UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE BIOGEN '755 PATENT LITIGATION	**Civil Action No.: 10-2734 (CCC)(JBC) (consolidated)** **OPINION**

CECCHI, District Judge.

Before the Court are: (1) EMD Serono, Inc. and Pfizer Inc.'s ("Serono") Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 103 (ECF No. 505); (2) Serono's Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 112 (ECF No. 501); (3) Bayer Healthcare Pharmaceuticals Inc.'s ("Bayer") Motion for Summary Judgment of Invalidity No. 1 – Obviousness-Type Double Patenting (ECF No. 503); (4) Bayer's Motion for Summary Judgment of Invalidity No. 2 – Anticipation by the Treatment References (ECF No. 506); (5) Bayer's Motion for Summary Judgment of Invalidity No. 3 – Lack of Written Description (ECF No. 509); (6) Bayer's Motion for Summary Judgment of Invalidity No. 4 – Anticipation by the Goeddel Patent (ECF No. 513); (7) Bayer's Motion for Summary Judgment No. 5 – Partial Summary Judgment Limiting Damages (ECF No. 517); and (8) Bayer's Motion for Summary Judgment No. 6 – Anticipation by the Weissmann Patent (ECF No. 624). Biogen MA, Inc. ("Biogen") opposes each motion. ECF Nos. 557, 558, 559, 560, 561, 562, 563, 633. The Court heard oral argument on August 10, 2017 and August 11, 2017. The Court has considered the parties' written submissions and oral presentations, including additional briefing subsequent to oral argument (ECF Nos. 656, 659). For the reasons discussed below, the Court denies each motion.

I. BACKGROUND

A. The Patents-In-Suit

In this patent infringement action, Biogen asserts claims of United States Patent No. 7,888,353 (the "'353 patent" or "patent-in-suit") against Defendants Biogen Idec, Inc. and Novartis Pharmaceuticals Corp. (collectively, "Biogen"). The '353 patent claims a method for treating or preventing viral diseases, reducing, or, in some, by administering, to a patient in need, recombinant polypeptide—human interferon beta (also "interferon-β" or "IFN-β")—that is produced by a non-

α, β and γ." (Id. para. 149-50) "Interferon-β is a protein naturally produced by the human body. Bayer's Reply to Biogen's Response to Bayer's Statement of Undisputed and Disputed Material Facts ("SOF") (Motion No. 2), EGF-NO-598, [E][12] Specifically, Interferon-β is produced in β 'is produced in' diploid fibroblast cells" and "in milder amounts in in lymphoblastoid cells." (2755 patent, at [30-53].) "[Hu]IFN-β is usually not detectable in normal or healthy cells." (Id. at 2:40) "Instead, 2:40) "Instead, "the protein is produced as a result of the cell's exposure to "an IFN-inducer." (Id. at 2:41-42) (JA at 2:41-42) "Such "IFN-inducers "are usually viruses but they also can be non-viral in character, such as natural or synthetic double-stranded

agents and methods." (Id. at 6:54-59) (Id. at 6:54-59.)

Certain additional scientific concepts are relevant to the resolution of the motions discussed below. The protein interferon-β is made up of building blocks called amino acids. Amino acids. DNA sequences are made up of nucleotides that each contains a base—adenine ("A"), cytosine ("C"), cytosine ("C"), guanine ("G"), or thymine ("T"). (Bayer's Reply to Biogen's Response to Bayer's SOF ("Mayer's SOF") (Motion No. 6), ECF No. 643-1 ¶ 14. A triplet of DNA nucleotides is known as a "codon," which codes, "which codes for a specific amino acid. Id. ¶ 15. Many amino acids have multiple corresponding codons. Id. ¶ 16. Different DNA

(the "British Application"). During prosecution of the '609 application, on April 15, 1982, the U.S. Patent and Trademark Office ("PTO") made a restriction requirement, separating the pending claims into five groups, one of which included a claim directed to a method of to a method of treatment. Biogen's Response to Bayer's SOF (Motion No. 1), (BCE-No. 539) ¶ 10; The '609 ¶ 10. The '609 application was abandoned in 1994. Id. ¶ 14; 1994. Id. ¶ 14.

Between the PTO's restriction requirement in April of 1982, April of 1982, and the filing of the '930 application in May of 1995, Biogen filed two divisional applications of applications that contained method-of-

States for the treatment of MS via immunomodulation." C.A. No. 10-276O, ECF No. 1 at ¶¶ 50-73, ECF No. 61 at ¶¶ 60-83.) Biogen's infringement claims against Serono are based on the sale of interferon-β product Rebif® in the United States for the treatment of MS via immunomodulation. C.A. No. 10-276O, ECF No. 21 at ¶¶ 32-49, ECF No. 61 at ¶¶ 42-59.) Bayer, Novartis, and Serono claim that the '355 patent claims are invalid, not infringed, and/or unenforceable. On October 1, 2010, the previous Magistrate Judge entered a Pretrial Scheduling Order. Scheduling Order consolidating Bayer's declaratory judgment action with Biogen's patent infringement suit. Bayer Mot. ECF No. 37.

III. LEGAL STANDARD

Summary judgment is appropriate if the "depositions, documents, electronically stored information, affidavits or declarations, stipulations, admissions, interrogatory answers, or other materials" demonstrate that there is no genuine issue as to any material fact, and, construing all facts and inferences in a light most favorable to the non-moving party, the moving party is "entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a), (c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *Paladino v. Avnet Computer Techs., Inc.*, 134 F.3d 1054, 1060 (11th Cir. 1998).

skill in the art ("POSA")[4] as of June 6, 1996, and accordingly those claims are invalid under 35 U.S.C. § 103.[5] A patent claim is invalid if the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. § 103(a). Obviousness is a legal conclusion based on underlying factual determinations, including (1) the scope and content of the prior art, (2) the differences between the claims and the prior art, (3) the level of ordinary skill in the art, and (4) objective indicia of non-obviousness. *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1351 (Fed.

647 at 6-11. Serono acknowledges that if the Court determines that Biogen is not bound by the statements in the Fiers Affidavit, then conflicting evidence warrants denial of its motion. 8/10 Tr., ECF No. 750 at 159:9-14.

To the extent that Serono relies on the Fiers Affidavit as an admission of the obviousness of the '755 patent claims, there are genuine issues of material fact regarding the content of the document and context in which it was submitted that are appropriate for a jury's consideration in the first instance and, hence, preclude summary judgment. Construing the facts in the light most

drawn by a party or inventor in a foreign proceeding in place of its own or its own analysis.[8]

Serono primarily relies on *In re Cygnus Telecommunications Technology, LLC, Patent Litigation*, 536 F.3d 1343 (Fed. Cir. 2008), for the proposition that a party cannot create a genuine issue for trial simply by contradicting its prior sworn statements or statements without explaining the contradiction or attempting to resolve the disparity. In *Cygnus*, the Fed. Cir. affirmed the district court's grant of summary judgment of invalidity under 35 U.S.C. § 102(b)'s on-sale bar. During prosecution of the application that issued as the patent-in-suit, patent-in-suit, the inventor submitted a

Serono also cites cases in this district and the Federal Circuit for the proposition that a party is bound by and cannot later contradict admissions previously made in or duly made in a foreign patent tribunal.[10] None of these cases address the particular issue raised here—namely, whether an inventor's sworn statements made in a foreign patent proceeding involving a separate, foreign patent application are binding on a party in the context of an obviousness determination in litigation in the United States. At most, these cases suggest that the Court may consider statements that are statements made to foreign patent offices as relevant evidence in its overall analysis. Thus, Serono's cited cases do not support its position

methods of treating patients using recombinant polypeptides, not the proteins, nor the transformed non-human hosts themselves or methods of expression using those hosts in ECF. No. 558 at ECF No. 558 at 20. Biogen relies on this Court's construction of the claim language "produced by a non-human host" as "not [a] method step" but instead "merely descriptive of the recombinant polypeptide to polypeptide to be administered." In other words, making the polypeptide is not a claim element. claim element.

Serono relies on *University of Rochester v. G.D. Searle & Co.*, *Pharmacia & Co.*, 358 F.3d 916 (Fed. Cir. 2004) for the proposition that characterizing a claim as a method of using method of using a compound as opposed

based on the specification's "vague functional description" and it was "[n]ot" and it was "undisputed that there was no pre-existing awareness in the art of any compound having [PGHS-2] vis-a-vis [PGHS-2] selective activity." *Id.* at 928, 930. 928, 930.

This Court finds instructive the discussion of *Rochester* in *Eli Rochester* in *Erfinderpraxis Urol Pep GbR v. Eli Lilly & Co.*, No. 15-1202, 2016 WL 6138124 (E.D. Tex. Oct. 21, 2016). The claims at issue in *UroPep* were directed to a method of treating benign prostatic hyperplasia ("BPH") by administering "an effective amount of an inhibitor of phosphodiesterase (PDE) V." *Id.* at *2. The

> of particular inhibitors, that the use of compounds of compounds having the inhibiting feature for a particular therapeutic purpose, that is purpose, the particular risk presented in *Rochester*—that the inventor is seeking claim coverage for a genus of compounds that perform that perform a particular function, while only disclosing a small and unrepresentative subset of such compounds—is not directly presented here presented here.

UroPep, 2016 WL 6138124, at *16. Similarly, here, the '255 patent, the '755 patent claims are directed to the use of recombinant polypeptides having a certain feature (i.e., they were (i.e., they were made using a non-human host) for a particular therapeutic purpose. As Biogen points Bouty also points out, the invention is not "new expression systems to recombinantly express IFN-β" or "new hosts to use new hosts to use to recombinantly express

convincing evidence that a [POSA] would [not be] able to practice the claimed invention without undue experimentation." *Allergan, Inc. v. MSN Labs., Inc.*, 796 F.3d 1293, 1303 (Fed. Cir. 2015) (citation and internal quotations omitted). "Enablement is determined as of the effective filing date of the patent's application." *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010). Enablement is a question of law based on underlying factual inquiries. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (holding that the analysis of undue experimentation "is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual

Serono also cites Federal Circuit decisions assessing enablement of "claims drawn to recombinant production of polypeptides in broad groups of host cells" *Id.* at 13. Serono contends that under this "controlling Federal Circuit precedent," where the old where the claimed host groups at issue were narrower in scope than the "non-human host" genus of the '755 pat of the '755 patent claims, and where the priority dates were later than April 1981, it was determined that practicing that practicing recombinant techniques in one or a few types of host cells did not enable claims to broad ranges o broad ranges of host cells.[15] *Id.* at 4-5, 13-15. Thus, according to Serono, no reasonable jury could correctly could conclude that the '755 patent's

1362, 1374-75 (Fed. Cir. 1999) (affirming district court's finding after bench trial that claims to antisense technology were not enabled after considering several Wands factors, including the fact that the specification provided "little guidance or direction as to the practice of antisense in cells other than *E. coli*"); *In re Goodman*, 11 F.3d 1046, 1050-52 (Fed. Cir. 1993) (affirming PTO's rejection of claims to a method for producing mammalian peptides in plant cells where the patentee did not adequately rebut the record evidence showing that practicing that process gene transformation in all plants would have required extensive experimentation); *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir.

Moreover, the Court disagrees with Sarepta that there is no fact there is no factual dispute as to whether the '755 patent claims are fully enabled. The expert witnesses in the cases in this case have advanced detailed and plausible, but conflicting opinions concerning the adequacy of the adequacy of the '755 patent's disclosure and what was known in the art as of April 1981. For example, the experts dispute the number of known non-human cell lines as of April 1981 that could be used, could be used, by responsibly express interferon-β. See, e.g., Bilger's Response to Sarepta's SOF, ECF No. 560-1 ECF No. 580 ¶¶ 12-22 (citing Green Decl. ¶¶ 114-21; Kaufman Decl. ¶¶ 18-40). The record also reveals, also reveals disputes regarding what was

(D. Del. Mar. 14, 2011) (denying summary judgment where experts "advanced detailed and plausible, but conflicting opinions"); Ing., opinions").

Accordingly, the Court denies Sérono's motion for summary judg summary judgment of invalidity for lack of enablement under 35 U.S.C. § 35 U.S.C. § 112.

iii. Written Description Description

The written description requirement codifies that "the disclosure "the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had the inventor had possession of the claimed

recombinant DNA in one or two working examples of "non-human host" vs "human host" fall as a matter of law to support a showing that the inventor possessed the full scope of the full scope of the claimed hosts. *Id.* at 21-23. Thus, even under the clear and convincing evidence standard, Sarono could, Sarono contends, a reasonable jury would be compelled to find that the '755 patent specification provides an inadequate written description of the claimed invention.

By contrast, Biogen asserts that the proper question is whether POSA would have perceived that Dr. Fiers possessed methods for determining whether biological activity and using

specification, viewed in light of the facts known to [POSA] as of [the SAS] as of the priority date of the ['755] patent, render the specification insufficient to provide the necessary and necessary written description of the inventions of the ['755] patent is "a factual issue" for the jury to decide the judge to decide. *Ortho Pep*, 2016 WL 6138124, at *18. Overall, the Court finds that the instant motion presents a "battle" of the experts" that is not amenable to resolution prior to the presentation of evidence. *See Crown Packaging*, 635 F.3d at 1384; *B-K Lighting*, 374 F. App'x at 952; *Tyco Int'l Servs.*, 748 F. App'x at 330; *Total Containment*, 1999 WL 717948, at *4; *Leader Techs.*, 2011 WL 1514701, at *2.

the "two-way" test, the Court determines whether the asserted patent's claim is patentably distinct from the reference patent's claim and the reference patent's claim is patentably distinct from the asserted patent's claim. *See In re Hubbell*, 709 F.3d 1140, 1149 (Fed. Cir. 1149 (Fed. Cir. 2013) (citing *Berg*, 140 F.3d at 1432); *In re Braat*, 937 F.2d 589, 594 (Fed. Cir. 1991) ("The two-way test arose out of a concern to "prevent rejections for [OTDP] when the applicant's filed first claim filed first for a basic invention and later for an improvement but through no fault of the applicants, the PTO decided the applications in the reverse order of filing." *Hubbell*, 709 F.3d at 1149 (quoting *Berg*, 140 F.3d at 1432).

5. A method for treating a disease selected from the group [sic] consisting of osteosarcoma, cervical dysplasia, leukoplasia, leukemia, multiple myeloma, basal cell carcinoma, lymphoid malignancies, breast carcinoma, glioma, melanoma, papilloma virus, hepatitis virus, hepatitis, viral encephalitis, cytomegalovirus, herpes infections, and fetal loss, and multiple sclerosis, in a patient, comprising administering administration of an effective amount of an IFN-β protein, wherein the IFN-β protein IFN-β protein has phe (F), tyr (Y), trp (W), or ribs (R) substituted for the val (V) at the val (V) at position 101 in wild type IFN-β, numbered in accordance with wild type IFN-β, and wherein the administration results in a therapeutic benefit.

Claim 8 of the '332 patent recites:

8. The method according to claims 5 or 6, wherein the protein wherein the mutein

claiming methods of treatment at any time after the PTO's April 15, 1983 April 15, 1982 restriction requirement and during the pendency of the '608 application, including during the ITC during the pendency of Interference No. 101,096. [15] 8/110 Tr. at BCF No. 1761, at 1053:2-8. Bayer also contends that even if the analysis were solely focused on Biogen's prosecution activity during the "tolling the "pre-pendency period," which Bayer and Biogen appear to agree is from March 1994 to October 24, 1986 October 2000 (see id. at 108:3-19, 128:19-129:1), the undisputed record shows that Biogen was at least partially responsible for the delay. Bayer points to, inter alia, Biogen's (1) withdrawal of the treatment claims after the 1982

and the '755 patent as the earlier-filed "foundational" patent, to which term, to which the two-way test is meant to apply. ECF No. 559 at 14, 15-16; see also Brief, 937 F.2d at 593 (7 F.3d at 593 (stating that "applications for basic and improvement patents should not be penalized by the rate of progress of the applications through the PTO, a matter over which the applicant does not [applicant does not have complete control]").

The Court finds that there are disputed factual issues that precludes that precludes granting Bayer's motion, regardless of whether the focus is solely on the co-pendency period. See Engineered Prods. Co. v. Donaldson Co., Inc., 225 F. Supp. 2d 1069, 1111 (N.D. Iowa 2002), D. Iowa 2002), vacated in part on other

Hence, the record contains sufficient evidence from which a reasonable jury could find for either Biogen or Bayer on the issue of whether the PTO was solely responsible for the delay in prosecution of the '755 patent.

Even were the Court to agree with Bayer that the Bonfire way to the apple way test applies, it would still conclude that summary judgment is inappropriate. As an initial matter, Biogen avers that Bayer's experts have offered no opinions as to whether claim 1 of the '755 or the '755 patent is patentably distinct over the '332 patent claims. ECF No. 559 at 30-33. At this stage, this Court cannot conclude that

recombinant interferon-β is made from Chinese hamster ovary ("CHO") cells are the same "polypeptide" under the parties' agreed-upon definition of the claim terms, i.e., they share the same "linear array of amino acids." Based on this branch in sequence, Bayer contends, native interferon-β and recombinant interferon-β are the same product, and because "a different source and process of obtaining the same product of the claims" cannot confer novelty as a matter of law," summary judgment of anticipation is appropriate. (ECF Nos. 511 - ECF No. 511-17 at 12.) Serono joined Bayer's motion. (ECF No. 529, ECF No. 529.

interferon-β made in a non-human host cell. Bayer's Reply to Biogen's Response to Bayer's SOF (Motion No. 2), ECF No. 598, ¶ 15. In addition, the Court finds that at this stage Bayer is not entitled to a judgment as a matter of law based on its contention that their shared amino acid sequence renders native interferon-β and recombinant interferon-β the same for purposes of anticipation. The Court agrees with Biogen that Bayer reads the claim term "polypeptide" in isolation rather than in the context of the claim. Claim 1 requires that the polypeptide have "antiviral activity" and be administered in a "therapeutically effective amount," which expert

judgment should issue" if "structure alone is enough to distinguish." *Id.* at 6:23-7:6; *see id.* at 15:4-8, 18:1-3. In addition, the Court disagrees with Bayer that the record is undisputed with respect to a lack of any functional difference. Considering the evidence in the light most favorable to Biogen, a reasonable jury could find that there are functional differences between native interferon-β and recombinant interferon-β,[20] (*see* Biogen's Response to Bayer's SOF (Motion No. 2), ECF No. 575 ¶ 10; ECF No. 656 at 2-3, 8, 16; Tr., ECF No. 751 at 53:13-18, 78:4-7, 86:10-19), or at least find that Bayer has failed to show by clear and convincing evidence that no functional

is not representative of a large, densely populated genus of (poly)peptides, (poly)peptides, and (2) as of the invention date there was no known correlation between the structure and activity(ies) and activity) of interferon-β muteins (i.e., no structural features common to the members of the genus of (poly, genus of (poly)peptides)). Serono joined Bayer's motion. [ECF No. 530]. ECF No. 530.

As discussed above with respect to Serono's motion for summation for summary judgment of invalidity for lack of written description, it is the method of treatment, not the genus, not the genus of expression systems, which needs to be described. Similarly, here, the Court concludes that concludes that it is not the recombinant

whether the '755 patent discloses specific examples of interferon-β (or interferon-β) proteins or guideposts to identify muteins with antiviral activity. (Biogen's Response to Bayer's SOF to (Bayer's SOF) (Motion No. 3), ECF No. 576 ¶¶ 3, 4). The parties and their experts also dispute whether (quote) "whether the '755 patent discloses a correlation between the structural features of interferon-β and its mutein-β and its proteins and their functional biological activity" (id. ¶¶ 1, 2). Indeed, the parties and their experts dispute the scope of claim 1. Biogen and its experts contend that the claim "is relatively narrow and fairly narrow and the criteria make clear that the claims only cover the use of recombinant IFN-β and recombinant polypeptides that are closely

for patent." 35 U.S.C. § 102(e)(2). "Anticipation is a question of fact." *Purdue Pharma*, 811 F.3d at 1351. at 1351.

The Goeddel patent issued on October 24, 1995 from a U.S. patent application that claims priority to U.S. Application No. 190,399 (the "'399 application"), filed on September 25, 1980. ECF No. 514, FFCL ¶ 6. Based on a review of the parties' briefs and oral briefs and oral argument, resolving the anticipation question here entails deciding: (1) whether the Goeddel patent is entitled to a September 25, 1980 filing date; (2) whether claim 1 of the '755 patent; the '755 patent is entitled to a June 6, 1980

question of fact and enablement is a question of law, based on underlying facts. *Allergan*, 796 F.3d at 1308-09. Bayer contends that since Biogen did not present evidence rebutting Bayer's expert's testimony on this issue, summary judgment is appropriate. Appropriate. - ECF No. 514-15 at 6; ECF No. 600 at 4-6. No. 600 at 4-6.

The record demonstrates genuine disputes regarding whether the '179 or whether the Goeddel patent is entitled to a September 25, 1980 filing date. A reasonable jury could conclude, and Biogen asserts, that the Goeddel patent claims are not adequately supported by the '799 application '799 application but rather rest in part

British Application's disclosure. A reasonable jury could find, as Bayer and its experts contend, that references to "immunomodulation" are absent from the British Application and were only later added in the '609 application, evidencing that Dr. Fiers had not conceived of treatment by immunomodulation by June 6, 1980. ECF No. 914-15 at 13-16; 14-Alert at 13-46. Alternatively, a reasonable jury could find, as Biogen and its experts assert, that the British Application's application "is replete with examples and references to the immunomodulatory properties of IFN" and a POSA "would understand this as disclosing the use of IFN to affect the immune system regardless of [regardless of] whether the term

testing is required. Id. By contrast, Bayer contends that the Goeddel patent's DNA molecule meets claim 1's hybridization limitation because it is degenerate to degenerate to—i.e., encodes the same polypeptide (interferon-β) as—Serono's DNA molecule, which Biogen tested and accused of infringing claim 1. EOR, No. 600 at 15. A reasonable jury, taking all the evidence in the light most favorable to Biogen, could find that Bayer has not proven, by clear and, by clear and convincing evidence, that the Goeddel patent discloses each and every element of claim 1. Of claim 1. This is a further reason to conclude that summary judgment is inappropriate. inappropriate.

35 U.S.C. § 154(c)(3). Bayer argues that the two conditions of § 154(c)(3) of § 154(c) are met: (1) "substantial investment was made" in the development of Bayer's Betaseron® (or Betaseron®) approved by the FDA in 1993—prior to June 8, 1995; and (2) Biogen received the benefit of the benefit of the 17-years-from-issuance term for the '755 patent, which provided Biogen's later expiration date (September 15, 2026) than it would have had if instead the patent were to expire 20 years from filing (2009). ECF No. at 518-27 at 3. Thus, according to Bayer, Bayer's allegedly infringing acts of selling acts of selling Betaseron® between 2009 and the present "became infringing" by reason of § 154(c)(3), (d); 154(c)(1). *Id.* at 11.

of detrimental reliance on an expected shorter term. *Id.* at 12-14 n. *Id.* at 12-14.

The Court finds that Bayer has not established that equitable term equitable remuneration under § 154(c) applies in this case. Bayer has not identified a case that has applied the equitable remuneration provision of § 154(c)(3) to a patent that issued from an application that application that was pending in the PTO on June 8, 1995. Although Bayer dismisses as dicta or minimally supported the discussions of equitable remuneration under § 154(c) in *Merck & Co., Inc. v. Kessler*, *Inc. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996) and *TAP Pharmaceutical Products, Inc. v. Atrix Laboratories, Inc.*, *Laboratories, Inc.*, 2005 WL 2006 WL 873822, 2005 WL

*25 (N.D.N.Y. Mar. 31, 2015) ("'Inexorable' means that the profits flow automatically from the subsidiary to the parent; in other words, the subsidiary's profits are the parent's profits.").

In opposition, Biogen contends that it may recover the profits it itself lost on intercompany, arm's length sales to U.S. Corp. It is undisputed that Biogen and U.S. Corp., although related, function as separate companies. Biogen's Response to Bayer's SOF ¶ 8. Biogen explains that it sells the Avonex® drug substance (interferon-β) and the finished Plegridy® and Tecfidera® to U.S. Corp. in return for payment of an intercompany purchase price. 8/11 Tr., ECF No. 751 at 2804-

inappropriate. inappropriate.

iii. Whether Rebif® should be taken into account as a non-infringing alternative

Bayer further argues that if Biogen is allowed to pursue lost profits, the hypothetical marketplace must include Serono's Rebif® as a non-infringing alternative. ECF No. 518-27 at 24-40. In response, Biogen contends that there is evidence in the record that Serono would not have exercised its option, which is a sufficient dispute of fact to deny summary judgment. ECF No. 562 at 33-34. For the reasons discussed in the Court's Opinion regarding Serono's motion for partial

inserts (HFIF3 and HFIF6) recited in claim 2). Id. at 14-18. Accor 14-18> According to Bayer, since the Weissmann patent meets the hybridization limitation, and since it is, and since it is undisputed that the prior-art patent meets all the other limitations of claim 1, the Weissmann patent assigns patent anticipates claim 1.

The parties previously agreed on the following construction of the construction of the hybridization limitation of claim 1: of claim 1:

> capable of hybridizing to a pair of more of the nucleotide the nucleotide sequences inserted at the PstI restriction site of GpBR322 selected pBR322 selected from the group consisting of GpBR322(Pst)/HFIF1, GpBR322(Pst)/HFIF2, GpBR322(Pst)/HFIF3 (DSM1791), GpBR322(Pst)/HFIF5 (DSM 1792), and GpBR322(Pst)/HFIF6 (DSM 1793), and GpBR322

By contrast, Biogen contends that Bayer has failed to show that the Weissmann patent discloses each and every element of claim 1. Specifically, according to Biogen, claim 1 requires the existence of both the DNA sequence for interferon-α and Clone 4 and Clone 4. While the Weissmann patent discloses a genus of thousands of DNA sequences that code for interferon-α, it discloses neither Clone 4, Clone 4-specific DNA sequences that would hybridize to (hybridize to the disclosed interferon-α DNA sequences), nor any specific DNA sequences that are degenerate to (degenerate to the disclosed interferon-α DNA sequences). NEC Exh. 63 at 25-26. Biogen also argues, in its own light, that its own expert's

and the claim L-DNA inserts do not hybridize. Moreover, a reasonable jury could reject either or both Bayer's and Biogen's experts' experiments as poorly designed or improperly conducted.

Accordingly, the Court denies Bayer's motion for summary judgment of invalidity based on anticipation by the Weissmann patent.

V. CONCLUSION

For the reasons discussed above, the Court denies Serono's and Serono's and Bayer's motions for summary judgment (D.I. Nos. 501, 503, 505, 506, 509, 513, 517, 624, 513, 517, 624) and will enter an appropriate Order