UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

INSTITUT PASTEUR AND BIO-RAD LABORATORIES, INC.,

Plaintiffs,

vs.

ABBOTT LABORATORIES

Defendant.

Case No. 17-7104

COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiffs Institut Pasteur and Bio-Rad Laboratories, Inc., by their attorneys, for their Complaint in this action allege:

PARTIES

1. Institut Pasteur ("Pasteur") is a private institution located at 25-28 rue du Docteur Roux, 75015 Paris, France

2. Bio-Rad Laboratories, Inc. ("Bio-Rad") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2000 Alfred Nobel Drive, Hercules, California 95457.

3. On information and belief, Abbott Laboratories ("Abbott") is a corporation organized and existing under the laws of the State of Illinois, having its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064-6400.

JURISDICTION

4. This action arises under the Patent Act of 1952, as amended, 35 U.S.C. §§ 1 et seq.

5. This Court has subject matter jurisdiction to hear this action under 28 U.S.C. §§ 1331, 1338(a) and 1367(a).

THE PATENT IN SUIT

6. Pasteur is the owner of U.S. Patent No. 6,544,728 B1 (the "'728 Patent"), which was duly and lawfully issued by the United States Patent and Trademark Office on April 8, 2003. A true and correct copy of the '728 Patent, including a Certificate of Correction dated August 12, 2003, is attached hereto as Exhibit A.

7. The '728 Patent is entitled "Methods and Kits for Diagnosing Human Immunodeficiency Virus Type 2 (HIV-2), Proteins of HIV-2, and Vaccinating Agents for HIV-2." The '728 Patent discloses and claims in vitro diagnostic methods for detecting the presence or

absence of antibodies that bind to antigens of HIV-2 and kits for performing these methods.

8. Bio-Rad is the exclusive licensee of the '728 Patent with the right to grant sub-licenses.

9. Abbott is a former licensee under the '728 Patent whose license was terminated on March 7, 2017.

FACTUAL BACKGROUND

10. Plaintiff Pasteur is an international research and education institute that has been on the forefront in advancing science, medicine, and public health. It is a non-profit foundation with four core missions of public interest: research, education, the health of populations and people, and innovation development and technology transfer. One of the major targets of Pasteur's research was and continues to be HIV and Acquired Immune Deficiency Syndrome ("AIDS").

11. Dr. Luc Montagnier and members of his group at Pasteur are widely recognized as being the first to isolate the human retrovirus now called "HIV-1" in 1983, which they determined was responsible for causing AIDS. For their work on discovering HIV-1, Dr. Montagnier and two others were jointly awarded the Nobel Prize in Physiology or Medicine in 2008.

12. By 1986, scientists determined there were at least two HIV viruses, now called "HIV-1" and "HIV-2." While HIV-2 is not as prevalent as HIV-1, it nevertheless can cause AIDS in infected individuals. These two HIV viruses are somewhat related in their morphology, tropism and in vitro effect on the cells and cell lines that they infect, but they differ in a number of properties including size and antigenic cross-reactivity. Because of the differences between these viruses, the methods and reagents used to detect the presence of HIV-1 could not be relied on to detect HIV-2 in a patient or blood bank sample. This created an urgent need for methods to detect the presence of antibodies against HIV-2 in patients or in blood bank supplies, so that HIV-2 infected individuals and blood products could be detected. Such detection would help to insure

the safety of the blood supply, inform patient treatment and actions, and help contain the spread of HIV-2 so as to avoid a second AIDS epidemic. Today in the United States, blood screening for HIV must include screening for the presence of HIV-2 (as well as HIV-1).

13. To address the need to detect HIV-2 infection, Dr. Montagnier and his group at Pasteur discovered and described novel in vitro methods and reagents that could be used to detect HIV-2 infection in patients and in blood bank supplies. Dr. Montagnier and his colleagues discovered and disclosed that certain man-made polypeptides could be used to detect the presence of antibodies that are generally present in samples from individuals infected with HIV-2. In particular, they disclosed the amino acid sequences of polypeptides that can be used to detect antibodies to HIV-2, the DNA sequences that can be used to make ("express") such polypeptides in the laboratory using recombinant DNA techniques, and methods and kits employing such polypeptides that can be used to detect antibodies to HIV-2.

14. While the man-made polypeptides of the invention have some similarities to naturally-occurring proteins of the HIV-2 virus (e.g., env proteins that are part of the viral envelope), which can be used to detect the presence or absence of antibodies to HIV-2, there are a number of significant structural and functional differences between naturally-occurring HIV-2 proteins and the man-made polypeptides of the invention. For example, use of recombinant DNA techniques to express HIV-2 env polypeptides in the laboratory provides greater safety because man-made HIV-2 env expression products, unlike env polypeptides purified from cultures of HIV-2, are free from contaminating HIV-2 viruses. In addition, naturally-occurring HIV env proteins generally exist as dimers or even trimers, while man-made recombinant env polypeptides do not. Based in part on the dimer and trimer nature of the naturally-occurring proteins, naturally-occurring env proteins have conformational and geometric structures that make them different

from the man-made polypeptides of the invention. The conformational and structural differences produce functional differences between how the naturally-occurring proteins and the man-made polypeptides of the invention interact with antibodies. Other structural differences between the man-made polypeptides of the invention and naturally-occurring HIV-2 proteins, such as env proteins, include differences in glycosylation.

15. Defendant Abbott sells at least two products which infringe certain claims of the '728 Patent. As described below, the ABBOTT PRISM HIV O Plus and ARCHITECT HIV Ag/Ab Combo (the "Accused Products") detect antibodies against HIV-2 by utilizing the method described in claim 4 '728 Patent and, together with their relevant controls, constitute kits described in claim 6 of the '728 Patent.

FIRST CLAIM FOR RELIEF
INFRINGEMENT OF CLAIM 4 OF THE '728 PATENT

16. Each of the preceding paragraphs 1 to 15 is incorporated herein as if set forth in full.

17. Since March 7, 2017, Abbott has infringed, and continues to infringe, claims 4 and 6 of the '728 Patent in the United States, including in this district. Abbott's infringing activities include using, offering to sell and selling in the United States, and making in the United States or importing into the United States in vitro diagnostic kits for detecting the presence or absence of antibodies to HIV-2, including kits marketed under the trade names ABBOTT PRISM HIV O Plus and ARCHITECT HIV Ag/Ab Combo.

18. Claim 4 of the ’728 Patent reads as follows:

> 4. An in vitro diagnostic method for detecting the presence or absence of antibodies that bind to antigens of a Human Immunodeficiency Virus Type 2 (HIV-2), comprising:
>
> (a) contacting a biological sample with one or more isolated polypeptide expression products of HIV-2 selected from the group consisting of polymerase and env protein; and
>
> (b) detecting the formation of antigen-antibody complex between said polypeptide expression products and antibodies present in the biological sample.

19. As reflected in the ABBOTT PRISM HIV O Plus package insert, the ABBOTT PRISM HIV O Plus is designed and commercialized for detecting the presence or absence of antibodies in human plasma or serum specimens that bind, inter alia, to antigens of HIV-2. See Exhibit B.

20. Use of the ABBOTT PRISM HIV O Plus, as directed in the package insert, comprises (a) contacting a biological sample (e.g., a human plasma or serum specimen) with one or more isolated polypeptide expression products of HIV-2 selected from the group consisting of polymerase and env protein (namely, a recombinant env expression product attached to microparticles); and (b) detecting the formation of antigen-antibody complex between the polypeptide expression product and antibodies present in the biological sample (namely, by using (i) a biotinylated HIV-2 peptide probe that binds to a complex formed between an antibody and an env expression product on a microparticle, and (ii) an acridinium-labelled anti-biotin conjugate that binds to the biotinylated HIV-2 peptide probe and emits a chemiluminescent signal).

21. End users, including Abbott customers who use the ABBOTT PRISM HIV O Plus in the United States in accordance with its package insert directions, practice the method described in claim 4 of the ’728 Patent or its equivalent, thereby directly infringing the ’728 Patent under 35 U.S.C. § 271(a) with respect to units of the ABBOTT PRISM HIV O Plus product sold after March

7, 2017.

22. Abbott's own use of the ABBOTT PRISM HIV O Plus in the United States since March 7, 2017, for example during quality control, demonstrations, and customer support activities, infringes the '728 Patent under 35 U.S.C. § 271(a).

23. The ABBOTT PRISM HIV O Plus is especially adapted for performing the method described in claim 4 of the '728 Patent or its equivalent, constitutes a material part of the invention, and has no substantial use other than performing the method described in claim 4 of the '728 Patent or its equivalent.

24. At all material times since March 7, 2017, Abbott knew of the '728 Patent (as demonstrated, inter alia, by Abbott's having entered into a sublicense with Bio-Rad under the '728 Patent and other patents owned by Pasteur); Abbott knew that use of the ABBOTT PRISM HIV O Plus in accordance with its package insert directions comprises performance of the steps recited in claim 4 of the '728 Patent or their equivalents; and Abbott knew that the ABBOTT PRISM HIV O Plus is especially adapted for performing the method described in claim 4 of the '728 Patent or its equivalent.

25. Since March 7, 2017, Abbott has continued to sell and offer for sale the ABBOTT PRISM HIV O Plus in the United States with directions for practicing the method claimed in claim 4 of the '728 Patent or its equivalent.

26. Since March 7, 2017, Abbott has actively induced others to infringe and has contributed to infringement of claim 4 of the '728 Patent, in violation of 35 U.S.C. §§ 271(b) and (c), by assisting, facilitating, and encouraging end users of the ABBOTT PRISM HIV O Plus to perform acts known by Abbott to infringe claim 4 of the '728 Patent, with the intent that those end users practice the method claimed by claim 4 of the '728 Patent or its equivalent.

27. As reflected in the ARCHITECT HIV Ag/Ab Combo package insert, the ARCHITECT HIV Ag/Ab Combo is an assay designed and commercialized for detecting the presence or absence of antibodies in human plasma or serum specimens that bind, inter alia, to antigens of HIV-2. See Exhibit C.

28. Use of the ARCHITECT HIV Ag/Ab Combo, as directed in the package insert, comprises (a) contacting a biological sample (e.g., a human plasma or serum specimen) with one or more isolated polypeptide expression products of HIV-2 selected from the group consisting of polymerase and env protein (namely, a recombinant env expression product called "gp36" attached to microparticles); and (b) detecting the formation of antigen-antibody complex between the polypeptide expression product and antibodies present in the biological sample (namely, by using an acridinium-labelled synthetic HIV-2 peptide that binds to a complex formed between an antibody and an env expression product on a microparticle and emits a chemiluminescent signal). See Exhibits C and D.

29. End users, including Abbott customers who use the ARCHITECT HIV Ag/Ab Combo in the United States in accordance with its package insert directions, practice the method described in claim 4 of the '728 Patent or its equivalent, thereby directly infringing the '728 Patent under 35 U.S.C. § 271(a) with respect to units of Abbot's ARCHITECT HIV Ag/Ab Combo product sold since March 7, 2017.

30. Abbott's own use of the ARCHITECT HIV Ag/Ab Combo in the United States since March 7, 2017, for example during quality control, demonstrations and customer support activities, infringes the '728 Patent under 35 U.S.C. § 271(a).

31. The ARCHITECT HIV Ag/Ab Combo is especially adapted for performing the method described in claim 4 of the '728 Patent or its equivalent, constitutes a material part of the

invention, and has no substantial use other than performing the method described in claim 4 of the ’728 Patent or its equivalent.

32. At all material times since March 7, 2017, Abbott knew of the ’728 Patent; Abbott knew that use of the ARCHITECT HIV Ag/Ab Combo in accordance with its package insert directions comprises performance of the steps recited in claim 4 of the ’728 Patent or their equivalents; and Abbott knew that the ARCHITECT HIV Ag/Ab Combo is especially adapted for performing the method described in claim 4 of the ’728 Patent or its equivalent.

33. Since March 7, 2017, Abbott has continued to sell and offer for sale the ARCHITECT HIV Ag/Ab Combo in the United States with directions for practicing the method claimed in claim 4 of the ’728 Patent or its equivalent.

34. Since March 7, 2017, Abbott has actively induced others to infringe and has contributed to infringement of claim 4 of the ’728 Patent, in violation of 35 U.S.C. §§ 271(b) and (c), by assisting, facilitating, and encouraging end users of the ARCHITECT HIV Ag/Ab Combo to perform acts known by Abbott to infringe claim 4 of the ’728 Patent, with the intent that those end users practice the method claimed by claim 4 of the ’728 Patent or its equivalent.

35. Abbott’s infringement has been willful and will continue unless abated.

SECOND CLAIM FOR RELIEF
INFRINGEMENT OF CLAIM 6 OF THE ’728 PATENT

36. Each of the preceding paragraphs 1 to 35 is incorporated herein as if set forth in full.

37. Claim 6 of the ’728 Patent reads as follows:

> 6. An in vitro diagnostic kit for detecting the presence or absence of antibodies in a biological sample that bind to antigens of a Human Immunodeficiency Virus Type 2 (HIV-2), comprising:
>
> one or more isolated polypeptide expression products of HIV-2 selected from the group consisting of polymerase and env protein;
>
> reagents for detecting the formation of antigen-antibody complex between said polypeptide expression products and antibodies present in the biological sample; and
>
> a biological reference sample lacking antibodies recognized by said polypeptide expression products;
>
> wherein said polypeptide expression products, reagents and biological reference material are present in an amount sufficient to detect the formation of antigen-antibody complex.

38. As reflected in the ABBOTT PRISM HIV O Plus package insert, the ABBOTT PRISM HIV O Plus is designed and commercialized for detecting the presence or absence of antibodies in human plasma or serum specimens that bind, inter alia, to antigens of HIV-2.

39. The ABBOTT PRISM HIV O Plus comprises an isolated polypeptide product of HIV-2 selected from the group consisting of polymerase and env protein, namely: a recombinant env expression product attached to microparticles. See Exhibit B.

40. The ABBOTT PRISM HIV O Plus further comprises reagents for detecting the formation of antigen-antibody complex between the polypeptide expression product and antibodies present in a biological sample, namely: (i) a biotinylated HIV-2 peptide probe that binds to a complex formed between an antibody and an env expression product on a microparticle, and (ii) an acridinium-labelled anti-biotin conjugate that binds to the biotinylated HIV-2 peptide probe and emits a chemiluminescent signal. See Exhibit B.

41. The ABBOTT PRISM HIV O Plus further comprises a biological reference sample lacking antibodies recognized by the polypeptide expression product, namely: a negative calibration control (“Cal–”) comprising recalcified human plasma, as well as an HIV-2 positive

control, namely: recalcified, inactivated human plasma reactive for HIV-2. See Exhibit B.

42. The env expression product-bearing microparticles, biotinylated HIV-2 peptide probe, acridinium-labelled anti-biotin conjugate and biological reference material of the ABBOTT PRISM HIV O Plus are present in an amount sufficient to detect the formation of antigen-antibody complex. See Exhibit B.

43. The ABBOTT PRISM HIV O Plus is a kit described by claim 6 of the '728 Patent or its equivalent.

44. Abbott's unauthorized importation or manufacture, sale, and offer for sale in the United States since March 7, 2017 of the ABBOTT PRISM HIV O Plus directly infringes the '728 Patent under 35 U.S.C. § 271(a).

45. End users, including Abbott customers, who use the ABBOTT PRISM HIV O Plus in the United States directly infringe claim 6 of the '728 Patent under 35 U.S.C. § 271(a) with respect to units of the ABBOTT PRISM HIV O Plus sold since March 7, 2017.

46. Abbott's unauthorized sale and offer for sale in the United States since March 7, 2017 of the ABBOTT PRISM HIV O Plus, with the directions contained in the package insert, induces and contributes to infringement of claim 6 of the '728 Patent under 35 U.S.C. §§ 271(b) and (c).

47. As reflected in the ARCHITECT HIV Ag/Ab Combo package insert, the ARCHITECT HIV Ag/Ab Combo is designed and commercialized for detecting the presence or absence of antibodies in human plasma or serum specimens that bind, inter alia, to antigens of HIV-2. See Exhibit C.

48. The ARCHITECT HIV Ag/Ab Combo comprises an isolated polypeptide product of HIV-2 selected from the group consisting of polymerase and env protein, namely: a recombinant

env expression product called "gp36" attached to microparticles. See Exhibits C and D.

49. The ARCHITECT HIV Ag/Ab Combo further comprises reagents for detecting the formation of antigen-antibody complex between the polypeptide expression product and antibodies present in a biological sample, namely: an acridinium-labelled synthetic HIV-2 peptide that binds to a complex formed between an antibody and an env expression product on a microparticle and emits a chemiluminescent signal. See Exhibit C.

50. The ARCHITECT HIV Ag/Ab Combo is sold with negative and positive controls for use at least once every 24 hours each day of use that are required components for the ARCHITECT HIV Ag/Ab Combo, including a "Negative Control" comprising recalcified negative human plasma that is nonreactive for anti-HIV-2, a "Positive Control 1" comprising recalcified, inactivated plasma that is reactive for anti-HIV-1 and non-reactive for anti-HIV-2, and a "Positive Control 2" comprising recalcified inactivated human plasma that is reactive for HIV-2. See Exhibit E.

51. The env expression product-bearing microparticles, acridinium-labelled synthetic HIV-2 peptide, and biological reference material of the ARCHITECT HIV Ag/Ab Combo are present in an amount sufficient to detect the formation of antigen-antibody complex. See Exhibits C and D.

52. The ARCHITECT HIV Ag/Ab Combo in combination with its controls is a kit described by claim 6 of the '728 Patent or its equivalent.

53. Abbott's unauthorized importation or manufacture, sale, and offer for sale in the United States since March 7, 2017 of the ARCHITECT HIV Ag/Ab Combo with its controls directly infringes claim 6 of the '728 Patent under 35 U.S.C. § 271(a).

54. End users, including Abbott customers who use the ARCHITECT HIV Ag/Ab

Combo in accordance with its package insert directions in the United States, make and use the kit described in claim 6 of the '728 Patent or its equivalent, thereby directly infringing the '728 Patent under 35 U.S.C. § 271(a) with respect to units of the ARCHITECT HIV Ag/Ab Combo sold since March 7, 2017.

55. The ARCHITECT HIV Ag/Ab Combo is especially adapted for making and using the kit described in claim 6 of the '728 Patent or its equivalent, constitutes a material part of the invention, and has no substantial use other than making and using the kit described in claim 6 of the '728 Patent or its equivalent.

56. Abbott's unauthorized sale and offer for sale in the United States since March 7, 2017 of the ARCHITECT HIV Ag/Ab Combo and its controls, with the directions contained in the package insert, induces and contributes to infringement of claim 6 of the '728 Patent under 35 U.S.C. §§ 271(b) and (c).

57. Abbott's unauthorized importation or manufacture, sale and offer for sale of the ABBOTT PRISM HIV O, ARCHITECT HIV Ag/Ab Combo and controls in the United States since March 7, 2017 has damaged Plaintiffs, who are entitled to lost profits on sales they would have made had Abbott not been selling these infringing products and/or a reasonable royalty for Abbott's infringing sales.

58. Abbott's infringement has been willful and will continue unless abated.

THIRD CLAIM FOR RELIEF
BREACH OF CONTRACT

59. Each of the preceding paragraphs 1 to 58 is incorporated herein as if set forth in full.

60. In a patent license agreement (the "License Agreement") effective as of October 15, 1991, Bio-Rad's predecessor-in-interest granted, and Abbott accepted, a sub-license under

certain Pasteur-owned patents, including the '728 Patent.

61. The License Agreement authorized Abbott to make, use and sell diagnostic products whose use or sale would infringe one or more Valid Claims of the licensed patents. In exchange, Abbott obligated itself to pay royalties on its sales of the licensed products.

62. The License Agreement defines the term "Valid Claim" to mean a claim in a licensed patent "which claim has not been disclaimed or held invalid in a non-appealed or unappealable final decision rendered by a court of competent jurisdiction."

63. While Abbott initially paid royalties on sales of the licensed products in accordance with the License Agreement, it ceased paying the contractually required royalties as of June 30, 2015.

64. On December 22, 2016, Bio-Rad notified Abbott that it was in material breach of the License Agreement and requested that Abbott cure its breach within 60 days.

65. On March 7, 2017, after Abbott had failed to cure its breach, Bio-Rad terminated the License Agreement with immediate effect.

66. Abbott's failure to pay contractually-required royalties on sales of licensed products during the term of the License Agreement constitutes a breach of contract for which Plaintiffs are entitled to damages.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs pray that the Court:

(i) declare, adjudge and decree that Abbott's unauthorized manufacture or importation, use, offer for sale and sale of the Accused Products in the United States has infringed claims 4 and 6 of the '728 Patent;

(ii) declare, adjudge and decree that Abbott's unauthorized offer for sale and sale of the Accused Products in the United States has actively induced and contributed to infringement of claims 4 and 6 of the '728 Patent;

(iii) award compensatory damages as provided by law, including damages adequate to compensate for infringement arising from Abbott's unauthorized manufacture, importation, use, offer for sale, and sale of the Accused Products;

(iv) award enhanced damages for Abbott's willful infringement;

(v) award all available equitable relief, including but not limited to a running royalty, for Abbott's continuing willful infringement;

(vi) declare, adjudge and decree that Abbott has breached its contractual obligations under the license agreement;

(vii) award compensatory damages as provided by law for Abbott's breach of the license agreement;

(viii) declare, adjudge, and decree that this case is exceptional and award Plaintiffs their reasonable attorney's fees and costs pursuant to 35 U.S.C. §285; and

(ix) award such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all matters so triable.

Dated: October 2, 2017 Respectfully submitted,

/s/ Stephen Swedlow

Stephen Swedlow (IL Bar No. 6234550)
QUINN EMANUEL URQUHART & SULLIVAN, LLP
191 N. Wacker Drive, Suite 2700,
Chicago, IL 60606
Telephone: (312) 705-7400
Facsimile: (312) 705-7401
stephenswedlow@quinnemanuel.com

Kevin P.B. Johnson (CA Bar No. 177129)
QUINN EMANUEL URQUHART & SULLIVAN LLP
555 Twin Dolphin Dr., 5th Floor
Redwood Shores, CA 94065
Telephone: (650) 801-5015
Facsimile: (650) 801-510
kevinjohnson@quinnemanuel.com

David Bilsker (CA Bar No. 152383)
QUINN EMANUEL URQUHART & SULLIVAN, LLP
50 California Street, 22nd Floor
San Francisco, CA 94111
Telephone: (415) 875-6432
Facsimile: (415) 875-6700
davidbilsker@quinnemanuel.com

Attorneys for Plaintiff
Bio-Rad Laboratories, Inc.

/s/ *Gary M. Ropski*

Stephen S. Rabinowitz (*pro hac vice pending*)
Mitchell Epner (*pro hac vice pending*)
HUGHES HUBBARD & REED LLP
One Battery Park Plaza
New York, New York 10004-1482
Telephone: (212) 837-6000
Facsimile: (212) 422-4726
stephen.rabinowitz@hugheshubbard.com
mitchell.epner@hugheshubbard.com

Salvatore J. Arrigo (*pro hac vice pending*)
ARRIGO, LEE & GUTTMAN LLP
2200 Pennsylvania Ave. N.W.
4th Floor East
Washington, D.C. 20037
Telephone: (202) 507-5889
Facsimile: (202) 688-2790
sal@arrigo.us

Gary M. Ropski (IL Bar No. 2376636)
Laura A. Lydigsen (IL Bar No. 6286759)
BRINKS GILSON & LIONE
NBC Tower, Suite 3600
455 North Cityfront Plaza Drive
Chicago, Illinois 60611
Telephone: (312) 321-4200
Facsimile: (312) 321-4299
gropski@brinksgilson.com
llydigsen@brinksgilson.com

Attorneys for Plaintiff Institut Pasteur