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12 ROCHE MOLECULAR SYSTEMS, INC.

13
14 UNITED STATES DISTRICT COURT
15 FOR THE NORTHERN DISTRICT OF CALIFORNIA
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18 ROCHE MOLECULAR SYSTEMS, INC.,

19 Plaintiff,

20 v.

21 CEPHEID,

22 Defendant.
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Case No.

COMPLAINT

DEMAND FOR JURY TRIAL

1 Plaintiff Roche Molecular Systems, Inc., by its attorneys, for its Complaint in this action alleges:

2 **PARTIES**

3 1. Roche Molecular Systems, Inc. (“Roche”) is a corporation organized and existing under
4 the laws of the State of Delaware, having its principal place of business at 4300 Hacienda Drive,
5 Pleasanton, California 94588.

6 2. On information and belief, Cepheid (“Cepheid”) is a corporation organized and existing
7 under the laws of the State of California, having its principal place of business at 904 Caribbean Drive,
8 Sunnyvale, California 94089.

9 **JURISDICTION**

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

11 4. This Court has subject matter jurisdiction to hear this action under 28 U.S.C. §§ 1331 and
12 1338(a).

13 **INTRADISTRICT ASSIGNMENT**

14 5. This action is an Intellectual Property Action and should be assigned on a district-wide
15 basis under Civil L.R. 3-2(c) and 3-5(b).

16 **THE PATENT IN SUIT**

17 6. Roche is a co-owner of and owns all substantial rights in U.S. Patent No. 5,643,723 to
18 Persing et al. (the “Persing patent”), which was duly and legally issued by the United States Patent and
19 Trademark Office on July 1, 1997 and expired on July 1, 2014. A true and correct copy of the Persing
20 patent is attached hereto as Exhibit A.

21 7. The Persing patent is entitled “Detection of a Genetic Locus Encoding Resistance to
22 Rifampin in Mycobacterial Cultures and in Clinical Specimens.” The Persing patent discloses and claims
23 methods for detecting the presence of the bacterium *Mycobacterium tuberculosis* (“MTB”) in a
24 biological sample; methods for identifying MTB that is resistant to an antibiotic called “rifampicin;” and
25 synthetic DNA molecules called “primers” that are useful for performing these methods. MTB is the
26 bacterium that causes the human disease known as tuberculosis (TB).

FACTUAL BACKGROUND

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2 8. Cepheid has been offering for sale and selling in the United States, under the name
3 “Xpert[®] MTB/RIF Assay,” an assay for detecting MTB in a biological sample and identifying
4 rifampicin-resistant MTB which assay comprises one or more primers claimed in the Persing patent.

5 9. David H. Persing (“Dr. Persing”), the first-named inventor of the Persing patent, assigned
6 to Mayo Foundation for Medical Education and Research (“Mayo Foundation”) his entire right, title and
7 interest in both the application that issued as the Persing patent and the invention disclosed therein.
8 Mayo Foundation has conveyed to Roche all Mayo’s rights in the Persing patent.

9 10. On information and belief, Dr. Persing joined Cepheid as a director in May 2004, and in
10 August 2005 was appointed Executive Vice President and Chief Medical and Technology Officer of
11 Cepheid.

12 11. On May 22, 2006, Cepheid entered into a “Cooperative Research and Development
13 Agreement” with the Foundation for Innovative New Diagnostics (“FIND”) to develop a PCR-based
14 diagnostic test for detecting MTB and identifying rifampicin-resistant MTB in human sputum samples.

15 12. On information and belief, Dr. Persing participated in the development and evaluation by
16 Cepheid of its PCR-based assay for detecting the presence of MTB in a biological sample and for
17 identifying rifampicin-resistant MTB, and in the commercialization of this assay under the name Xpert[®]
18 MTB/RIF Assay.

19 13. On September 12, 2007, Roche identified the Persing patent to Cepheid by title and patent
20 number in a list of patents that were available for licensing. Notwithstanding its development of the
21 Xpert[®] MTB/RIF Assay and the participation of Dr. Persing in the development, evaluation and
22 commercialization of this assay, Cepheid elected not to take a license under the Persing patent.

23 14. Use of Cepheid’s Xpert[®] MTB/RIF Assay in accordance with its accompanying directions
24 practices methods claimed in the Persing patent or their equivalent.

25 15. At all material times during its development and commercialization by Cepheid, the
26 Xpert[®] MTB/RIF Assay comprised one or more primers claimed in the Persing patent, was especially
27 adapted for practicing methods claimed in the Persing patent or their equivalent, and had no substantial
28 use other than for performing methods claimed in the Persing patent or their equivalent.

PRAYER FOR RELIEF

WHEREFORE Plaintiff prays that the Court:

(i) declare, adjudge, and decree that Cepheid’s manufacture, offer for sale, and sale of the Xpert® MTB/RIF Assay in the United States infringed the Persing patent;

(ii) declare, adjudge, and decree that use of the Xpert® MTB/RIF Assay in the United States infringed the Persing patent;

(iii) declare, adjudge, and decree that Cepheid’s offer for sale and sale of the Xpert® MTB/RIF Assay in the United States actively induced and contributed to infringement of the Persing patent;

(iv) award compensatory damages as provided by law, including damages adequate to compensate for infringement arising from Cepheid’s manufacture, use, offer for sale, and sale of its Xpert® MTB/RIF Assay;

(v) 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

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

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all matters so triable.

Dated: July 16, 2014

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