UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

Abbott Laboratories, Plaintiff, v. Grifols Diagnostic Solutions Inc., Grifols Worldwide Operations Limited and Novartis Vaccines and Diagnostics, Inc. Defendants.	Case No. 1:19-cv-6587

COMPLAINT

Plaintiff Abbott Laboratories for its complaint against Grifols Diagnostic Solutions Inc., Grifols Worldwide Operations Limited, and Novartis Vaccines and Diagnostics, Inc., hereby alleges as follows:

INTRODUCTION

1. Abbott seeks to invalidate a patent that claims 35-year old technology. U.S. Patent 7,205,101 claims technology that is not eligible to be patented, is well beyond the scope of what is actually contained in its 35-year old patent disclosure, and was already covered by patent claims that expired a decade ago. It should be declared invalid.

2. This case traces its roots to the early 1980's. At the time, the first cases of AIDS had recently been reported and, in the face of substantial uncertainty, scientists were hard at work to find the cause. In 1983-84, three groups independently identified viruses that later became known as HIV as the cause. Each of those groups gave the isolate of the virus it had characterized a different name: LAV (by Dr. Luc Montagnier's group at the French Institut Pasteur), HTLV-III (by Dr. Robert Gallo's group at the National Institutes of Health), and ARV (by Dr. Jay Levy at the University of California, San Francisco).

3. Abbott was also actively addressing the AIDS epidemic in the mid-1980's. As one example, Abbott was hard at work at the time developing a test to screen blood for exposure to HIV. In March of 1985, the FDA approved the first test to screen blood for HIV, and this test was developed by Abbott. Abbott also received patent protection for its work, including U.S. Patent No. 4,748,110 on an immunoassay for HIV antigens.

4. Another company researching HIV at this time was Chiron Corporation ("Chiron"). Chiron's work involved sequencing a strain of HIV called ARV-2.

5. Chiron sought patents for its work sequencing the ARV-2 strain of HIV, filing its first application, No. 06/667,501, on October 31, 1984. Chiron abandoned that application, but pursued continuation applications, including Application No. 07/138,894 that was filed on December 24, 1987. That application issued on October 20, 1992 as U.S. Patent No. 5,156,949. The '949 Patent expired in 2009.

6. Chiron continued to seek additional patents after the '949 Patent. In all, eighteen separate applications were filed claiming priority to the same application in 1984 resulting in twelve additional patents. These patents share the same disclosure, claim priority to the same patent application, and recite the same sequence of ARV-2 that was disclosed in 1984. Despite all the ways in which these patents are identical, Chiron, Grifols, and Novartis have benefited from multiple terms of patent protection—spanning more than thirty years for a single invention.

7. One of these patent applications led to the patent at issue in this case. U.S. Patent No. 7,205,101 was applied for on May 17, 1995, more than a decade after Chiron's original application was filed. The '101 Patent did not issue until April 17, 2007, almost twelve years after its application was filed and almost twenty-three years after the original application was filed. It

is slated to expire in 2024, forty years after ARV-2 was first sequenced and identified in a patent application.

8. In total, thirteen patents have been obtained based on the same work, with patent protection extending for more than forty years after the original patent application was filed.

9. Through these patents, Chiron, Grifols, and Novartis have improperly sought to expand the duration of their patent monopoly and the scope of their claims well beyond what the inventors allegedly invented and what is eligible subject matter for patent protection.

10. Unsurprisingly, after seeking so many patents from a single application, Chiron and its successors have sought claims that are obvious in light of those they already obtained and that have expired. For example, the ’101 Patent purports to exclude others from practicing a method that was necessary to practice claims in the ’949 Patent; a patent which expired a decade ago in 2009.

11. This violates both the letter and purpose of the patent system. Double patenting is a doctrine that protects against this very scenario. Specifically, obviousness-type double patenting prevents a patentee from improperly extending its monopoly by obtaining protection for the same invention or obvious variants of what it has claimed in another patent. Chiron and its successors have done precisely that here.

12. Chiron, Grifols, and Novartis have also improperly sought patent protection beyond the scope of what the inventors knew and disclosed in the 1984 application. Chiron discovered the sequence of a single strain of HIV in 1984. By seeking patent claims well beyond the discovery of that single sequence and applications thereof, the ’101 Patent improperly seeks patent coverage well beyond the scope of the inventors’ disclosure and contribution to society.

13. The ’101 Patent also is invalid for attempting to claim so broadly as to cover naturally occurring processes and for lacking an inventive concept necessary for patent eligibility.

14. This is not a case in which Chiron, Grifols, and Novartis have received no benefit from their ownership of patents related to Chiron’s work. For more than twenty years, Abbott has paid royalties to Chiron, then Novartis, then Grifols pursuant to a license it took in 1996 to settle litigation between Abbott and Chiron. These royalties were paid for years past the expiration of the ’949 Patent and paid through the expiration of several other patents in this family as well.

15. Over the past year, Abbott has engaged with Grifols to discuss the fact that Grifols’ patents do not cover Abbott’s products. Grifols has made clear its position that the products infringe the ’101 Patent.

16. On October 3, 2019, Abbott gave Grifols notice of termination of its license to the ’101 Patent. The license agreement contemplates that upon its termination, disputes regarding infringement and invalidity shall be resolved in district court.

17. Given the position Grifols has taken regarding the scope of its patent vis-a-vis Abbott’s products, and Abbott’s desire for certainty that it is free of any obligation to pay for an invalid patent, Abbott seeks a declaratory judgment that the ’101 Patent is invalid.

NATURE OF THE ACTION

18. Abbott brings this action seeking, as of November 2, 2019, a declaratory judgment that U.S. Patent No. 7,205,101 (“the ’101 Patent”) is invalid under 35 U.S.C. § 100 *et seq.* The ’101 Patent is attached to this Complaint as Exhibit A.

PARTIES

19. Plaintiff Abbott Laboratories is an Illinois corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064-3500. Abbott has made and makes

products used to test for HIV, including the Abbott PRISM HIV O Plus assay and the Abbott ARCHITECT HIV Ag/Ab Combo assay, at facilities within this judicial district.

20. Grifols Worldwide Operations Limited ("Grifols Worldwide") is a company organized under the laws of the Republic of Ireland with a principal place of business at Grange Castle Business Park, Grange Castle, Clondalkin, Dublin 22, Ireland. On information and belief, Grifols Worldwide owns an undivided one-half ownership interest in U.S. Patent No. 7,205,101.

21. Grifols Diagnostic Solutions Inc. ("Grifols Diagnostic") is a Delaware corporation with its principal place of business at 4560 Horton Street, Emeryville, California 94608.

22. Novartis Vaccines and Diagnostics, Inc. ("Novartis") is a Delaware corporation with its principal place of business at One Health Plaza, East Hanover, New Jersey 07936-1080. On information and belief, Novartis owns an undivided one-half ownership interest in U.S. Patent No. 7,205,101.

JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 2201, 1331, and 1338(a) because this action arises under the patent laws, and seeks relief under the Federal Declaratory Judgment Act. 28 U.S.C. § 2201.

24. This Court has personal jurisdiction over Grifols Diagnostic because Grifols Diagnostic has purposefully availed itself of the benefits of this State. This availment includes conducting regular business in this state and, specifically related to this declaratory judgment claim, Grifols Diagnostic has availed itself of the benefits of this State at least by conducting business pursuant to a license agreement it had with Abbott, a resident of this State, by which Abbott paid royalties to Grifols. The performance of that license was substantially connected with this State and with the '101 Patent.

25. This Court has personal jurisdiction over Grifols Worldwide because it has purposefully availed itself of the benefits of this State. This availment includes entering into a co-ownership agreement concerning the patent at issue in this case, which was previously licensed to Abbott, a resident of this District. The performance of that license was substantially connected with this State and the '101 Patent. Moreover, Grifols Worldwide is subject to personal jurisdiction because Grifols Diagnostic has, on information and belief, acted as Grifols Worldwide's agent with respect to the '101 Patent and Abbott. As Grifols Diagnostic acted as Grifols Worldwide's agent, personal jurisdiction over Grifols Worldwide is appropriate based on Grifols Diagnostic's actions. Upon information and belief, Grifols Worldwide transacts business within this State.

26. This Court has personal jurisdiction over Novartis because it has purposefully availed itself of the benefits of this State by previously filing suit in this District. *See Seattle Children's Hospital et al. v. Akorn, Inc.*, No. 10-cv-05118 (N.D. Ill.). Moreover, Novartis has purposefully availed itself of the benefits of this State as it has entered into a co-ownership agreement concerning the patent at issue in this case, which was previously licensed to Abbott, a resident of this District. Novartis at one time received royalties from Abbott in connection with that license. The performance of that license is substantially connected with this State and the '101 Patent. Upon information and belief, Novartis transacts business within this State.

27. Venue is proper in this district under 28 U.S.C. § 1391(b), (c), (d), and/or 1400(b) because, *inter alia*, Abbott resides in this District and makes the products which would be the basis for any infringement action in this District.

RELEVANT PATENTS

The '949 Patent

28. U.S. Patent No. 5,156,949 is entitled "Immunoassays for Antibody to Human Immunodeficiency Virus Using Recombinant Antigens." The '949 Patent is attached to this Complaint as Exhibit B.

29. The '949 Patent lists Paul A. Luciw and Dino Dina as inventors.

30. The face of the '949 Patent lists Chiron Corporation as the assignee.

31. The '949 Patent was filed on December 24, 1987 and claims priority to October 31, 1984.

32. The '949 Patent issued on October 20, 1992.

33. The '949 Patent expired on October 20, 2009.

34. Claim 2 of the '949 Patent is recited below:

> **2.** A method of detecting antibodies to a human immunodeficiency virus (HIV) in a human sample comprising:
>
> a) providing a solid support having bound thereto a recombinant polypeptide comprising at least an immunogenic portion of the envelope (env) domain of said HIV, wherein said recombinant polypeptide is the expression product of cellular hosts transformed by a heterologous expression vector comprising a DNA sequence encoding said recombinant polypeptide under the control of transcriptional and translation initiation and termination regulatory sequences functional in said cellular hosts;
>
> b) contacting said solid support with said human sample to provide a sample-contacted support;
>
> c) washing said sample-contacted support to provide a washed support; and
>
> d) determining whether human antibodies are bound to said washed support.

The '101 Patent

35. U.S. Patent No. 7,205,101 is entitled "Human Immunodeficiency Virus (HIV) Nucleotide Sequences, Recombinant Polypeptides, and Applications Thereof."

36. The '101 Patent lists Paul A. Luciw and Dino Dina as inventors.

37. The face of the '101 Patent lists Novartis Vaccines and Diagnostics as the assignee. The U.S. Patent and Trademark Office assignment database lists Novartis Vaccines and Diagnostics and Grifols Worldwide Operations Limited as co-owners of the '101 Patent.

38. The '101 Patent was filed on May 17, 1995 and claims priority to October 31, 1984.

39. The '101 Patent claims priority to the same 1984 application as the '949 Patent.

40. The '101 Patent issued on April 17, 2007.

41. The '101 Patent is slated to expire on April 17, 2024.

42. Claim 1 of the '101 Patent is recited below:

> **1.** A method for replicating DNA specific for HIV, which comprises:
>
> (a) providing a DNA construct comprising an origin of replication recognized by a unicellular microorganism and a DNA sequence comprising at least a 20 bp sequence of a human immunodeficiency virus (HIV) genome; and
>
> (b) growing a unicellular microorganism containing said DNA construct under conditions whereby said DNA sequence is replicated.

FIRST CLAIM FOR RELIEF

Declaratory Judgment of Invalidity of the '101 Patent

43. Abbott repeats and re-alleges paragraphs 1-42 as if fully set forth herein.

44. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks, as of November 2, 2019, a declaration that claims of the '101 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, such as double patenting.

45. At least claim 1 of the '101 Patent is invalid for obviousness-type double patenting because it is not patentably distinct over an invention claimed in the '949 Patent and the patents share a common inventor, applicant, or owner.

46. At least claim 1 of the '101 Patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

47. At least claim 1 of the '101 Patent is invalid for failing to claim eligible subject matter because it is directed to a law of nature, natural phenomena, or abstract idea, and lacks an inventive concept.

48. A present, genuine, and justiciable controversy exists between Abbott and Defendants regarding, *inter alia*, the validity of the claims of the '101 Patent.

49. Abbott is entitled to a declaration that one or more claims of the '101 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation or unenforceability, such as double patenting.

PRAYER FOR RELIEF

WHEREFORE, Abbott requests the following relief:

a) That a judgment be entered declaring that the claims of the '101 Patent are invalid and/or unenforceable for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of sections 101, 102, 103, 111, 112, 116, 135, 256, 282, and 287, or other judicially-created bases for invalidity or unenforceability, such as double patenting;

b) That a judgment be entered declaring that this case is exceptional under 35 U.S.C. § 285, and accordingly that Abbott is entitled to recover reasonable attorneys' fees and costs upon prevailing in this action; and

c) That Abbott be awarded such other relief that the Court deems just and equitable, or which the Court deems just and proper.

DATED: October 3, 2019

Respectfully submitted,

/s/ Bryan S. Hales

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