

Kennedy's assertions, that Abbott does not and will not owe royalties to Kennedy for that patent. A true and correct copy of the '442 patent is attached as Exhibit A.

NATURE OF ACTION

1. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

PARTIES

2. Plaintiff Abbott Laboratories is an Illinois corporation that has a principal place of business in Illinois and conducts business in this District. Abbott Laboratories is engaged in the development, sale and distribution of a broad range of pharmaceutical drugs and other health-care products.

3. Plaintiff Abbott Biotechnology Limited is a corporation organized under the laws of Bermuda, with a place of business at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda. Through intermediate organizations, Plaintiff Abbott Biotechnology Limited is owned by Plaintiff Abbott Laboratories.

4. Since 2003, Abbott has been marketing in the United States its highly acclaimed HUMIRA[®] product, an inventive human, high-affinity and neutralizing "anti-TNF α " antibody. HUMIRA[®] has been used to treat hundreds of thousands of patients who suffer from various TNF-related conditions, including rheumatoid arthritis.

5. Defendant Kennedy Institute Trust is organized and exists under the laws of the United Kingdom, having a place of business at 65 Aspenlea Road, Hammersmith, London W6 8LH England. Defendant Kennedy is also the owner of certain United States patents, including U.S.

Patent No. 6,270,766 (“the ’766 patent,” a true and correct copy of which is attached as Ex. B) and the ’442 patent.

6. Since 2002, Abbott has been licensed under the ’766 patent and related intellectual property. Abbott makes quarterly royalty payments to Kennedy pursuant to the terms of the license.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338 and 28 U.S.C. §§ 2201 *et seq.*

8. Plaintiff Abbott, having paid royalties for many years under the ’766 patent, reasonably expected that its obligations would end upon expiration of the ’766 patent in October 2012.

9. On January 26, 2011, however, counsel for Defendant Kennedy Institute Trust sent a letter to Plaintiff Abbott notifying it of the issuance of the ’442 patent and asserting that pursuant to its existing license obligations “Abbott will owe royalties to Kennedy” under the ’442 patent through August 21, 2018. While the amount of royalties Abbott currently pays under the license is presently unchanged by the issuance of the ’442 patent, the issuance of the ’442 patent has purportedly extended Abbott’s obligation to pay royalties pursuant to the license by almost six years. Specifically, Kennedy now contends that Abbott must pay royalties through the ’442 patent’s August 2018 expiration date, rather than ceasing payments as of the ’766 patent’s October 2012 expiration date.

10. As noted above, Abbott has been marketing and selling HUMIRA[®] in the United States since early 2003 and has no plans to cease such activities. Pursuant to the parties’ license

obligations, however, Abbott should owe no royalties beyond the expiration of the '766 patent because the newly issued '442 patent is invalid and thus an improper extension of Kennedy's patent monopoly. Kennedy has asserted its rights under this patent and has recently filed other patent infringement actions concerning the related '766 patent against other parties who refused to pay royalties. Abbott would risk an action for patent infringement if it terminated its agreement upon expiration of the '766 patent or otherwise did not make royalty payments under the '442 patent.

11. On information and belief, Kennedy exploits its patents (such as the '442 patent) only by enforcing them via judicial or extra-judicial means (i.e., having no products of its own, Kennedy exploits its patents solely by licensing and enforcing them).

12. Indeed, Kennedy has enforced its patents on several occasions when disputes have arisen. For example, in 2010, when a dispute arose as to royalties allegedly owed on Kennedy's '766 patent, Kennedy sued UCB Inc. for patent infringement. *See Mathilda & Terence Kennedy Instit. of Rheumatology Trust v. UCB Inc.*, 2010-cv-00650 (D. Del.) (filed Aug. 3, 2010). Likewise, in 2009, Kennedy sued Amgen, Inc. and others for infringement of the '766 patent. *See Mathilda & Terence Kennedy Instit. of Rheumatology Trust v. Amgen Inc. et al.*, 2009-cv-00805 (D. Del.) (filed Oct. 27, 2009). In 2008, when Abbott and Kennedy disputed the proper method for calculating the royalty amounts owed pursuant to their '766 patent licensing obligations, Kennedy initiated an arbitration against Abbott.

13. Under the totality of the circumstances, an actual controversy sufficient to establish declaratory judgment jurisdiction exists here between Abbott and Defendant Kennedy.

14. This Court has personal jurisdiction over the Defendant Kennedy Institute Trust. On information and belief, Kennedy conducts its patent licensing and enforcement activities through its New York patent counsel. These New York attorneys sent Abbott the January 2011 correspondence demanding that Abbott pay royalties under the '442 patent. On information and belief, these attorneys have also accepted service of process on behalf of Kennedy in prior litigation.

15. The agreement under which Abbott pays royalties to Kennedy is also governed by New York law and previous disputes under the agreement have been litigated and arbitrated in New York.

16. In October 2008, for example, Defendant Kennedy Institute Trust initiated an arbitration pursuant to this license against Plaintiff Abbott in New York concerning the proper method for calculating the royalties owed on Kennedy's '766 patent. Kennedy and the parties to that arbitration later consented to having a judge in New York (in this District) confirm that arbitration award. *Abbott Biotechnology Ltd. v. The Mathilda & Terence Kennedy Instit. of Rheumatology Trust*, No. 09-cv-03872-DC (S.D.N.Y. Apr. 29, 2009). A litigation relating to this Kennedy arbitration also took place in and was resolved by this District. *See, e.g., Centocor, Inc. v. The Kennedy Instit. of Rheumatology*, No. 08-cv-08824, 2008 WL 4726036 (S.D.N.Y. Oct. 29, 2008) (Chin, J.). In November 2003, Kennedy and Abbott representatives met in New York to address issues with respect to licensing Kennedy's '766 patent and related intellectual property.

17. Defendant Kennedy Institute Trust also granted its New York patent attorneys power of attorney to prosecute its patents before the Patent and Trademark Office ("PTO"), including Kennedy's '766 patent and the '442 patent-in-suit. And those New York attorneys did in fact

prosecute and obtain those patents for Kennedy and remain the primary contact for all future correspondence from the PTO.

18. Venue lies in this District pursuant to 28 U.S.C. § 1391(b).

FACTUAL BACKGROUND

The Parties' Licensing Relationship for the '766 Patent and '442 Patent

19. Defendant Kennedy Institute Trust is the owner of the '766 patent, issued by the PTO on August 7, 2001. As more fully described below, the '766 patent relates to methods for treating arthritis and other diseases by "co-administering" methotrexate and an anti-TNF α antibody.

20. On January 1, 1992, Defendant Kennedy entered into a licensing agreement with a Pennsylvania corporation, Centocor, Inc. (now Centocor Ortho Biotech Inc., "Centocor"). Among other things, the agreement granted Centocor the right to sublicense Kennedy patent rights. On December 23, 2002, Centocor entered into a sublicense agreement with Plaintiff Abbott for Kennedy's '766 patent and related intellectual property.

21. On July 29, 2004, Centocor and Defendant Kennedy entered into an amendment of their 1992 agreement. Among other things, the amendment recognizes the 2002 Centocor-Abbott sublicense agreement and allows Abbott to pay royalties due thereunder directly to Kennedy.

22. In October 2008, this Court recognized (and Abbott and Centocor agreed) that the Kennedy Institute is an intended third-party beneficiary of Plaintiff Abbott's sublicense agreement with Centocor. *Centocor, Inc. v. The Kennedy Instit. of Rheumatology*, No. 08-cv-08824, 2008 WL 4726036, at *3 (S.D.N.Y. Oct. 29, 2008) ("Here, it is undisputed that Kennedy is the intended third-party beneficiary of the [2002] Centocor-Abbott Agreement . . .").

23. Based on the December 2002 sublicense agreement, Abbott has paid tens of millions of dollars in royalties for Kennedy's '766 patent.

Kennedy's '766 Patent

24. Kennedy's '766 patent issued from U.S. patent application no. 08/690,775 (for convenience, "the '766 application"), filed on August 1, 1996.

25. During prosecution of the '766 application, Kennedy sought and was granted the benefit of an earlier filing date (or "priority") for the '766 patent's "co-administration" claims. In particular, Kennedy successfully argued for priority pursuant to 35 U.S.C. § 120 to U.S. patent application no. 07/958,248 ("the '248 application"), filed October 8, 1992.

26. The '766 patent expires 20 years from the filing date of the '248 application, that is, on October 8, 2012.

27. The '766 patent issued with 30 claims. Claims 1-7 and 28-30 are directed to methods of treating arthritis. Claims 8-14 are directed to methods of treating rheumatoid arthritis. Claims 15-21 are directed to methods of treating Crohn's disease. The remaining claims are directed to compositions used to carry out the methods. Claim 8 recites: "A method of treating rheumatoid arthritis in an individual in need thereof comprising co-administering methotrexate and an anti-tumor necrosis factor alpha antibody or an antigen-binding fragment thereof to the individual, in therapeutically effective amounts." Ex. B at col. 35, lines 59-63.

28. According to the '766 patent, "[a]s a result of Applicants' invention, a method is provided herein for treating and/or preventing a TNF-mediated disease in an individual,

comprising co-administering methotrexate and a tumor necrosis factor antagonist to the individual in therapeutically effective amounts.” *Id.* at col. 4, lines 41-45.

29. In a September 1999 submission to the PTO, Defendant Kennedy Institute Trust characterized the '766 patent invention as “the discovery that a TNF α antagonist can be administered to patients suffering from a TNF-mediated disease (such as an autoimmune or inflammatory disease) as adjuvant or concomitant therapy to methotrexate therapy.”

30. To overcome the PTO’s rejections concerning the patentability of the claimed invention, Defendant Kennedy Institute Trust pointed to allegedly “unexpected” results reported in the patent specification concerning the use of an anti-TNF antibody as “adjunctive” therapy with methotrexate in patients whose arthritis was not controlled by methotrexate alone.

31. Responding in May 2000 to the PTO’s assertion that such “unexpected” results were only shown under the limited conditions of “adjunctive” therapy in patients who did not respond adequately to methotrexate, Kennedy stated:

There is no technical reason to believe that the synergistic effects exemplified in the specification by combination therapy with methotrexate and a TNF α antagonist is limited to a certain patient population. That is, there is no technical reason to believe that treatment with a combination of methotrexate and a TNF α antagonist, in accordance with Applicants’ teachings, would not yield the superior therapeutic effects described in the subject application. The superior therapeutic effects are due to the co-administration of methotrexate and a TNF α antagonist functionally limited to therapeutically effective amounts, as described in the specification.

Following Kennedy’s assertion that the purportedly “unexpected,” “synergistic” and “superior” therapeutic results reported in the patent specification were representative of the methods claimed in the '766 patent, the PTO allowed the claims and issued the '766 patent.

Kennedy's '442 Patent-in-Suit

32. Kennedy's '442 patent issued from U.S. patent application no. 11/225,631 (for convenience, "the '442 application"), filed on September 12, 2005. The '442 application is from the same chain of applications that gave rise to the '766 patent.

33. The '442 patent is identical in all respects to the '766 patent, except for its claims.

34. During prosecution of the '442 application, despite having previously relied on the earlier October 1992 priority date during prosecution of the '766 application, Kennedy instead sought and was granted the benefit of a filing date (or "priority") for the '442 patent's claims that went back only to 1996. As a consequence, Kennedy obtained years of additional exclusivity for its '442 patent.

35. The '442 patent issued on December 7, 2010, and has a 20-year term starting from the filing date of the '766 application. With an additional 750 days of patent term adjustment granted by the PTO, the '442 patent will thus not expire until August 21, 2018.

36. The '442 patent issued with 22 claims. All the claims are directed to a method of treating an individual suffering from rheumatoid arthritis. Ex. A at cols. 35-36.

37. The methods claimed in the '442 patent are within the scope of, and obvious variants of, at least claims 1-14 of Kennedy's '766 patent.

38. For example, claim 14 of the '442 patent recites: "[a] method of treating an individual suffering from rheumatoid arthritis and already receiving methotrexate whose active disease is

incompletely controlled comprising administering to the individual with methotrexate therapy a different composition comprising an anti-human tumor necrosis factor- α monoclonal antibody, wherein such administration reduces or eliminates signs and symptoms associated with the rheumatoid arthritis.” *Id.* at col. 36, lines 10-17.

39. Although it asserted that such '442 claims to “adjunctive” therapy were “patentably distinct” from the '766 patent claims, Defendant Kennedy had already relied on the use of such “adjunctive” therapy and its purportedly “unexpected” effectiveness in earlier arguing to the PTO for the patentability of the '766 patent claims.

40. Kennedy’s arguments to the PTO for the separate patentability of the claims of the '442 patent contradict or ignore the arguments it made years ago during the prosecution of the '766 patent. For example, despite its prior assertion to the PTO during prosecution of the '766 patent that any “combination” of methotrexate and a TNF α antagonist would yield the “superior therapeutic effects” described in the '766 patent, Kennedy later argued in May 2010 while prosecuting the '442 patent that “[t]he advantages obtained using the adjunctive therapy described in the pending claims are NOT obtained with other types of combination therapy.”

41. In addition, Kennedy points to the *same studies and results* it used to show “unexpected” and “synergistic” benefits of the methods claimed in the '766 patent to argue for “unexpected” benefits of the methods now claimed in the '442 patent.

42. The patent laws do not allow Kennedy to prolong its period of patent exclusivity by obtaining new claims to the same invention or obvious variants of the same invention it claimed in the '766 patent.

COUNT I

(Declaratory Judgment of Invalidity of the '442 Patent)

43. Plaintiff Abbott re-alleges paragraphs 1-42 as if fully set forth herein.
44. An actual controversy pursuant to 28 U.S.C. §§ 2201 *et seq.* exists between Plaintiff Abbott and Defendant Kennedy concerning the validity of the claims of Kennedy's '442 patent.
45. The claims of the '442 patent are invalid for failing to meet the requirements of patentability under the federal patent laws, including for obviousness-type double patenting over the Kennedy '766 patent.
46. Abbott warrants a declaratory judgment that the claims of the '442 patent are invalid.

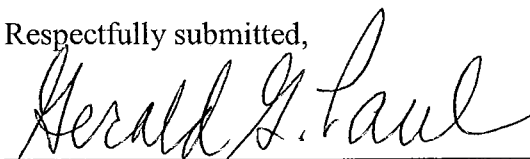
PRAYER FOR RELIEF

WHEREFORE, Plaintiff Abbott respectfully requests the following relief:

- (a) a declaration that the claims of U.S. Patent No. 7,846,442 are invalid and a final judgment incorporating same;
- (b) a "speedy hearing" on its declaratory-judgment action as authorized by Fed. R. Civ. P. 57;
- (c) entry of equitable relief, including injunctive relief that enjoins Defendant and any of its officers, agents, employees, assigns, representatives, privies, successors, and those acting in concert or participation with them from asserting or in any way claiming infringement of U.S. Patent No. 7,846,442;
- (d) a judgment holding that this is an exceptional case under 35 U.S.C. § 285 and awarding Abbott its reasonable attorneys' fees, costs, and expenses; and
- (e) such other relief deemed just and proper.

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Respectfully submitted,



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