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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

BAYER HEALTHCARE	)	
PHARMACEUTICALS INC.	)	
	)	
Plaintiff,	)	
	)	Civil Action No. _____
v.	)	
	)	
BIOGEN IDEC INC.	)	
	)	
Defendant.	)	
_____	)	

**COMPLAINT FOR DECLARATORY JUDGMENT OF  
PATENT INVALIDITY AND NON-INFRINGEMENT**

Bayer HealthCare Pharmaceuticals Inc. (“Bayer”) for its Complaint against Biogen Idec, Inc. (“Biogen”) alleges as follows:

NATURE OF THE ACTION

1. This is an action for declaratory relief pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201. Bayer seeks a declaration that United States Patent No. 7,588,755, “DNA Sequences, Recombinant DNA Molecules and Processes for Producing Human Fibroblast Interferon-like Polypeptides,” issued on September 15, 2009 (“the ’755 patent”) is invalid and a declaration that the importation into the United States, manufacture, use, offer for sale, or sale of Betaseron<sup>®</sup>, an FDA-approved protein pharmaceutical used to treat relapsing forms of multiple sclerosis, does not infringe the ’755 patent and does not induce

infringement of, or contribute to the infringement of the '755 patent by others. This action arises out of Biogen's repeated allegations that Bayer's Betaseron<sup>®</sup> product infringes the '755 patent, and is based on the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

#### THE PARTIES

2. Plaintiff Bayer HealthCare Pharmaceuticals Inc. ("Bayer") is a corporation organized and existing under the laws of the State of Delaware. Bayer maintains its principal place of business at 6 West Belt, Wayne, New Jersey. It also has a facility at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey.

3. Upon information and belief, Biogen Idec Inc. ("Biogen") is a corporation organized and existing under the laws of the State of Delaware. Upon information and belief, Biogen maintains its principal place of business at 14 Cambridge Center, Cambridge, Massachusetts.

#### JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

5. On information and belief, this Court has personal jurisdiction over Biogen because Biogen has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being hailed into court here. On information and belief, Biogen has had persistent and continuous contacts with this judicial district, including developing, selling, distributing, and/or manufacturing pharmaceutical products that are sold in this judicial district. Among the pharmaceutical products Biogen has developed, sold, distributed, and/or manufactured in this judicial district is AVONEX<sup>®</sup>. Biogen contends that the use of AVONEX<sup>®</sup> to treat multiple sclerosis is covered by the claims of the

'755 patent.

6. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

#### BACKGROUND

7. Betaseron<sup>®</sup> is a protein pharmaceutical based on the protein interferon beta-1b. In 1993, the Food and Drug Administration approved the use of Betaseron<sup>®</sup> in patients suffering from multiple sclerosis. Betaseron<sup>®</sup> is manufactured and distributed in the United States by Bayer.

8. Betaseron<sup>®</sup> (known as Betaferon<sup>®</sup> outside of the United States) has global sales in excess of one billion dollars.

9. The face of the '755 patent states that it is assigned to Biogen Idec MA Inc. On information and belief, Biogen Idec MA Inc. is now known as, or is the same entity as, Biogen. A copy of the '755 patent is attached as Exhibit A hereto.

10. The '755 patent purports to claim priority to GB App. No. 8011306, filed April 30, 1980.

11. Biogen contends that the '755 patent “covers the treatment of multiple sclerosis with [Biogen’s product] AVONEX<sup>®</sup> (Interferon beta-1a)[.]” Biogen also contends that the '755 patent “will expire in September 2026.”

12. On September 22, 2009, Jo Ann Taormina, Biogen’s Vice President, Chief Research and Development Counsel, sent a letter to Bayer AG’s Chief Legal Officer. The letter stated that Biogen was the assignee of the '755 patent and that the '755 patent had issued a week earlier. The letter enclosed a copy of the '755 patent for Bayer AG’s “convenience” and invited Bayer AG to discuss the “possibility of licensing Biogen Idec’s technology.”

13. Biogen's letter was routed to John Calvo, Senior Counsel at Bayer. Mr. Calvo responded to Ms. Taormina, and over the next five months, Mr. Calvo exchanged over a dozen emails regarding holding negotiations with Ms. Taormina and Bart Newland, Biogen's Vice President, Chief Intellectual Property Counsel. Bayer and Biogen exchanged drafts of a mutual confidentiality agreement regarding licensing negotiations, but the agreement was never finalized.

14. R. Scott Meece, Bayer's General Counsel and Senior Vice President, spoke with Mr. Newland by telephone on March 25, 2010. Mr. Newland represented that Biogen alleges that Bayer's sale and marketing of Betaseron<sup>®</sup> infringes the '755 patent.

15. On April 5, 2010, Mr. Newland spoke again with Mr. Meece. Mr. Newland reiterated Biogen's assertion that Bayer's sale and marketing of Betaseron<sup>®</sup> infringes the '755 patent. Bayer's counsel requested that Mr. Newland provide an explanation of Biogen's contention that Betaseron<sup>®</sup> infringes the '755 patent. Mr. Newland declined to provide an explanation.

16. During the April 5, 2010 telephone conversation, Mr. Newland indicated to Mr. Meece that Biogen would license the '755 patent non-exclusively to Bayer for a "high single digit royalty" and proposed a royalty rate of 8 to 8.5 percent. An 8 to 8.5% royalty on Bayer's sales of Betaseron<sup>®</sup> corresponds to annual payments of at least tens of millions of dollars.

17. Following the April 5, 2010 telephone call, Mr. Newland emailed Mr. Meece requesting a meeting in New York or at Biogen's headquarters, "with or without outside counsel." Mr. Meece declined the invitation, responding "Let's see after we look at the patent and history in detail."

18. On May 26, 2010, Biogen's outside counsel, Mr. Nicholas Groombridge spoke with Mr. Meece by telephone, re-stated Biogen's contention that Bayer's Betaseron<sup>®</sup> product infringes the '755 patent, and indicated Biogen's desire to "move things along."

19. On May 27, Mr. Meece responded to Biogen's counsel in a letter transmitted by email. The letter stated that Bayer had considered the '755 patent, and that it had decided to decline Biogen's offer of a license. The letter further stated that Bayer believed further negotiations would be unfruitful, given Bayer's belief that it does not require a license to the '755 patent. The letter stated that Bayer understood that the negotiations between Bayer and Biogen regarding the '755 patent had concluded.

COUNT I – DECLARATORY JUDGMENT OF INVALIDITY

20. Bayer incorporates each of the preceding paragraphs 1-19 as if fully set forth herein.

21. There is an actual controversy between Bayer on the one hand and Biogen on the other hand as to whether the '755 patent is valid.

22. The claims of the '755 patent are invalid for failure to comply with the conditions for patentability specified in 35 U.S.C. §§ 101, 102, 103, 112, *et seq.*, and/or under the judicially created doctrine of obviousness-type double patenting, *inter alia*, on the basis that they fail to comply with the enablement and written description requirements of 35 U.S.C. § 112, and/or that they are rendered obvious by at least the following prior art to the '755 patent: Knight et al., *Human Fibroblast Interferon: Amino Acid Analysis and Amino Terminal Amino Acid Sequence*, SCIENCE, vol. 207, pages 525-26 (1980); Nagata et al., *Synthesis in E. coli of a Polypeptide with Human Leukocyte Interferon Activity*, NATURE, vol. 284, pages 316-20 (1980); Taniguchi et al., *Human Leukocyte and Fibroblast Interferons Are Structurally Related*,

NATURE, vol. 285, pages 547-49 (1980); a pre-print of Taniguchi et al., *Human Leukocyte and Fibroblast Interferons Are Structurally Related*, NATURE, vol. 285, pages 547-49 (1980); Weissenbach et al., *Identification of the Translation Products of Human fibroblast Interferon mRNA in Reticulocyte Lysates*, EUR. J. BIOCHEM., vol. 98, pages 1-8 (1979), and/or prior art cited on the face of the '755 patent and during the patent's prosecution history.

23. Bayer hereby seeks a declaration that the claims of the '755 patent are invalid.

COUNT II – DECLARATORY JUDGMENT OF NON-INFRINGEMENT

24. Bayer incorporates each of the preceding paragraphs 1-23 as if fully set forth herein.

25. There is an actual controversy between Bayer on the one hand and Biogen on the other hand as to whether the importation into the United States, use, offer for sale, and/or sale of Betaseron<sup>®</sup> infringes the '755 patent or contributes to or induces infringement by others.

26. The importation into the United States, use, offer for sale, and/or sale of Betaseron<sup>®</sup> does not infringe the '755 patent or contribute to or induce infringement by others.

27. Bayer hereby seeks a declaration that the importation into the United States, use, offer for sale, and/or sale of Betaseron<sup>®</sup> does not infringe the '755 patent or contribute to or induce infringement by others.

PRAYER FOR RELIEF

WHEREFORE, Bayer respectfully requests that judgment be entered in favor of Bayer and against Biogen and requests the following relief:

- A. A declaration that the '755 patent is invalid;
- B. A declaration that the importation into the United States, use, offer

for sale, and/or sale of Betaseron<sup>®</sup> does not infringe the '755 patent or contribute to or induce infringement by others;

C. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

D. Costs and expenses in this action; and

E. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

/s/ Robert M. Goodman

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Dated: May 27, 2010