PATTERSON BELKNAP WEBB & TYLER LLP
William F. Cavanaugh, Jr. (SBN 133461)
Irena Royzman (*pro hac vice* to be filed)
1133 Avenue of the Americas
New York, NY 10036-6710
Telephone: (212) 336-2000
Facsimile: (212) 336-2222
wfcavanaugh@pbwt.com
iroyzman@pbwt.com

KIRKLAND & ELLIS LLP
Eric Cheng (SBN 274118)
3330 Hillview Avenue
Palo Alto, CA 94304
Telephone: (650) 859-7046
Facsimile: (650) 859-7500
eric.cheng@kirkland.com

Attorneys for Plaintiff
ALERE INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ALERE INC., Plaintiff, v. INSTITUT PASTEUR AND BIO-RAD LABORATORIES, INC., Defendants.	Case No. 3:17-cv-05812 **COMPLAINT FOR DECLARATORY JUDGMENT**

Plaintiff Alere Inc. ("Alere") hereby files this Complaint for Declaratory Judgment against Institut Pasteur ("Pasteur") and Bio-Rad Laboratories, Inc. ("Bio-Rad") (collectively, "Defendants") and alleges as follows:

NATURE OF THE ACTION

1. This complaint is an action for declaratory judgment of invalidity and non-infringement of U.S. Patent Nos. 6,544,728 ("the '728 patent") and 6,265,149 ("the '149 patent") (collectively, "patents-in-

suit") arising under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.* and the patent laws of the United States, 35 U.S.C. § 100 *et seq.*

2. This action arises out of a dispute between Alere and Defendants over whether claims of the patents-in-suit are invalid and not infringed and whether Alere has an obligation to continue to pay royalties on the patents-in-suit under a license agreement entered between Bio-Rad, a Bio-Rad subsidiary and Alere in 2008, as amended in 2015 ("License Agreement"). Pasteur, as the owner of the patents-in-suit, consented to the terms of the License Agreement. Bio-Rad requested by a letter of September 27, 2017 that Alere continue to pay royalties, and refrain from challenging validity of the patents-in-suit. In response, Alere invoked its rights under the doctrine announced in the Supreme Court's *Lear* decision because the relevant claims are invalid and Alere does not infringe any valid claim. *See Lear, Inc. v. Adkins*, 89 S. Ct. 1902 (1969). Alere brings this action to resolve whether the patents-in-suit are valid and infringed.

PARTIES

3. Alere is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 51 Sawyer Road, Suite 200, Waltham, MA 02453.

4. Pasteur is a private institution located at 25-28 rue du Docteur Roux, 75015 Paris, France.

5. 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.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. Defendants have consented to personal jurisdiction and venue in this judicial district for this action. In the License Agreement, the parties agreed that "[t]his Agreement shall be construed and enforced in accordance with the laws of the State of California, USA without giving effect to conflicts of law principles" and that "the exclusive jurisdiction and venue for any dispute or controversy arising from this Agreement shall be the courts in California, U.S.A." Pasteur signed the License Agreement (both in 2008 and 2015) to provide consent to the terms of the License Agreement.

8. This Court also has personal jurisdiction over Bio-Rad because, among other things, Bio-Rad's principal place of business is located within this judicial district.

9. By virtue of its consent to the terms of the License Agreement, including designating "the courts in California USA" which would include this court, as the exclusive forum to resolve any dispute or controversy arising out of this License Agreement, Pasteur is subject to the personal jurisdiction in this district.

10. Pasteur is further subject to personal jurisdiction in this district because, on information and belief, it has entered into a license agreement with Bio-Rad giving Bio-Rad the right to grant sub-licenses to, and enforce the patents-in-suit.

11. In the alternative, Pasteur is also subject to personal jurisdiction in this district under Fed. R. Civ. P. 4(k)(2) because Pasteur has purposely availed itself of the benefits and protections of the laws of the United States such that it should reasonably anticipate being involved in judicial proceedings in the United States as the result of procuring patents in the United States and entering into license agreements relating to those patents and obtaining royalties under those patents for the sale of products throughout the United States.

12. Venue is also proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

13. A real, immediate, substantial, and justiciable controversy exists between Alere and Defendants with respect to the validity and infringement of the '728 and '149 patents.

INTRADISTRICT ASSIGNMENT

14. Pursuant to Local Rule 3-2(c), intellectual property actions are assigned on a district-wide basis.

THE PATENTS-IN-SUIT

THE '728 PATENT

15. The '728 patent, entitled "Methods and Kits for Diagnosing Human Immunodeficiency Virus Type 2 (HIV-2), Proteins of HIV-2, and Vaccinating Agents for HIV-2," issued on April 8, 2003 from U.S. Patent Application No. 07/810,908, which was filed on December 20, 1991. The '728 patent states that it is related to a series of applications with the earliest one filed on March 3, 1986, which issued as U.S. Patent No. 4,839,288 ("the '288 patent").

16. Upon information and belief, Pasteur is the owner of the '728 patent, and Bio-Rad is an exclusive licensee of the '728 patent with the right to grant sublicenses.

17. A true and correct copy of the '728 patent is attached hereto as Exhibit A.

THE '149 PATENT

18. The '149 patent, entitled "In vitro diagnostic methods and kits for the detection of HIV-2-specific antibodies," issued on July 24, 2001 from U.S. Patent Application No. 08/470,491, which was filed on June 6, 1995. The '149 patent states that it is related to a series of applications with the earliest one filed on March 3, 1986, which issued as the '288 patent.

19. Upon information and belief, Pasteur is the owner of the '149 patent, and Bio-Rad is an exclusive licensee of the '149 patent with the right to grant sublicenses.

20. A true and correct copy of the '149 patent is attached hereto as Exhibit B.

BACKGROUND

21. The patents-in-suit are the product of Defendants' attempt to extend a patent monopoly well beyond the time proscribed by law. For nearly a decade, Alere and others have paid millions of dollars in royalties to Defendants under licenses to patents related to methods to detect HIV, of which only the patents-in-suit remain. In an effort to extend that royalty stream, the defendants pursued a strategy of filing multiple patents covering the same subject matter that now goes back decades. By way of example, back in 1991 Pasteur filed an application for what would become the '728 patent. That patent did not issue until 2003 and in the interim patents were issued to Pasteur that, as described below, render the claims of the '728 patent obvious. The same is true of the '149 patent. The application that led to it was filed in 1995. It did not issue until 2001 and again in the interim other patents were issued to Pasteur that make the claims of the '149 obvious. These interim patents have long since expired, and whatever the value of these alleged inventions, the defendants have been amply compensated. Defendants' efforts to extend their royalty stream should be rejected as a matter of law and public policy.

22. Alere is a world leader in rapid diagnostics at the point of care, with a focus on cardio metabolic disease, infectious disease and toxicology, including diagnostic assays of infections with Human Immunodeficiency Virus Types 1 (HIV-1) and/or Type 2 (HIV-2).

23. HIV is known for having a long time period between initial infection and the beginning of serious symptoms. As a result, many people are unaware of their HIV infection and can unknowingly spread the virus to others. Sensitive and rapid detection of HIV infection is critical in helping to minimize further transmission of the disease.

24. Alere markets Alere Determine™ HIV-1/2 Ag/AB Combo and Clearview® Complete HIV 1/2 (collectively, "products at issue") for sensitive and rapid diagnostics of infections with HIV-1 and HIV-2 viruses.

25. Alere Determine™ HIV–1/2 Ag/Ab Combo is an *in vitro*, visually read, qualitative immunoassay for the simultaneous detection of HIV-1 p24 antigen (Ag) and antibodies (Ab) to HIV-1 and HIV-2 in human serum, plasma, capillary (fingerstick) whole blood or venipuncture (venous) whole blood. It is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2, including an acute HIV-1 infection, and may distinguish acute HIV-1 infection from established HIV-1 infection when the specimen is positive for HIV-1 p24 antigen and negative for anti-HIV-1 and anti-HIV-2 antibodies. In certain studies conducted to evaluate sensitivity of the assay, it was found that the estimated sensitivity of Alere Determine™ HIV–1/2 Ag/Ab Combo was 99.9% for the detection of HIV-1 infection, and 100% for the detection of HIV-2 infection.

26. The Clearview® COMPLETE HIV 1/2 assay is a single-use, closed system immunochromatographic test used to detect antibodies to HIV-1 and HIV-2 viruses in fingerstick whole blood, venous whole blood, and serum or plasma specimens. It provides reactive test results in 15 minutes. In certain studies conducted to evaluate sensitivity of the assay, it was found that the calculated sensitivity of the Clearview® COMPLETE HIV 1/2 assay was 99.7% for the detection of HIV-1 infection, and 100% for the detection of HIV-2 infection.

27. The License Agreement was entered into by Bio-Rad, a Bio-Rad subsidiary and a predecessor of Alere on June 22, 2008, and was amended on December 28, 2015.

28. Pasteur signed both the June 22, 2008 agreement and the December 28, 2015 amendment to provide consent to the terms of the License Agreement.

29. Under the License Agreement, Alere was granted a royalty-bearing nonexclusive license under a number of patents (including the '149 patent and the '728 patent), to make, have made, use, import,

export, offer to sell and sell and have sold certain products for simultaneous detection of HIV-1 and HIV-2 antibodies and/or antigens.

30. On September 12, 2017, Alere sent Bio-Rad a letter requesting Bio-Rad's consent to a change of control under the License Agreement in connection with the acquisition of Alere by Abbott Laboratories ("Abbott").

31. On September 27, 2017, Bio-Rad responded with a letter, in which it provided consent subject to, among other things, Alere's confirmation of conditions.

32. Bio-Rad's request for confirmation of conditions finds no support under the License Agreement. The License Agreement has no provision requiring Alere to accept any conditions as a result of the change of control. Nor is Bio-rad permitted to unreasonably withhold consent for such change of control.

33. Bio-Rad's September 27, 2017 letter also seeks to impose a further restriction for Alere to obtain Bio-Rad's consent. Bio-Rad insists that its consent is contingent on Alere's giving up its ability to "directly or indirectly challenge, or assist any third party to challenge (i) the validity or enforceability of the Licensed Patents or (ii) the status of the Determine Products and Clearview Products as Licensed Products under the Licensed Patents."

34. In the context of license agreements such as the Alere License Agreement at issue here, courts have repeatedly found the restrictions that Bio-Rad attempts to impose for Alere to obtain Bio-Rad's consent to be against public policy and unenforceable. *See, e.g., Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401 (2015); *Rates Tech., Inc. v. Speakeasy, Inc.*, 685 F.3d 163 (2d Cir. 2012).

35. Bio-Rad's attempted restriction on Alere's ability to "directly or indirectly challenge, or assist any third party to challenge … (ii) the status of the Determine Products and Clearview Products as Licensed Products under the Licensed Patents" makes clear Bio-Rad's position that, in its view, Alere Determine™ HIV-1/2 Ag/AB Combo and Clearview® Complete HIV 1/2 infringe at least one claim of the patents-in-suit.

36. Bio-Rad's request also directly contravenes the License Agreement, which has no such requirement for consent to a change of control.

37. On October 3, 2017, Abbott completed its acquisition of Alere.

38. On October 9, 2017, Alere sent a letter to Bio-Rad. In the letter, Alere accepted Bio-Rad's consent subject to the understanding that Alere is able to challenge the validity and infringement of the Licensed Patents and that the conditions Bio-Rad seeks to impose on its consent contravenes the terms of the License Agreement.

39. In the same October 9, 2017 letter, Alere advised Bio-Rad that the '728 patent and the '149 patent are invalid for obviousness-type double patenting and for claiming patent ineligible subject matter under 35 U.S.C. § 101. Alere further advised Bio-Rad that its products do not infringe any valid claim in the patents-in-suit. Alere then informed Bio-Rad that the letter served as notice that Alere invoked its rights under the doctrine announced in the Supreme Court's *Lear* decision. *See Lear*, 89 S. Ct. 1902.

40. On October 2, 2017, Bio-Rad and Pasteur filed a complaint against Abbott for alleged infringement of the '728 patent. *Institut Pasteur and Bio-Rad Labs., Inc. v. Abbott Labs.*, Case No. 17-7104-RRP (N.D. Ill.). The Illinois action was filed after Abbott informed Bio-Rad that certain patents, including the '728 patent and the '149 patent, are invalid and not infringed by Abbott's products, and that for that reason, Abbott ceased its royalty payments to Bio-Rad pursuant to its rights under the doctrine announced in the Supreme Court's *Lear* decision.

41. It is evident that defendants believe the patents-in-suit are valid, given the recent lawsuit filed against Abbott asserting the ’728 patent and Bio-Rad's response to Alere's request for consent. Bio-Rad has also made clear its position that Alere has on-going royalty obligations, including demanding that Alere refrain from challenging validity or infringement of the patents-in-suit. In response, Alere has invoked its rights pursuant to the Supreme Court's *Lear* decision. All of the foregoing create a real, immediate, substantial, and justiciable controversy between Alere and Defendants with respect to the validity and infringement of the patents-in-suit.

COUNT I: DECLARATION OF INVALIDITY OF THE '728 PATENT

42. Alere incorporates and realleges the allegations in Paragraphs 1- 41 as if fully set out and stated herein.

43. 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.

44. The '728 patent is directed to *in vitro* diagnostic methods for detecting antibodies to HIV-2 using HIV-2 polymerase or envelope "polypeptide expression products."

45. Claims of the '728 patent are invalid under section 35 U.S.C. § 100 *et seq*.

46. For example, claims of the '728 patent are invalid for at least obviousness-type double patenting, over one or more earlier expiring patents in the same patent family, such as U.S. 6,048,685 ("the '685 patent"). As properly construed in view of the specification and the prosecution history, the differences between the claims in the earlier expiring patents and the challenged patents are not patentably distinct. *See Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1385 (Fed. Cir. 2010). In particular, the earlier expiring patent claims recite methods of using one or more proteins in diagnostic antibody-antigen assays that anticipate or render obvious the diagnostic assays and kits of the challenged claims. *See AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1379-80 (Fed. Cir. 2014). Moreover, the earlier expiring patents also recite isolated proteins that render their use in a diagnostic assay obvious. *Sun Pharm. Indus., Ltd*, 611 F.3d at 1387.

47. Claim 4, a representative claim of the '728 patent, requires "An in vitro diagnostic method" comprising "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 . . . . " Another representative claim, claim 6, of the '728 patent recites "An in vitro diagnostic kit . . . comprising . . . one or more isolated polypeptide expression products of HIV-2 selected from the group consisting of polymerase and env protein . . . . "

48. Claims 4 and 6 of the '728 patent are not patentably distinct over claims of the '685 patent. Claim 1 of the '685 patent claims "An in vitro diagnostic method for detecting [HIV-2]-specific antisera" comprising "contacting a biological sample with one or more purified HIV-2 polypeptides selected from the group consisting of . . . Env . . . . " Thus, like for claim 4 of the '728 patent, the full env protein is an element of claim 1 of the '685 patent and is used for the same method and purpose. Claim 3 of the '685 patent is to "An in vitro diagnostic kit for detecting [HIV-2]-specific antisera" comprising "one or more purified HIV-2 polypeptides selected from the group consisting of … Env …." Claim 6 of the '728 patent, which also claims such a kit, is not patentably distinct over claim 3.

49. As a further example, claims of the '728 patent are also invalid under 35 U.S.C. § 101, because they encompass a natural phenomenon and merely append conventional steps specified at a high level of generality. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377 (Fed. Cir. 2015); *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S. Ct. 1289, 1292 (2012).

50. There is a real, immediate, substantial, and justiciable controversy between Alere and Defendants concerning the invalidity of the claims of the '728 patent that is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

51. Alere is entitled to a judicial declaration that the claims of the '728 patent are invalid.

COUNT II: DECLARATION OF NON-INFRINGEMENT OF THE '728 PATENT

52. Alere incorporates and realleges the allegations in Paragraphs 1- 51 as if fully set out and stated herein.

53. 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.

54. The products at issue have not infringed and do not directly or indirectly infringe any valid claim of the '728 patent. For example, the products at issue all contain fragments of env protein, not "isolated polypeptide expression products of HIV-2 selected from . . . polymerase and env protein," which refer to the full polymerase or env protein. The claims of the '728 patent do not mention "fragments," and the specification and prosecution history consistently differentiate between "peptides"—to refer to fragments of proteins, such as env1 or gag1—and "polypeptides" or "polypeptide expression products"—to refer only to full proteins, such as env protein. Further, in response to a rejection during prosecution of the '728 patent, applicants explained that the "polypeptide expression products encompassed by the invention" are recited in original claim 41, a list of full proteins, and the text of Example 4 of the specification, a list of full proteins.

55. There is a real, immediate, substantial, and justiciable controversy between Alere and Defendants concerning whether the products at issue infringe any valid claim of the '728 patent that is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

56. Alere is entitled to a judicial declaration that the products at issue do not infringe any valid claim of the '728 patent.

COUNT III: DECLARATION OF INVALIDITY OF THE '149 PATENT

57. Alere incorporates and realleges the allegations in Paragraphs 1- 56 as if fully set out and stated herein.

58. 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.

59. The '149 patent is directed to methods and kits for detecting HIV-2 antibodies using a peptide fragment of HIV-2 envelope protein.

60. Claims of the '149 patent are invalid under section 35 U.S.C. § 100 *et seq*.

61. For example, claims of the '149 patent are invalid for at least obviousness-type double patenting, over one or more earlier expiring patents in the same patent family such as the '685 patent and U.S. 6,261,762 ("the '762 patent"). As properly construed in view of the specification and the prosecution history, the differences between the claims in the earlier expiring patents and the challenged patents are not patentably distinct. *See Sun Pharm. Indus., Ltd.*, 611 F.3d at 1385. In particular, the earlier expiring patent claims recite methods of using one or more proteins or protein fragments (peptides) in diagnostic antibody-antigen assays that anticipate or render obvious the diagnostic assays and kits of the challenged claims. *See AbbVie Inc.*, 764 F.3d at 1379-80. Moreover, the earlier expiring patents also recite isolated proteins or protein fragments that render their use in a diagnostic assay obvious. *Sun Pharm. Indus., Ltd*, 611 F.3d at 1387.

62. Claim 13, a representative claim of the ’149 patent, is invalid due to obviousness-type double patenting in view of the claims of the '685 patent. Claim 1 of the '685 patent discloses the full-length env polypeptide. The patent applicant argued during prosecution of the '149 patent, however, that even though the specification only disclosed the full-length env protein, it was entitled to claim fragments:

> [A] skilled artisan would have been able to make and use the claimed fragments of HIV-2 Env and HIV-2 Gag as of the earliest priority date of this application. The skilled artisan had the tools to identify antigenic determinants and test the fragments to ensure that they will have an immunological cross-reaction, binding with antibodies in AIDS patient sera.

'149 patent file history (July 18, 2000 Response at 6) (citing Cohen Dec. at ¶ 12). Thus, the applicant admitted that identifying fragments capable of being used in a kit for detecting anti-HIV-2 antibodies in

a biological sample would be obvious in view of the full env protein. The '149 patent is, therefore, not patentably distinct over the claims of the expired '685 patent.

63. As a further example, the '149 patent is also invalid for obviousness-type double patenting in view of the claims of the '762 patent. Claim 10 of the '762 patent is to a "kit for the in vitro detection of antibodies selectively binding to the HIV-1 and HIV-2 viruses" comprising a peptide fragment of env. The '149 patent, which broadly requires "a peptide fragment of HIV-2 Env"—without specifying any particular env fragments—is not patentably distinct from the claims of the expired '762 patent.

64. As a further example, claims of the '149 patent are also invalid under 35 U.S.C. § 101, because they encompass a natural phenomenon and merely append conventional steps specified at a high level of generality. *Ariosa Diagnostics, Inc.*, 788 F.3d at 1377; *Mayo Collaborative Servs.*, 132 S. Ct. at 1292.

65. There is a real, immediate, substantial, and justiciable controversy between Alere and Defendants concerning the invalidity of the claims of the '149 patent that is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

66. Alere is entitled to a judicial declaration that the claims of the '149 patent are invalid.

COUNT IV: DECLARATION OF NON-INFRINGEMENT OF THE '149 PATENT

67. Alere incorporates and realleges the allegations in Paragraphs 1- 66 as if fully set out and stated herein.

68. 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.

69. The products at issue have not infringed and do not directly or indirectly infringe any valid claim of the '149 patent.

70. There is a real, immediate, substantial, and justiciable controversy between Alere and Defendants concerning whether the products at issue infringe any valid claim of the '149 patent that is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

71. Alere is entitled to a judicial declaration that the products at issue do not infringe any valid claim of the '149 patent.

//

//

PRAYER FOR RELIEF

WHEREFORE, Alere respectfully requests that the Court enter judgment against Defendants as follows:

A. That the claims of the '728 patent and the '149 patents are invalid;

B. That the products at issue have not infringed and are not infringing either directly, indirectly, or otherwise any valid claim of the '728 and '149 patents;

C. That this case is "exceptional" within the meaning of 28 U.S.C. § 285 and an award to Alere of reasonable attorney fees and expenses is appropriate;

D. That Alere is entitled to an award of costs; and

E. Such other and further relief that this Court deems just and proper.

DATED: October 10, 2017

Respectfully submitted,

/s/ William F. Cavanaugh, Jr.

PATTERSON BELKNAP WEBB & TYLER LLP
William F. Cavanaugh, Jr. (SBN 133461)
Irena Royzman (*pro hac vice* to be filed)
1133 Avenue of the Americas
New York, NY 10036
Tel.: (212) 336-2000
Fax: (212) 336-2222

KIRKLAND & ELLIS LLP
Eric Cheng (SBN 274118)
3330 Hillview Avenue
Palo Alto, CA 94304
Telephone: (650) 859-7046
Facsimile: (650) 859-7500

Attorneys for Plaintiff Alere Inc.