at this point, no likelihood of trial disruption, as neither party argues that the May 31, 2011 trial date is threatened by this dispute. Nor does the Court find evidence of bad faith or willfulness in Lupin’s not disclosing the defenses at issue sooner.

The only *Pennypack* factor favoring exclusion here is Lupin’s lack of an adequate explanation for its tardiness. Lupin’s position that its failure to disclose its defenses sooner was caused by Abbott’s delay in producing third-party notice letters is inadequate and unpersuasive, as Lupin has an ability and a duty to develop its own defenses. Nonetheless, as already noted, the overall balance does not favor exclusion. Accordingly, the Court will deny Abbott’s motion to preclude.

**C. Abbott’s Request to Supplement its Motion to Exclude**

In its response to Lupin’s motion for leave to file a sur-reply brief on Abbott’s motion to exclude, Abbott requests leave to supplement its motion to exclude. Abbott wishes to exclude additional arguments which Abbott alleges Lupin raises for the first time in its rebuttal expert reports.

The Court will deny Abbott’s request. The proper way for Abbott to have made this

request would have been in a separate motion. *See* D. Del. L.R. 7.1.2(a) (“Unless otherwise ordered, all requests for relief shall be presented to the Court by motion.”). The Court should not have to go hunting for hidden motions that are embedded in parties’ briefs on other motions.

**D. Abbott’s Motion to Strike Defenses Not Contained In Lupin’s Paragraph IV Notice Letter and Related Counterclaims**

Abbott further moves to strike all of Lupin’s invalidity defenses because none were stated in Lupin’s Paragraph IV notice letter. The Hatch-Waxman Act states that a “notice required under this subparagraph shall . . . include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” 21 U.S.C. § 355(j)(2)(B)(iv)(II). Abbott acknowledges that the Federal Circuit has held that this statutory requirement “cannot be enforced by a private party in a patent infringement action.” *Minnesota Mining & Mfg. Co v. Barr Labs., Inc.*, 289 F.3d 775, 777 (Fed. Cir. 2002). Rather, the issue of a Paragraph IV letter’s adequacy is a matter for the FDA to resolve, with recourse available under the Administrative Procedures Act if necessary. *See id.* at 783. Abbott asks the Court to distinguish *3M* on procedural grounds: whereas *3M* involved a dismissed infringement suit, here the infringement dispute remains alive. Abbott concedes that other district courts – including this District – have followed *3M* in the context of live patent disputes. *See Abbott Labs. v. Sandoz Inc.*, 09-cv-215-GMS, 09-cv-972-GMS, D.I. 51 (D. Del Sept. 20, 2010); *Abbott Labs. v. Apotex Inc.*, 2010 WL 2899113, at \*3 (N.D. Ill. Jul 9, 2010); *Biovail Labs., Inc. v. Torpharm, Inc.*, 2003 WL 21254417, at \*2 (N.D. Ill. May 29, 2003).

Abbott essentially raises policy arguments against application of *3M*. In Abbott’s view, under *3M* Lupin’s noncompliance with the Hatch-Waxman Act will go unpunished, despite the

fact that Lupin had all the information available to assert its invalidity defenses at the time it filed its notice letter. Also, Abbott – and all similarly-situated patentees – will be left with no mechanism for enforcement of this provision of the Hatch-Waxman Act. This will permit ANDA applicants to instigate premature litigation, depriving patentees of the full benefit of the automatic thirty-month stay. Moreover, to Abbott the detailed statement requirement is directed at curtailing conduct such as has been displayed by Lupin in this case: an ANDA filer prematurely filing a placeholder notice letter and free-riding on the efforts of subsequent filers.

Lupin responds that the Court should apply *3M* and deny Abbott’s motion. Abbott’s suggested distinction of *3M*, Lupin argues, is insufficient because *3M* did not depend on the status of the underlying infringement action. Rather, *3M* held that the Hatch-Waxman Act did not create a private right of action to enforce the notice letter requirements. Lupin emphasizes that district courts have followed *3M*, finding it to be binding authority, in the context of a live infringement dispute. Lupin also asserts that any enforcement gap in the Hatch-Waxman Act can be filled only by Congress. Lupin adds that, since the pertinent provision states that a notice letter should “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid *or* will not be infringed,” there is no requirement to specify both non-infringement and invalidity positions; disclosing just the former suffices. 21 U.S.C. § 355(j)(2)(B)(iv)(II) (emphasis added). Additionally, Lupin cites to cases finding that an ANDA applicant is not limited to the defenses asserted in its Paragraph IV notice letter. *See Astra Aktiebolag v. Kremers Urban Dev. Co.*, 2000 WL 257125, at \*1 (S.D.N.Y. Mar. 8, 2000); *Abbott v. Apotex*, 2010 WL 2899133, at \*3; *Takeda Chem. Indus., Ltd., v. Mylan Labs., Inc.*, 2005 WL 1457696, at \*1 (S.D.N.Y. June 15, 2005).

Further, Lupin argues that Abbott's position preempts Fed. R. Civ. P. 15 (which allows a defendant to amend its answer as a matter of course), disregards the evolving nature of defense strategies in patent litigation, and ignores the purpose of notice letters (to provide information for a patentee to decide whether to file suit). Lupin also refutes Abbott's prejudice argument, asserting that Abbott has long been aware of the asserted defenses, and has had the opportunity to fully litigate them (because Abbott received ample notice through Lupin's answer and counterclaims). Finally, Lupin argues that the *Pennypack* factors favor the admissibility of its defenses: they are vital to Lupin's case, there is no requirement to voice all defenses in a notice letter, and Abbott will suffer no prejudice.

Despite extensive argument by the parties, the Court can easily resolve this dispute based on binding Federal Circuit precedent. The parties agree that *3M* addresses the issue at bar, is binding authority, and has been followed by district courts. The Court declines Abbott's invitation to deviate from precedential authority. The Court has no authority to penalize deficiencies in Paragraph IV notice letters; the Hatch-Waxman Act creates no private cause of action for such notice letter shortcomings. *See 3M*, 289 F.3d at 783. Regardless of the merits of the policy arguments advocated by the parties, the Court is bound by *3M*. Accordingly, the Court will deny Abbott's motion to strike defenses not asserted in Lupin's Paragraph IV notice letter.

**E. Cross-Motions for Summary Judgment on Obviousness-Type Double-Patenting Defense**

**1. Applicable Legal Principles**

The double-patenting doctrine prevents a patentee from receiving two patents to effectively extend the term of exclusivity for a single invention. *See Takeda Pharma. Co., Ltd. v.*

*Doll*, 561 F.3d 1372, 1375 (Fed. Cir. 2009). The doctrine takes two forms: statutory and non-statutory. *See id.* Statutory, or “same invention,” double-patenting is based on the statutory grant of patents for any new and useful invention. *See* 35 U.S.C. § 101; *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1372-73 (Fed. Cir. 2005). “Non-statutory, or obviousness-type, double patenting is a judicially created doctrine designed to foreclose claims in separate applications or patents that do not recite the same invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection.” *Takeda Pharma.*, 561 F.3d at 1375. At bottom, the double patenting doctrine seeks to curtail “unjustified timewise extension of the right to exclude.” *In re Schneller*, 397 F.2d 350, 354 (C.C.P.A. 1968).

Under the obviousness-type double-patenting doctrine, a patentee is prohibited “from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent.” *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed.Cir.2001). Accordingly, an obviousness-type double-patenting inquiry is a two-step process: “First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences.” *Id.* at 968. Next, the court decides if the differences between the two claims show them to be “patently distinct.” *Id.* “A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.” *Id.* When this is the case, the later claim is invalidated under the doctrine. The party asserting a double-patenting defense must adduce clear and convincing evidence of the deficiency. *See Symbol Tech., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed.Cir.1991).

## 2. Decision

The parties have filed mirror-image cross-motions for summary judgment on Lupin's invalidity defense of obviousness-type double-patenting. (*See* D.I. 147; D.I. 151) Lupin argues that, as a matter of law, the later-issued but earlier-expiring '930 patent is a double-patenting reference against the earlier-issued but later-expiring '428 patent. Therefore, Lupin moves for summary judgment of invalidity of the '428 patent. Abbott responds that the '930 patent cannot be a double-patenting reference and, thus, moves for summary judgment of no invalidity. The Court holds that the '930 patent cannot be used as an invalidating reference against the '428 patent for an obviousness-type double-patenting defense and, accordingly, will grant Abbott's motion for summary judgment of no invalidity and deny Lupin's motion for summary judgment of invalidity.

The Uruguay Round Agreements Act of 1994 ("URAA") brought U.S. patent laws into accordance with the Uruguay round negotiations of the General Agreement on Tariffs and Trade. The URAA included a provision, which became effective on June 8, 1995, that changed the term for a U.S. patent from seventeen years from the patent issue date to twenty years from the earliest effective filing date. *See* Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532(a), 108 Stat. 4809, 4983-85 (1994). Patents that issued before the effective date of the URAA expire on the later of two dates: (1) seventeen years from the issue date or (2) twenty years from the effective filing date. Patents issued after the URAA effective date have a term of twenty years from the earliest effective filing date. As a result, the '428 patent, which was filed on January 14, 1995 (pre-URAA) and issued on June 27, 2000, expires seventeen years after its issue date, on

May 27, 2017.<sup>2</sup> The '930 patent, however, was filed on March 6, 1997 (post-URAA) and issued on October 10, 2000, resulting in a term which runs twenty years from its September 20, 1993 priority date, thus expiring on September 20, 2013.

As the parties note, there is conflicting non-binding persuasive authority addressing the issue in dispute. The Board of Patent Appeals and Interferences (the "BPAI") considered the issue in *Ex Parte Pfizer Inc.*, 2010 WL 532133 (B.P.A.I. Feb 2, 2010), in which the BPAI held that two later-issued but earlier-expiring patents qualified as double-patenting references against an earlier-issued but later-expiring patent. The BPAI stated:

Although [Pfizer] has cited to several cases which refer to double patenting over a prior patent, none of these cases involve the unusual circumstance created here by GATT.

...

According to [Pfizer] . . . the [earlier-issued but later-expiring] 012 patent will extend Appellant's right to exclude the public from practicing [certain] portions of the [later-filed but earlier-expiring] Campbell 511 and 945 patent . . . from October 16, 2015 to October 22, 2019. This is precisely what obviousness-type double patenting was intended to prevent. Therefore, under the circumstances of this case, it is the patent term and not the patent issue date that determines if a claim of [later-filed but earlier-expiring] Campbell 511 or 945 qualifies as a double patenting reference against a claim of the 012 patent.

2010 WL 532133, at \*21.

To the contrary, however, is a more recent decision by Chief Judge Bartle of the Eastern

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<sup>2</sup>The expiration date of the '428 patent is not exactly seventeen years from the issue date because it is subject to a terminal disclaimer shortening the term by one month.



District of Pennsylvania, sitting as a visiting judge in this District. Chief Judge Bartle held that a later-issued but earlier-expiring patent could not serve as a double-patenting reference against two earlier-issued but later-expiring patents, explicitly rejecting *Pfizer*. See *Brigham & Women's Hosp. Inc. v. Teva Pharma, USA Inc.*, 2011 WL 63895, at \*11 (D. Del. Jan. 7, 2011). Chief Judge Bartle stated:

The court is not persuaded by the Board's reasoning [in *Pfizer*]. The Board argues that the double-patenting doctrine is designed to prevent unjust extension of a patent term, but its opinion makes no effort to explain why the shorter period must prevail. The opinion does not explain why a later-issued patent with a shorter term should be used to abridge the term of a valid, earlier-granted patent with a longer term.

. . . Here, as in *Pfizer*, the legal changes to the patent terms, the timing of the applications, and the length of prosecution caused the species patent term to expire before the genus.

Had the patent law not been changed, the later-issued '244 patent would have extended beyond the '068 and '003 patent terms, as is typical with selection inventions. In such a case, we would proceed to determine whether the later species claims were patentably indistinct from the earlier-expiring genus claims. Here, even if the claims in the '244 patent were identical to those in the '068 or '003 patents, the '244 patent's term could not extend the patent protection to which plaintiffs were already entitled on the '068 and '003 patents. Accordingly, the court finds that the later-filed, later-issued '244 patent could not and did not create an 'unjustified timewise extension' of the earlier-filed, earlier-issued '068 or '003 patents.

2011 WL 63895, at \*11 (internal quotation marks omitted).

The Court concludes that Chief Judge Bartle's decision is persuasive and properly resolves the dispute at bar. Abbott has obtained no timewise extension of the earlier-issued but

later-expiring '428 patent through the '930 patent; the term of the '428 patent is the same as it would have been had the '930 patent never issued.

Moreover, the obviousness-type double-patenting doctrine is intended to address *unjustifiable* extensions of patent terms. Here, however, there is no undeserved, extended patent term resulting from improper gamesmanship by the patentee. Abbott did not obtain the later expiration date for the '428 patent through a strategic abuse of the patent system. Rather, an act of Congress – which implemented the results of international trade negotiations – yields an earlier expiration date for the '930 patent while permitting the '428 patent to continue to benefit from the now-repealed U.S. law. Abbott has received no undeserved benefit.

Accordingly, the Court will grant summary judgment of no invalidity to Abbott and deny Lupin's cross-motion for summary judgment of invalidity.

#### **IV. CONCLUSION**

For the reasons discussed, the Court will grant Lupin's Motion for Leave to File a Surreply Brief in Opposition to Abbott's Motion to Exclude Expert Evidence (D.I. 133) and Abbott's Motion for Summary Judgment of No Invalidity of U.S. Patent No. 6,080,428 for Double Patenting (D.I. 151). Further, the Court will deny Abbott's Motion to Preclude Defenses Not Disclosed in Defendants' Interrogatory Responses and to Strike Defenses Not Contained in Defendants' Paragraph IV Letter and Dismiss Related Counterclaims (D.I. 111), Abbott's request to supplement its motion to preclude, and Lupin's Motion for Summary Judgment of Invalidity of the '428 Patent (D.I. 147). An appropriate order will be entered.