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14 GENMARK DIAGNOSTICS, INC.

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16 UNITED STATES DISTRICT COURT
17 SOUTHERN DISTRICT OF CALIFORNIA

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19 GENMARK DIAGNOSTICS, INC.,
a Delaware corporation,

20 Plaintiff,

21 v.

22 VIRONOVATIVE BV, a Dutch
23 Limited Liability Company,

24 Defendant.

Case No. '14CV1140 JAH NLS

**COMPLAINT FOR
DECLARATORY JUDGMENT**

DEMAND FOR JURY TRIAL

1 Plaintiff GENMARK DIAGNOSTICS, INC. (“GENMARK”) alleges as
2 follows:

3 **PARTIES**

4 1. Plaintiff GENMARK is a Delaware corporation with its principal place
5 of business at 5964 La Place Court, Carlsbad, California, 92008-8829.

6 GENMARK is qualified and duly authorized to conduct business in the State of
7 California.

8 2. On information and belief, defendant VIRONOVATIVE BV
9 (“VIRONOVATIVE”) is a Dutch limited liability company with its principal place
10 of business at Marconistraat 16 3029 AK Rotterdam, The Netherlands.

11 **JURISDICTION AND VENUE**

12 3. This is an action for declaratory judgment of invalidity and
13 noninfringement of United States Patent Nos. 7,449,324 (“the ‘324 Patent”),
14 7,531,342 (“the ‘342 Patent”), 7,704,720 (“the ‘720 Patent”) and 8,715,922 (“the
15 ‘922 Patent”) (collectively, “the Patents at Issue”) arising under the Declaratory
16 Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United
17 States, 35 U.S.C. §§ 1 *et seq.* This Court has jurisdiction over the subject matter of
18 this action pursuant to 28 U.S.C. § 1331 and 1338(a).

19 4. This Court has personal jurisdiction over defendant
20 VIRONOVATIVE. VIRONOVATIVE has engaged in patent enforcement
21 activities in the United States and in this District. Specifically, VIRONOVATIVE
22 has licensed U.S. patents to multiple entities headquartered in the U.S., including
23 entities headquartered in this District. Additionally, VIRONOVATIVE for the past
24 several months has repeatedly contacted employees of GENMARK through email
25 and telephone, attempting to license the Patents at Issue and threatening legal action
26 if GENMARK did not take a license. The most recent contact was in May 2014.

27 5. Venue is proper in this judicial district pursuant to 28 U.S.C.
28 §§ 1391(b), (c) & (d).

GENERAL ALLEGATIONS

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2 6. GENMARK is a molecular diagnostics company focused on
3 developing and commercializing a proprietary electrochemical detection technology
4 that enables fast, accurate and highly sensitive detection of up to 72 distinct
5 biomarkers in a single sample. GENMARK's systems have received Section
6 510(k) clearance from the United States Food and Drug Administration, or FDA,
7 and are designed to support a broad range of molecular diagnostic tests with a
8 compact and easy-to-use workstation and self-contained, disposable test cartridges.
9 GENMARK is also developing next-generation instrument systems to integrate
10 automated nucleic acid extraction and amplification with GENMARK's proprietary
11 electrochemical detection technology to enable technicians to place a raw or a
12 minimally prepared patient sample directly into a test cartridge and obtain results
13 without any additional steps.

14 7. One of the products GENMARK sells is an assay called the
15 Respiratory Viral Panel (RVP). The RVP is used in the diagnosis of respiratory
16 infection.

17 8. VIRONOVATIVE is a Dutch research entity that owns a number of
18 patents generally in the area of human metapneumovirus (hMPV). hMPV is one of
19 the viruses known to cause respiratory infection. VIRONOVATIVE's technology
20 relates to the isolation and detection of the hMPV virus. VIRONOVATIVE
21 licenses its patents for this technology to a variety of medical diagnostic product
22 manufacturers, of which many are U.S. based manufacturers and some are resident
23 in this District.

24 9. In 2013, VIRONOVATIVE contacted representatives of GENMARK
25 and asserted that the GENMARK RVP infringed VIRONOVATIVE technology
26 and that GENMARK needed a license from VIRONOVATIVE. During these
27 discussions that took place over several months, VIRONOVATIVE asserted that it
28 is the assignee and/or exclusive licensee of the following patents in diagnostic and

1 other technology:

2 (A) United States Patent No. 7,449,324 (“the ‘324 Patent”), filed on
3 February 21, 2003 and issued on November 11, 2008, entitled
4 “Metapneumovirus strains and their use in vaccine formulations and as
5 vectors for expression of antigenic sequences.” A true and correct
6 copy of the ‘324 Patent is attached to this Complaint as Exhibit A.

7 (B) United States Patent No. 7,531,342 (“the ‘342 Patent”), filed on
8 February 21, 2003 and issued on May 12, 2009, entitled
9 “Metapneumovirus strains and their use in vaccine formulations and as
10 vectors for expression of antigenic sequences.” A true and correct copy
11 of the ‘342 Patent is attached to this Complaint as Exhibit B.

12 (C) United States Patent No. 7,704,720 (“the ‘720 Patent”) filed on April
13 23, 2004 and issued on April 27, 2010, entitled “Metapneumovirus
14 strains and their use in vaccine formulations and as vectors for
15 expression of antigenic sequences and methods for propagating virus.”
16 A true and correct copy of the ‘720 Patent is attached to this Complaint
17 as Exhibit C.

18 (D) United States Patent No. 8,715,922 (“the ‘922 Patent”) filed on
19 November 25, 2003 and issued on May 6, 2014, entitled “Virus
20 causing respiratory tract illness in susceptible mammals.” A true and
21 correct copy of the ‘922 patent is attached to this Complaint as Exhibit
22 D.

23 10. VIRONOVATIVE communicated its demands both orally and in
24 writing to GENMARK management asserting that GENMARK, by its manufacture,
25 offers for sale, and/or sales of RVP and other diagnostic tools and procedures, and
26 other products, infringes and/or has infringed the Patents at Issue. In April 2014,
27 VIRONOVATIVE gave GENMARK a “take or leave it” demand and threatens to
28 enforce the patents against GENMARK if GENMARK does not agree to the

1 proposed licensing terms.

2 11. The VIRONOVATIVE threats were clear and unambiguous and these
3 communications give GENMARK a reasonable apprehension that
4 VIRONOVATIVE intends to file suit if GENMARK refuses to enter into such a
5 license.

6 12. GENMARK disputes VIRONOVATIVE's positions with respect to
7 the Patents at Issue. Namely, GENMARK disputes that the claims of the
8 aforementioned patents are valid. GENMARK also disputes that its conduct
9 infringes any of the aforementioned patents, or any valid and enforceable claim of
10 any of these patents.

11 13. An actual and justiciable controversy exists between GENMARK and
12 VIRONOVATIVE concerning whether GENMARK infringes any valid claim of
13 the VIRONOVATIVE patents. GENMARK now seeks a declaratory judgment that
14 the claims of the VIRONOVATIVE patents are invalid and/or that GENMARK
15 does not infringe any valid claim of the VIRONOVATIVE patents.

16 **FIRST CLAIM FOR RELIEF**

17 (Non-Infringement of United States Patent No. 7,449,324)

18 14. GENMARK realleges and incorporates by reference the allegations
19 stated in paragraphs 1 through 13 of this Complaint.

20 15. GENMARK is not directly infringing, contributorily infringing, or
21 actively inducing others to infringe as alleged by VIRONOVATIVE any valid and
22 enforceable claim of the '324 Patent as properly construed.

23 **SECOND CLAIM FOR RELIEF**

24 (Invalidity of United States Patent No. 7,449,324)

25 16. GENMARK realleges and incorporates by reference the allegations
26 stated in paragraphs 1 through 13 of this Complaint.

27 17. The claims of the '324 Patent are invalid under the patent laws of the
28 United States, as codified in Title 35 of the United States Code.

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THIRD CLAIM FOR RELIEF

(Non-Infringement of United States Patent No. 7,531,342)

18. GENMARK realleges and incorporates by reference the allegations stated in paragraphs 1 through 13 of this Complaint.

19. GENMARK is not directly infringing, contributorily infringing, or actively inducing others to infringe as alleged by VIRONOVATIVE any valid and enforceable claim of the ‘342 Patent as properly construed.

FOURTH CLAIM FOR RELIEF

(Invalidity of United States Patent No 7,531,342)

20. GENMARK realleges and incorporates by reference the allegations stated in paragraphs 1 through 13 of this Complaint.

21. The claims of the ‘342 Patent are invalid under the patent laws of the United States, as codified in Title 35 of the United States Code.

FIFTH CLAIM FOR RELIEF

(Non-Infringement of United States Patent No. 7,704,720)

22. GENMARK realleges and incorporates by reference the allegations stated in paragraphs 1 through 13 of this Complaint.

23. GENMARK is not directly infringing, contributorily infringing, or actively inducing others to infringe as alleged by VIRONOVATIVE any valid and enforceable claim of the ‘720 Patent as properly construed.

SIXTH CLAIM FOR RELIEF

(Invalidity of United States Patent No 7,704,720)

24. GENMARK realleges and incorporates by reference the allegations stated in paragraphs 1 through 13 of this Complaint.

25. The claims of the ‘720 Patent are invalid under the patent laws of the United States, as codified in Title 35 of the United States Code.

SEVENTH CLAIM FOR RELIEF

(Non-Infringement of United States Patent No. 8,715,922)

1 6. Enter a declaratory judgment that the manufacture, use, sale, or offer for sale
2 of GENMARK's product(s) does not constitute an inducement to infringe or
3 contributory infringement of any valid and enforceable claim of the '720 Patent;

4 7. Enter a declaratory judgment that the manufacture, use, sale, or offer for sale
5 of GENMARK's product(s) does not infringe any valid and enforceable claim of
6 the '922 Patent; and

7 8. Enter a declaratory judgment that the manufacture, use, sale, or offer for sale
8 of GENMARK's product(s) does not constitute an inducement to infringe or
9 contributory infringement of any valid and enforceable claim of the '922 Patent;

10 9. As to the Second, Fourth, Sixth and Eighth Claims for Relief, enter a
11 declaratory judgment declaring that the claims of each of the VIRONOVATIVE
12 patents are invalid;

13 10. Declare this case exceptional under 35 U.S.C. § 285 and award GENMARK
14 its reasonable attorneys' fees, expenses and costs incurred in this action; and

15 11. Grant GENMARK such other action and further relief as this Court may
16 deem just and proper, or that GENMARK may be entitled to as a matter of law or
17 equity.

18 Dated: May 6, 2014

MORGAN, LEWIS & BOCKIUS LLP

21 By s/ Daniel Johnson, Jr.

22 Daniel Johnson, Jr.
23 Attorneys for Plaintiff

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DEMAND FOR JURY TRIAL

GENMARK hereby requests a trial by jury.

Dated: May 6, 2014

MORGAN, LEWIS & BOCKIUS LLP

By s/ Daniel Johnson, Jr.
Daniel Johnson, Jr.
Attorneys for Plaintiff