

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**SIEMENS HEALTHCARE
DIAGNOSTICS INC.,**

Plaintiff,

v.

ENZO LIFE SCIENCES, INC.,

Defendant.

Civil Action No. _____

JURY TRIAL DEMANDED

COMPLAINT UNDER 35 U.S.C. § 146 AND JURY DEMAND

Plaintiff Siemens Healthcare Diagnostics, Inc. (“Siemens” or “Plaintiff”) for its complaint against the defendant Enzo Life Sciences, Inc., (“Enzo” or “Enzo Life Sciences,” or Defendant), states as follows:

THE NATURE OF THE ACTION

1. This is a civil action under 35 U.S.C. § 146 to remedy the judgment and decisions that were adverse to Plaintiff’s predecessor, Bayer Healthcare LLC (“Bayer”) in interference No. 105,489. An interference is a proceeding before the United States Patent and Trademark Office (“USPTO”) to determine the first party to invent the technology in question. The ‘489 interference was between Bayer and Defendant Enzo. Because Enzo filed its U.S. patent application No.: 08/479,995 (“the ‘995 application, Ex. 1) before Bayer filed its application which became U.S. Patent 5,124,246 (“the ‘246 patent,” Ex. 2), Enzo was named the “Senior Party” in the interference.

2. On May 14, 2010, the USPTO erroneously ruled that Enzo invented the technology in question before Siemens. The USPTO defined the technology in question based on

the language contained in several claims of Siemens' '246 patent. If not reversed, the USPTO's erroneous ruling will provide Enzo exclusive patent rights to the inventions described in Siemens' expired '246 patent. The erroneous ruling would also effectively prohibit the public from practicing the technology in question for almost double the statutory term, as set forth below.

THE PARTIES

3. Siemens is a California corporation with places of business in, among others, Norwood, Massachusetts; Walpole, Massachusetts; and Deerfield, Illinois. Siemens acquired Bayer Healthcare LLC, and is the real party in interest to the '246 patent. Siemens manufactures products covered by claims of the '246 patent in its Walpole, Massachusetts facility.

4. Upon information and belief, Enzo Life Sciences is a New York corporation having offices at 60 Executive Boulevard, Farmingdale, New York 11735. Upon information and belief, Enzo Life Sciences is a wholly-owned subsidiary of Enzo Biochem, Inc., which is a New York corporation having offices at 527 Madison Avenue, New York, New York 10022 and at 60 Executive Boulevard, Farmingdale, New York 11735.

5. Upon information and belief, Enzo purposefully conducts continuous and systematic business within the Commonwealth of Massachusetts.

JURISDICTION AND VENUE

6. This Court is vested with subject matter jurisdiction pursuant to 35 U.S.C. § 146, and 28 U.S.C. §§ 1331 and 1338(a).

7. Venue is proper in this judicial district under 28 U.S.C. § 1391 and Fed. R. Civ. P. 4(k)(2).

FACTS GIVING RISE TO THE COMPLAINT

8. Plaintiff Siemens has the entire right, title and interest to the '246 patent. The '246 patent, titled "Nucleic Acid Multimers and Amplified Nucleic Acid Hybridization Assays

Using Same,” issued on June 23, 1992, based on application No. 07/340,031 filed on April 18, 1989. The ‘246 patent expired on June 23, 2009.

9. Enzo purports to be the assignee and real-party-in-interest of the ‘995 application at issue in the interference. The ‘995 application, titled “Assay Method Utilizing Polynucleotide Sequences,” was filed on June 7, 1995.

10. On August 7, 2006—over fourteen years after the ‘246 patent issued—the USPTO declared the interference between the ‘246 patent and Enzo’s ‘995 application.

11. In declaring the interference, the USPTO determined that certain claims of the Enzo ‘995 application and Siemens’ ‘246 patent “interfere” because they claim a common invention. In the interference, the relevant claim with respect to the ‘246 patent is Claim 53.

12. The interference is based on a single “count” (here Count 1), which defines the invention contested in the interference. Count 1 is the “nucleic acid hybridization assay” of Claim 53 of Siemens’ ‘246 patent. Only the first inventor of the count is entitled to a patent covering the count.

13. Numerous claims correspond to Count 1. They are Claims 39-41 and 43-56 of the ‘246 patent and all claims of Enzo’s ‘995 application, namely, claims 283-362, 364, 365, 382, 383, 400, 401, 403, 404, 406, 407, 409-439, 441-505, 507, 508, 510, 511, and 528-547 (Ex. 3).

14. Claim 53 of Siemens’ ‘246 patent, depends from Claim 51, which depends from independent Claim 39. Claims 39, 51 and 53 of the ‘246 patent are recited below:

39. A synthetic linear nonhomopolymeric nucleic acid multimer useful as a means for amplifying a detectable signal in an assay involving nucleic acid hybridization consisting essentially of:
- (a) at least one first single-stranded oligonucleotide unit that is capable of hybridizing specifically to a first single-stranded nucleic acid sequence of interest; and
 - (b) a multiplicity of second single-stranded oligonucleotide units all of which are capable of hybridizing specifically to a second

single-stranded nucleic acid sequence of interest, wherein the first single-stranded oligonucleotide unit is bonded directly or indirectly to the multiplicity of second single-stranded oligonucleotide units only via covalent bonds.

51. The nucleic acid multimer of claim 39 wherein the second single-stranded nucleotide sequence of interest is a sequence of a single-stranded labeled oligonucleotide.

53. A nucleic acid hybridization assay wherein:

- (a) the multimer of claim 51 is hybridized via the first oligonucleotide unit to single-stranded analyte nucleic acid bound to a solid phase or to a single-stranded oligonucleotide bound to the analyte;
- (b) unbound multimer is removed;
- (c) single-stranded labeled oligonucleotide is hybridized to the multimer via the second oligonucleotide units;
- (d) unbound labeled oligonucleotide is removed; and
- (e) the presence of label bound to the multimer is detected.

15. When the interference was declared on August 7, 2006, Enzo's '995 application was pending at the USPTO for more than 23 years through a chain of abandoned continuing applications. A continuing application is directed to the same invention as a prior application and follows the prior filed application. The continuing application is given the benefit of the earlier filing date of the application on which it is based. Enzo's '995 application purports to relate back to an application filed on May 5, 1983.

16. Enzo's '995 application claims the benefit of the filing dates of five earlier-filed U.S. patent applications Nos. 06/491,929, 06/922,757, 07/607,787, 07/805,274, and 08/342,667. Each of these was filed as a continuation of the preceding application. Enzo abandoned each of these applications without a single claim ever issuing as a patent and refilled them as continuing applications. As a result, Enzo artificially and illegally extended the potential expiration date of any patent that might result from these applications.

17. Enzo's '995 application is the latest application in a chain of applications that Enzo alleges relates back to Enzo's May 1983 patent application. This chain of applications contains at least 771 application claims.

18. In a recent press release about the interference, Enzo asserted that "Enzo developed its signal amplification technology in the early 1980s, filing its original patent application on May 5, 1983." *See* Corporate Press Release, Enzo Biochem, Inc., dated March 1, 2010 (Ex. 4).

19. If this Court does not reverse the erroneous decisions and judgment of the USPTO and Enzo's '995 application is allowed to issue as a patent, it will be Enzo's first patent to issue in the 27-year old chain of patent applications. Because Enzo's first application was filed before the 1995 amendments to the Patent Act, Enzo would have a patent monopoly of 17 years from the date its patent issues. For example, if the '995 application were to issue in 2010, its potential term would extend to 2027, which is about 44 years after Enzo purportedly developed its signal amplification technology, which it purportedly described in its 1983 patent application.

20. During the unduly long 23-year pendency of Enzo's applications, Enzo repeatedly abandoned allowed claims to delay issuance of its patent. Enzo's first application was filed in 1983 and applications filed then were not published by the USPTO pre-grant. (The American Inventors Protection Act of 1999 requires publication of U.S. patent applications that were filed on or after November 29, 2000). Enzo did not take any steps to have its patent application published or otherwise inform the public about its submarine patent application. During this unduly long pendency of Enzo's applications, the public may have been practicing Enzo's pending claims for years, without having any knowledge about them (and may have relied on the fact that no Enzo patent claims or applications were published).

21. Enzo recently stated in a press release that Siemens' "'VERSANT® Branched DNA (bDNA) Assays' [utilize] the technology whose claim has now been resolved in Enzo's favor by the interference judgment.'" (*See* Corporate Press Release, Enzo Biochem, Inc., dated March 1, 2010, Exhibit 5). If Enzo's statements are true and its patent claims are granted after the unreasonable and inexcusable 23-year delay in prosecution, Enzo would profit from its undue delay to the detriment of both the public and Siemens. Both the public and Siemens will suffer material prejudice directly attributable to the delay Enzo caused.

22. Enzo recently stated its intent to reap maximum commercial benefit from a patent that, if issued, claims technology that it says it developed in the early 1980s. Enzo's President, Barry Weiner, stated that "[t]his technology is the basis for several significant products in clinical diagnostics and in the life sciences field which are currently marketed or licensed by various commercial entities." *See* Corporate Press Release, Enzo Biochem, Inc., dated March 1, 2010, Ex. 5). In this same press release, Enzo stated that "[a]ccording to trade reports, industry-wide annual sales of diagnostic products utilizing the nucleic acid signal amplification technology are estimated to exceed \$100 million in the United States alone." (*Id.*)

CLAIMS FOR RELIEF

23. Plaintiff Siemens incorporates the preceding paragraphs of this Complaint by reference.

24. Siemens seeks relief here under 35 U.S.C. § 146 because it is dissatisfied with the decision of the USPTO on the interference.

25. This Action is filed with respect to each and every judgment or decision adverse to Siemens in the interference. The particular decisions set forth below are by way of example and do not include an exhaustive list. The evidence introduced at the interference, as well as other evidence which may be introduced during this Action, will show that the decisions made by the USPTO were erroneous and that judgment should have been entered in favor of Siemens.

26. The USPTO's decisions and judgments in the interference on the preliminary motions that Siemens was allowed to make, as well as the decision to preclude Siemens from making certain motions, were based upon erroneous determinations adverse to Siemens, including, but not limited to, those set forth below.

27. The USPTO has special rules and procedures regarding interference motions. Under one of these, on October 13, 2006, the USPTO filed and mailed Paper No. 22, entitled "Order – Bd.R. 104(c) – Priority Times" (Ex. 6). In that Paper, the USPTO denied Siemens's request to file a motion for judgment under 37 C.F.R. § 41.121(a)(i)(3) that Enzo's involved claims are unpatentable as anticipated by or obvious in light of the prior art under 35 U.S.C. § 102 and § 103. The USPTO's refusal to allow Siemens to file such a motion harmed Plaintiff. The refusal contributed to an erroneous outcome of the interference.

28. In the October 13, 2006, Paper No. 22, the USPTO also denied Siemens to file a motion for judgment under 37 C.F.R. § 41.121(a)(i)(3) that certain of Senior Party Enzo's claims

are multiple dependent claims (which refer and depend on more than one other claim) that depend on other multiple dependent claims in violation of 35 U.S.C. § 112 paragraph 5. The USPTO's refusal to allow Siemens to file such a motion harmed Plaintiff. The refusal contributed to an erroneous resolution to the interference.

29. On February 22, 2010, the USPTO filed and mailed Paper 60 entitled "Decision – Bd.R. 125 on Motions" (Ex. 7), erroneously holding that Enzo's involved claim 360, based on a long-abandoned claim 239, is not barred under 35 U.S.C. § 135(b). Section 135(b) bars a patent application claim (that is the same as, or for the substantially the same subject matter as, a patent claim) from becoming a patent claim unless the application claim was created more than one year before the USPTO granted the patent.. The USPTO's holding that Enzo claim 360 was not barred is based on erroneous claim construction, and has harmed Plaintiff. The decision contributed to an erroneous outcome of the interference.

30. The USPTO's erroneous holding that Enzo's involved claim 360 is not barred under 35 U.S.C. § 135(b), led the USPTO, on February 22, 2010, to erroneously dismiss Siemens' motion for judgment that no interference in fact exists between the '246 patent and Enzo's claims 507, 508, 510, 511, and 528-531. This motion was contingent on the grant of the motion that Enzo's claims 283-362, 364, 365, 382, 383, 400, 401, 403, 404, 406, 407, 409-439, and 441-505 are not barred under 35 U.S.C. § 135(b). The USPTO's decision has harmed Plaintiff. The decision contributed to an erroneous outcome of the interference.

31. In its February 22, 2010, Decision, the USPTO erroneously declined to exercise its discretion to decide Siemens' motion for judgment under 37 C.F.R. § 41.121(a)(i)(3) that Enzo's involved claims are unenforceable due to prosecution laches.

32. Enzo repeatedly abandoned allowed claims to delay issuance of its patent.

Enzo's delay spanned at least 23 years (from when its parent application was filed in 1983 until the declaration of interference in 2006). Enzo filed numerous unpublished continuing applications which it repeatedly abandoned. The prosecution laches result from Enzo's undue delay in prosecuting its patent applications before the USPTO. Enzo consistently delayed and prolonged the prosecution process. At one point, Enzo abandoned an application for several months before reviving it. As a result of Enzo's actions, the public was unable to learn of the existence of this "submarine" application or the claims Enzo ultimately sought. As a result of Enzo's unreasonable and inexcusable 23-year delay in prosecution, Plaintiff Siemens and the public will suffer material prejudice directly attributable to the delay. The USPTO's decision harmed Plaintiff. It contributed to an erroneous outcome of the interference. The USPTO's decision will have a profound and negative impact on the public.

33. On February 23, 2010, the USPTO filed and mailed Paper 61 entitled "Judgment – Bd.R. 127" (Ex. 8), erroneously entering judgment against Siemens for count 1 and cancelling claims 39-41 and 43-56 of the '246 patent. The USPTO's holding has harmed Plaintiff. It resulted in an erroneous outcome of the interference.

34. On May 14, 2010, the USPTO filed and mailed Paper 66 entitled "Decision – Bd.R. 125(c) on request for rehearing" (Ex. 9), erroneously denying Siemens' request for rehearing of the Decision on its motion for repose under 35 U.S.C. § 135(b). The USPTO's holding is based on erroneous application of the doctrine of claim differentiation. The doctrine narrows the scope of the abandoned claim 239 in view of abandoned claim 238. The holding is also based on the erroneous conclusion that one skilled in the art would have understood claim 239 "to include more than one non-radioactive signaling portion." This is despite the fact that

claim 239 should be interpreted to mean a *single* item “selected from the group consisting of” the list of items recited in the claim. The USPTO’s holding has harmed Plaintiff. It contributed to an erroneous outcome of the interference.

35. Upon information and belief, no appeal has been taken to the United States Court of Appeals for the Federal Circuit.

PRAYER

WHEREFORE, Plaintiff Siemens prays that the Court grant:

1. Leave to introduce the record of interference No. 105,489 before the USPTO’s Board of Patent Appeals and Interferences (“Board”) and to take discovery and introduce additional evidence to supplement the record in this action regarding issues that were properly raised before the Board;
2. *De novo* consideration of the interference record, if introduced, and the supplemental evidence adduced by way of additional discovery with respect to the issues of patentability and priority as to Count 1 and other matters as referenced herein or which Siemens asserts are related to this matter;
3. Reversing all portions of the Board’s decisions or judgment adverse to Siemens, including reversing the Board’s February 22, 2010, Decision, February 23, 2010, Judgment, and May 14, 2010, Decision against Siemens and ordering and decreeing, *inter alia*, that claims 39-41 and 43-56 of the ‘246 patent are not cancelled;
4. Determining that Enzo’s ‘995 application is unenforceable due to prosecution laches;
5. Determining that all claims of the Enzo ‘955 application corresponding to the count are unpatentable to Enzo;
6. Entering judgment for Siemens and against Enzo in the ‘489 interference;

7. Declaring this action an exceptional case;
8. Awarding Siemens its costs in this action, including its reasonable attorneys'

fees; and

9. Awarding Siemens such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Dated: July 9, 2010

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