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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

VIRONOVATIVE, B.V.,
a Dutch limited liability company,

Plaintiffs,

v.

GENMARK DIAGNOSTICS, INC.,
a Delaware corporation,

Defendant.

Case No. **'15CV0021 MMAJMA**

COMPLAINT FOR DIRECT AND INDUCED INFRINGEMENT OF U.S. PATENT NO. 8,927,206 AND

DEMAND FOR JURY TRIAL

Plaintiff VIRONOVATIVE, B.V. ("ViroNovative" or "Plaintiff"), alleges as follows:

PARTIES

1. ViroNovative is a Dutch limited liability company with its principal place of business at Marconistraat 16 3029 AK Rotterdam, The Netherlands.

2. GenMark Diagnostics, Inc. ("GenMark" or "Defendant") is a Delaware corporation with its principal place of business at 5964 La Place Court, Carlsbad, California, 92008-8829.

JURISDICTION AND VENUE

3. This is a civil action for patent infringement arising under the patent laws of the United States, specifically 35 U.S.C. §§ 271, 281, 283, 284, and 285. This Court has subject matter jurisdiction over the patent infringement claim(s) under 28 U.S.C. §§ 1331 and 1338(a).

4. This Court also has diversity jurisdiction under 28 U.S.C. § 1332, because one party is a citizen of one state, California, and the other party is a citizen of a foreign state, the Netherlands, and the amount in controversy exceeds the jurisdictional amount of $75,000, excluding interest and costs.

5. This Court has personal jurisdiction over Defendant. Defendant has its corporate headquarters in this district and is engaged in regular and substantial business in the State of California and in the Southern District of California. GenMark has also filed a lawsuit against ViroNovative in this District (Case No. '14CV1140-JAH-NLS, filed May 6, 2014), which remains pending.

6. Venue is proper pursuant to 28 U.S.C. §§ 1391(b), (c) & (d), and 1400(b), because Defendant has committed acts of patent infringement in this district and Defendant maintains a regular place of business in this district.

GENERAL ALLEGATIONS

7. ViroNovative is a Dutch research company dedicated to finding better methods to detect, treat, and prevent human metapneumovirus (hMPV). hMPV was discovered in 2001 at the Department of Virology at Erasmus Medical Center of the University of Rotterdam in The Netherlands. ViroNovative was formed in 2002 as an Erasmus subsidiary company, and its hMPV patent portfolio now includes six issued U.S. patents and several pending U.S. patent applications. ViroNovative's patented

technology uses unique hMPV markers and methods to accurately and rapidly detect hMPV in samples of patients suffering from respiratory disease. ViroNovative licenses its patented technology to 13 major medical diagnostics companies around the world.

8. GenMark is a U.S. medical device manufacturer that develops multiplex systems to detect various markers of disease. GenMark markets its products to third party end users, such as hospitals, clinical laboratories, and government agencies. It competes directly with ViroNovative's licensees. Among the products GenMark manufactures, markets, and sells to end users is the eSensor respiratory viral panel (RVP), which is marketed as offering comprehensive detection of 14 respiratory virus types and subtypes, including hMPV. GenMark is not a licensee of any of ViroNovative's patents.

A. Detection of hMPV

9. hMPV is common in adults and is a major pathogen associated with respiratory complications in high-risk populations (*e.g.*, lung transplants, immunocompromised, and the elderly). It is the second most common cause of lower respiratory infection in children. The wide spectrum of known hMPV strains cause symptoms that are similar to those caused by respiratory syncytial virus (RSV) and influenza virus, for which treatment may differ. Thus, early and accurate detection of hMPV is important to rule out other causes of respiratory illness and to determine appropriate and cost-effective treatment regimens.

10. Biologically, hMPV is a negative, single-stranded RNA virus that belongs to a family of viruses called paramyxoviruses. Its RNA genome encodes eight proteins. Figure 1 below illustrates the general structure of a metapneumovirus (top) and its genomic map (bottom). Note the Nucleocapsid (N) gene on the left (3') side of the map.

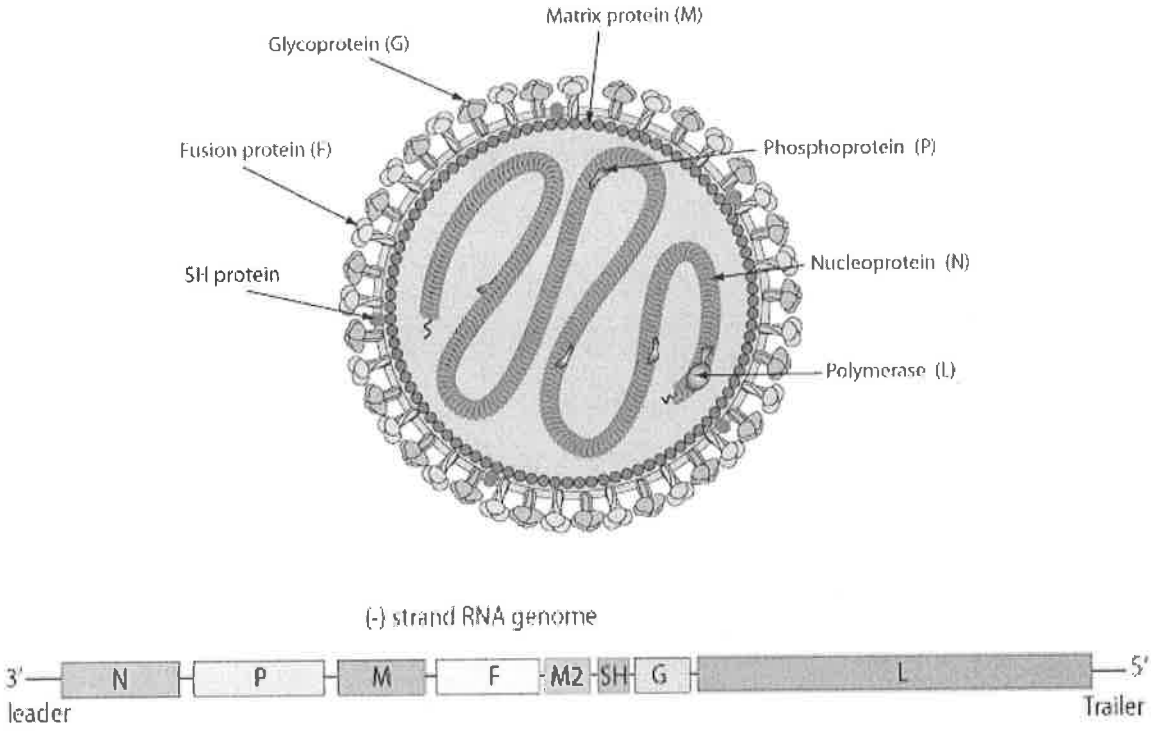

FIGURE 1[1]

11. One method of detecting hMPV uses reverse-transcriptase polymerase chain reaction (RT-PCR). In RT-PCR, isolated single-stranded viral RNA is first converted to double stranded complementary DNA (cDNA) using target-specific primers. The cDNA can then be copied (amplified) many times and hybridized to hMPV-specific nucleotides for detection. Figure 2 below illustrates the RT-PCR method.

[1] *Available at* http://viralzone.expasy.org/all_by_protein/89.html (last visited January 5, 2015).

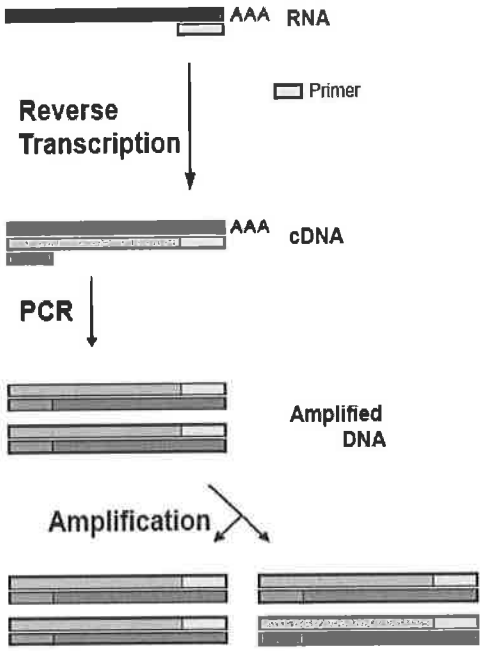

FIGURE 2[2]

B. U.S. Patent 8,927,206 ("the '206 Patent")

12. U.S. Patent Application No. 10/466,811 ("the '811 Application"), entitled "Virus Causing Respiratory Tract Illness in Susceptible Mammals," was filed on March 4, 2004 as the U.S. national stage entry of the Patent Cooperation Treaty ("PCT") Application No. PCT/NL/02/00040[3] (the "PCT Application). The '811 Application was published on June 2, 2005[4] and issued on January 6, 2015 as U.S. Patent 8,927,206 ("the '206 Patent" or "the Asserted Patent"). A copy of the '206 Patent is attached hereto as Exhibit A.

[2] *Available at* http://en.wikipedia.org/wiki/Reverse_transcription_polymerase_chain_ reaction (last visited January 5, 2015).

[3] The "PCT Application" was originally filed on January 18, 2002 and published on July 27, 2002 as WO/2002/057302.

[4] US2005/011819 ("the U.S. Publication"). Publication makes the U.S. and the PCT applications available for viewing by any member of the public, including Genmark.

13. The '206 Patent includes 28 claims directed to methods for identifying and diagnosing hMPV in a viral isolate. Five of these claims are independent. Table 1 shows the elements of representative claims 19 and 28.[5]

Table 1

Claim 19	Claim 28
A method of detecting if a polynucleotide from human metapneumovirus is present in a mammalian subject, the method comprising:	A method of detecting if a polynucleotide from human metapneumovirus is present in a mammalian subject, the method comprising:
performing an nucleic acid amplification reaction on a sample derived from the mammalian subject utilizing a set of primers for the amplification of at least a portion of the N gene of human metapneumovirus to create an amplified product, wherein the N gene, when transcribed and translated, produces a polypeptide at least 90% homologous to SEQ ID NO: 1;	performing an nucleic acid amplification reaction on a sample derived from the mammalian subject utilizing a set of primers for the amplification of at least a portion of the N gene of human metapneumovirus to create an amplified product, wherein the N gene, when transcribed and translated, produces a polypeptide at least 90% homologous to SEQ ID NO: 1;
contacting the amplified product with a DNA molecule that hybridizes with the amplified product;	contacting the amplified product with a DNA molecule of at least 25 nucleotides in length that specifically hybridizes with the amplified product;
hybridizing the DNA molecule to the amplified product; and	hybridizing the DNA molecule to the amplified product; and
detecting the hybridized DNA molecule,	detecting the hybridized DNA molecule;
wherein the detection of the hybridized DNA molecule indicates the presence of human metapneumovirus in the mammalian subject.	wherein the detection of the hybridized DNA molecule indicates the presence of human metapneumovirus in the mammalian subject.

[5] Table 1 is provided for illustrative purposes and is not intended to limit or waive ViroNovative's right to assert additional claims of the '206 Patent in the present action or in future proceedings.

14. The aforementioned methods thus generally recite the steps of: a) amplifying a particular nucleic acid in a sample; b) contacting/hybridizing the amplified product with a DNA molecule; and c) detecting the hybridized molecule.

15. The only difference between claims 19 and 28 is that claim 28 recites "contacting the amplified product with a DNA molecule ***of at least 25 nucleotides in length that specifically*** hybridizes with the amplified product."

16. Amplification of the nucleic acid according to claims 19 and 28 involves use of primers specific to "at least a portion of the [nucleocapsid] N gene" of hMPV. Amplification expands the amount of nucleic acid in a sample that is *specifically* associated with hMPV. The amplified nucleic acid is hybridized with a DNA molecule that is specific for the amplified nucleic acid, and the hybridized product is detected.

C. Genmark's eSensor RVP System

17. GenMark makes, uses, sells, offers to sell, and/or imports into the United States a medical device called the eSensor Respiratory Viral Panel (RVP). RVP uses an electrochemical chip to detect up to 14 respiratory virus types and subtypes—including hMPV—in a single patient sample.

18. In 2011, GenMark submitted an FDA 510(k) application for its eSensor Respiratory Viral Panel[6] and received regulatory clearance to market RVP in the U.S. on September 10, 2012.[7] The FDA's "Decision Summary" is attached hereto as Exhibit B, the contents of which are incorporated herein by this reference.

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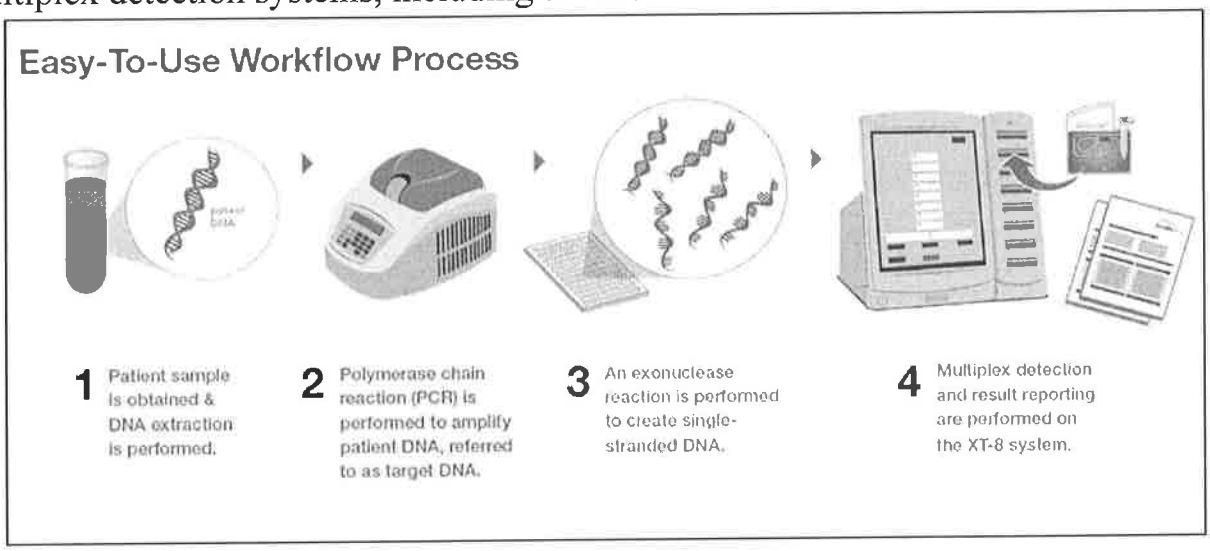
[6] The original applicant for this application is Clinical Micro Sensors, Inc. Upon information and belief, Genmark Diagnostics, Inc., is the dba for Clinical Micro Sensors, Inc.

[7] 510(k) Number K113731. The FDA's "Decision Summary" is also available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K113731 (last visited January 5, 2015). A medical device manufacturer is required to obtain regulatory clearance from the Food and Drug Administration before they can legally market certain new medical devices. A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective (*i.e.*, "substantially equivalent") as a legally marketed device.

19. The Decision Summary, which was based on GenMark's submission, identifies the RVP test as "A multiplexed nucleic acid test intended for use with the eSensor instrument for the qualitative in vitro detection and identification of multiple respiratory viral pathogen nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections."[8] Among the virus types and subtypes identified by the eSensor RVP is Human Metapneumovirus.[9] The Summary identifies the specific gene target for detection of Human Metapneumovirus as the nucleocapsid (N) gene of hMPV.[10]

20. On its website, GenMark outlines the "Easy to Use Workflow Process" (Figure 3, top) and "Innovative Technology" (Figure 3, bottom) involved in its multiplex detection systems, including the RVP.[11]



[8] Decision Summary, at p. 1.

[9] *Id.* at p. 2.

[10] *Id.* at p. 3 (table at bottom of page).

[11] *Available at* http://genmarkdx.com/technology/esensor.php (last visited January 5, 2015).

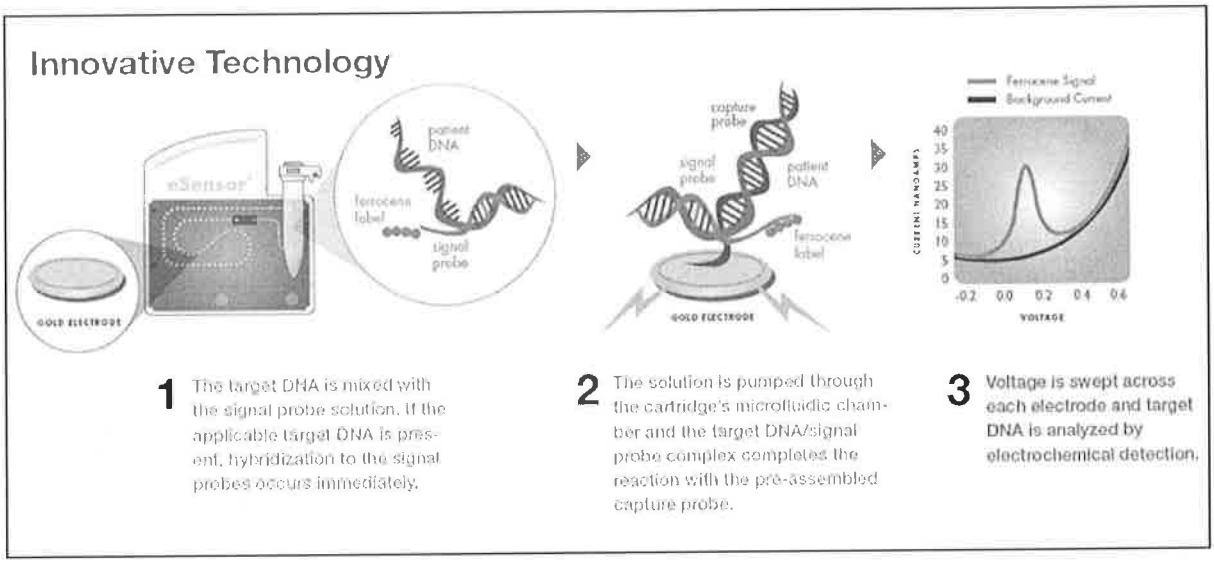


FIGURE 3

21. The aforementioned RVP technology thus generally requires the steps of: a) amplifying a particular nucleic acid in a sample; b) contacting/hybridizing the amplified product with a DNA molecule; and c) detecting the hybridized molecule.

22. FDA's Decision Summary (DS) also outlines the "Test Principle" behind the eSensor RVP:

> eSensor technology uses a solid-phase electrochemical method for determining the presence of one or more of a defined panel of virus target sequences. Purified DNA/RNA is isolated from the patient specimen and the extracted nucleic acid is reverse transcribed and/or amplified using virus specific primers with an RT-PCR enzyme mix. The amplified DNA is converted to single-stranded DNA via exonuclease digestion and is then combined with a signal buffer containing ferrocene labeled signal probes that are specific for the different viral targets. The mixture of amplified sample and signal buffer is loaded onto a cartridge containing single-stranded oligonucleotide capture probes bound to gold-plated electrodes. The cartridge is inserted into the XT-8 instrument where the single-stranded targets hybridize to the complementary sequences of the capture probes and signal probes. The presence of each target is determined by voltammetry, which generates specific electrical signals from the ferrocene-labeled signal probe. The eSensor RVP provides a qualitative result, the presence (Positive) or absence (Target Not Detected) of the viruses contained in the panel, along with the internal

MS2 control, based upon whether the underlying electrical signals are above or below a pre-defined cut-off signal intensity.[12]

23. Further, GenMark's RVP system relies on the *same gene target* (the N gene) that is recited in claims 19 and 28 of ViroNovative's '206 Patent.

24. FDA regulations require submission of a new 510(k) application if a change or modification of a cleared device's design or other technological characteristics *could* significantly affect safety or effectiveness. 21 C.F.R. § 807.81(a)(3)(i) (emphasis added). Upon information and belief, GenMark has not submitted a new 510(k) application for its RVP device. Thus, GenMark is continuing to use the N gene as the specific gene target for detection of hMPV.

25. Table 2 compares representative claim 19 of the '206 Patent with the described steps of GenMark's RVP system.[13]

Table 2

Claim 19	**Genmark's RVP System**
A method of detecting if a polynucleotide from human metapneumovirus is present in a mammalian subject, the method comprising:	"A multiplexed nucleic acid test…for the qualitative in vitro detection and identification of multiple respiratory viral pathogen nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections." Decision Summary, at p. 1. Among the virus types and subtypes identified by the eSensor RVP is human metapneumovirus. *Id.*, p. 2.

[12] Decision Summary, at p. 9

[13] Table 2 is provided for illustrative purposes and is not intended to limit or waive ViroNovative's right to assert additional claims of the '206 Patent against Genmark in the present action or in future proceedings. This table is not intended as a formal claim construction or infringement contention. ViroNovative reserves the right to propose specific claim constructions and infringement contentions in the present action or in future proceedings, as more information becomes available.

Claim 19	Genmark's RVP System
performing an nucleic acid amplification reaction on a sample derived from the mammalian subject utilizing a set of primers for the amplification of at least a portion of the N gene of human metapneumovirus to create an amplified product, wherein the N gene, when transcribed and translated, produces a polypeptide at least 90% homologous to SEQ ID NO: 1;	"Purified DNA/RNA is isolated from the patient specimen and the extracted nucleic acid is reverse transcribed and/or amplified using virus specific primers with an RT-PCR enzyme mix." Decision Summary, at p. 9. "Polymerase chain reaction (PCR) is performed to amplify patient DNA, referred to as target DNA." Easy-to-Use Workflow Process. The Decision Summary includes a table that identifies the gene target for Human Metapneumovirus as the nucleocapsid (N) gene. Decision Summary, at p. 3. Upon information and belief, this gene target, when transcribed and translated, produces a polypeptide at least 90% homologous to SEQ ID NO:1 (the N protein). SEQ ID NO:1 is identified in the '206 Patent as the amino acid sequence of the complete N protein of virus isolate 00-1. *See* p. 28 of Specification.
contacting the amplified product with a DNA molecule that hybridizes with the amplified product;	"The cartridge is inserted into the XT-8 instrument where the single-stranded targets hybridize to the complementary sequences of the capture probes and signal probes." Decision Summary, at p. 10.
hybridizing the DNA molecule to the amplified product; and	The cartridge is inserted into the XT-8 instrument where the single-stranded targets hybridize to the complementary sequences of the capture probes and signal probes. *Id.* at p. 10.
detecting the hybridized DNA molecule,	The presence of each target is determined by voltammetry, which generates specific electrical signals from the ferrocene-labeled signal probe. *Id.*

Claim 19	Genmark's RVP System
wherein the detection of the hybridized DNA molecule indicates the presence of human metapneumovirus in the mammalian subject.	The eSensor RVP provides a qualitative result, the presence (Positive) or absence (Target Not Detected) of the viruses contained in the panel, along with the internal MS2 control, based upon whether the underlying electrical signals are above or below a pre-defined cut-off signal intensity. *Id.*

26. As noted, the only difference between claims 19 and 28 is that claim 28 recites "contacting the amplified product with a DNA molecule ***of at least 25 nucleotides in length that specifically*** hybridizes with the amplified product." Upon information and belief, GenMark's RVP system utilizes a DNA molecule of at least 25 nucleotides in length that specifically hybridizes with the amplified product," as recited in claim 28.

27. Thus, while GenMark's RVP system can *also* be used to detect the presence of other markers of respiratory viruses, use of the RVP system according to GenMark's own product literature and FDA submissions necessarily entails performing all steps of at least claims 19 and 28 of the '206 Patent.

D. GenMark Is Actively Marketing Its Infringing RVP System

28. GenMark currently markets four tests that are FDA-cleared for in-vitro diagnostic (IVD) use: Cystic Fibrosis Genotyping Test, Respiratory Viral Panel, Thrombophilia Risk Test, and Warfarin Sensitivity Test. Upon information and belief, GenMark's RVP test accounts for a substantial portion of its revenue.

29. In its most recent SEC filing, GenMark reported third quarter 2014 revenue for its multiplex molecular diagnostic testing systems at $6.3 million, with a gross profit of $3.6 million (57%). Projected revenue for 2014 is over $29.0 million, with a gross profit of approximately $15.7 million (54%).

30. GenMark sells its Respiratory Viral Panel as part of an analyzer system called the XT-8. GenMark reported a total installed base of 502 XT-8 analyzers using

the eSensor technology at the end of the third quarter 2014, "all in end-user laboratories within the U.S. market."

E. Genmark Knew of the '206 Patent

31. GenMark knew about the '206 Patent both in the period before and at the time that ViroNovative filed the instant Complaint. In view of GenMark's recent litigious activity against ViroNovative and to protect its rights in its valuable intellectual property, ViroNovative is filing the instant Complaint on the same day that the '206 Patent issues. The '811 Application and its prosecution history have been publicly available, however, for many years before this Complaint was filed. Genmark is also well aware of ViroNovative's patent portfolio. It is common in this competitive industry for competitors to monitor the patents of other companies.

32. On January 2, 2015, counsel for ViroNovative sent a written Notice of Allowed Claims to Mr. Daniel Johnson, counsel for GenMark, informing GenMark of the issuance of the '811 Application and enclosing a copy of the allowed claims. A copy of the Notice is attached as Exhibit C hereto.

33. The '206 Patent belongs to a family of ViroNovative patent applications and issued patents that claim priority to the same PCT application, including, for example, issued patents **US 7,531,342** ("the '342 Patent"); **US 8,715,922** ("the '922 Patent"); **US 8,722,341** ("the '341 Patent"); and patent application publications US 2014/295409; US 2010/297730; US 2010/278813; US2005/118195; and US 2003/232061. In addition, ViroNovative is the owner of other U.S. patents and pending patent applications for hMPV technology related to the '206 Patent. Each of these documents was published and available to the public, including GenMark, prior to the issuance of the '206 Patent.

34. The '811 Application published on June 2, 2005, several years before the '206 Patent issued, and several years before any licensing discussions took place between GenMark and ViroNovative. GenMark's counsel has sophisticated resources

and can easily identify and monitor any pending ViroNovative patent applications, particularly when they are closely related members of the same patent family.

35. On March 27, 2013, counsel for ViroNovative sent a certified letter to Mr. Jeff Hawkins, GenMark's Senior Vice President of Marketing, providing GenMark with Notices of Allowance for some recently-issued members of this patent family. ViroNovative's counsel noted that other ViroNovative patents and patent applications were extant, and suggested that GenMark consider acquiring a license.

36. On May 6, 2014, GenMark filed a Complaint in this court, seeking a declaratory judgment of invalidity and non-infringement of four of ViroNovative's patents, all related to hMPV detection and/or isolation.[14] A true and correct copy of that complaint is attached hereto as Exhibit D.[15]

37. ViroNovative has moved this Court for dismissal of GenMark's declaratory action under Fed. R. Civ. P. 12(b)(6) for failure to state a claim.[16] In its original Complaint, GenMark made numerous allegations that demonstrated its intimate knowledge of ViroNovative's hMPV patent portfolio and licensing activity, going back at least to 2013. These allegations included:

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

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[14] *GenMark Diagnostics, Inc., v. ViroNovative B.V.*, Case No. '14CV1140-JAH-NLS, filed May 6, 2014 ("the -1140 Case") (Docket 1), at p. 4 (referencing U.S. Patents **7,449,324**, **8,715,922**, **7,449,324**, and 7,704,720).

[15] Excluding exhibits thereto. GenMark subsequently added a claim for declaratory judgment as to the '341 Patent, which issued on May 13, 2014, further demonstrating that GenMark is aware of ViroNovative's patent portfolio. *See* GenMark's Second Amended Complaint (Docket 16), at pp. 5, 12-14.

[16] Docket 28 in the -1140 Case, requesting dismissal of GenMark's Second Amended Complaint.

[17] Complaint for Declaratory Judgment (Docket 1), at p. 1.

- VIRONOVATIVE has licensed U.S. patents to multiple entities headquartered in the U.S., and threatening legal action if GENMARK did not take a license. The most recent contact was in May 2014.[18]

- VIRONOVATIVE for the past several months has repeatedly contacted employees of GENMARK through email and telephone, attempting to license the Patents at Issue.[19]

- In 2013, VIRONOVATIVE contacted representatives of GENMARK and asserted that the GENMARK RVP infringed VIRONOVATIVE technology and that GENMARK needed a license from VIRONOVATIVE. During these discussions that took place over several months, VIRONOVATIVE asserted that it is the assignee and/or exclusive licensee of the following patents in diagnostic and other technology [identifying all four patents].[20]

- VIRONOVATIVE communicated its demands both orally and in writing to GENMARK management asserting that GENMARK, by its manufacture, offers for sale, and/or sales of RVP and other diagnostic tools and procedures, and other products, infringes and/or has infringed the Patents at Issue.[21]

38. Thus, GenMark had both actual and constructive knowledge of the '206 Patent prior to and at the time that the instant Complaint was filed. In the alternative, GenMark was willfully blind to the existence of the '206 Patent, because GenMark subjectively believed that there was a high probability that the patent existed, and took deliberate actions to avoid learning of that fact.[22] These steps included ignoring the '206 Patent, despite the fact that: a) GenMark has recently asserted a declaratory judgment action against ViroNovative for closely-related patents; b) GenMark is clearly aware of ViroNovative's history of licensing its patented technology, and should, as a competitor in a small field, have been actively monitoring ViroNovative's

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[18] *Id.* at p. 2.
[19] *Id.*
[20] *Id.* at pp. 3-4.
[21] *Id.* at p. 4. ViroNovative's reference to GenMark's allegations is provided herein to illustrate GenMark's knowledge of the Patent-In-Suit, and should not be construed as an admission or recognition of the truth or falsity of the allegations themselves.
[22] *See Global Tech Appliances, Inc., v SEB S.A.*, 131 S. Ct. 2060, 2070 (2011).

patents; and c) ViroNovative had specifically put GenMark on notice of the existence of the patent family, and the prosecution history of the '206 Patent has been publicly available since at least 2005.

39. In addition, there is no dispute that GenMark has actual knowledge of the existence and claims of the '206 Patent with the filing of the instant lawsuit.\

F. Genmark and Third Parties Are Directly Infringing The '206 Patent Using Genmark's RVP

40. GenMark is directly infringing at least one claim of the '206 Patent.

41. Upon information and belief, GenMark representatives, including its sales persons, continue to demonstrate and train end users on the use of the RVP product, including by performing all the steps of at least claims 19 and 28 of the '206 Patent.

42. GenMark representatives, including its scientists, technicians, and product development team, also continue to perform all the steps of, at least, claim 19 of the '206 Patent in conducting testing to evaluate and validate the performance of the RVP system.

43. GenMark markets RVP to numerous third party end-users, including diagnostic laboratories and hospitals.

44. These third party end-users include ARUP Laboratories (Salt Lake City, Utah), which conducted an evaluation of GenMark's RVP system in 2013, including analyzing respiratory samples for hMPV. A copy of the poster presentation illustrating the results of that evaluation is attached hereto as Exhibit E.

45. Upon information and belief, other third party end users include at least the Children's Hospital of Philadelphia at the University of Pennsylvania (Philadelphia, Pennsylvania); Cleveland Clinic Laboratories (Cleveland, Ohio); Memorial Sloan-Kettering Cancer Center (New York, New York); and the University

of North Carolina School of Medicine (Chapel Hill, North Carolina), as well as numerous other molecular diagnostics laboratories across the country.[23]

46. When these third party end-users use GenMark's RVP system according to directions provided by GenMark to detect hMPV, they directly infringe the '206 Patent.

47. Upon information and belief, one or more of these third party end users are continuing to use GenMark's RVP system for commercial purposes, directly infringing at least one claim of the '206 Patent.

G. Genmark Knowingly Induced Its Customers To Infringe the '206 Patent

48. GenMark knowingly induces its customers to infringe the '206 Patent.

49. GenMark advertises and sells its RVP to end-user customers with instructions for the use thereof. In its product literature for the eSensor Respiratory Viral Panel, GenMark outlines the steps that an end-user (*e.g.*, a molecular diagnostics laboratory) should take to use the eSensor RVP. Upon information and belief, GenMark also provides ongoing training, technical support, and reagents to assist its customers in using the RVP system.

50. These affirmative steps to instruct end users in activities that constitute direct infringement demonstrate a specific intent by GenMark to induce infringement.

51. GenMark knows that practicing the use of the RVP system by these end users according to the instructions provided by GenMark will cause, and does cause, these end users to directly infringe the '206 Patent.

52. In the alternative, GenMark is willfully blind to the fact that practicing the use of the RVP system by these end user customers according to the instructions

[23] As noted, GenMark reported a total installed base of 502 XT-8 analyzers using the eSensor technology at the end of the third quarter 2014, "all in end-user laboratories within the U.S. market." Upon information and belief, many of these analyzers are equipped with the RVP system, and most end-users only utilize one or a very small number of such analyzers. Thus, there may be hundreds of GenMark customers currently using the RVP system.

provided by GenMark will cause, and does cause, these end users to directly infringe the '206 Patent, insofar as GenMark is aware that there is a high probability that such use by these end-users will infringe the '206 Patent and GenMark has taken deliberate actions to avoid learning of that fact.[24]

53. GenMark thus specifically intends for its end-user customers to infringe the '206 Patent.

54. GenMark competes directly against many of ViroNovative's licensees, using ViroNovative's patented technology.

55. The potential for sales of hMPV-related diagnostics could exceed $1 billion per year at full market penetration. Thus, GenMark's infringement of the '206 Patent and its inducement of third parties to directly infringe the '206 Patent not only deprives ViroNovative of immediate opportunities to commercialize its patent; it also encourages ViroNovative's existing licensees to drop their licenses or disregard ViroNovative's patents as unenforceable.

FIRST CLAIM FOR RELIEF

(Direct Infringement of U.S. Patent 8,927,206)

56. The preceding paragraphs are incorporated by reference, as if set forth fully herein.

57. ViroNovative is the exclusive owner and assignee of the entire right, title and interest in and to U.S. Patent 8,927,206 ("the '206 Patent).

58. The '206 Patent was duly and legally issued by the United States Patent Office on January 6, 2015.

59. The '206 Patent is valid and enforceable.

[24] *See Global Tech*, 131 S. Ct. at 2070.

60. GenMark has infringed and continues to infringe the '206 Patent by, for example, using its RVP system in a manner which practices the methods of one or more claims of the '206 Patent.

61. Specifically, GenMark's use of the RVP system infringes at least claims 19 and 28 of the '206 Patent by incorporating all of the elements of "A method of detecting if a polynucleotide from human metapneumovirus is present in a mammalian subject…," as recited in claims 19 and 28.

62. Upon information and belief, GenMark's infringement of the '206 Patent has been deliberate, willful, and with full knowledge of the '206 Patent, and GenMark has taken no steps to modify the use of its RVP product to avoid infringement of the '206 Patent, despite this knowledge.

63. GenMark's activities directly infringe at least one claim of the '206 Patent either literally or under the doctrine of equivalents, without authority or license from ViroNovative, and in violation of ViroNovative's rights.

64. GenMark's infringing activities entitle ViroNovative to an award of damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by GenMark, together with interest and costs.

65. GenMark's infringement of ViroNovative's rights in the '206 Patent is causing ViroNovative irreparable injury and will cause further irreparable injury unless Defendant is preliminarily and permanently enjoined under 35 U.S.C. § 283.

66. This case is an exceptional case justifying an award of attorneys' fees and treble damages against Defendant. 35 U.S.C. §§ 284 & 285.

SECOND CLAIM FOR RELIEF
(Induced infringement of U.S. Patent 8,927,206)

67. The preceding paragraphs are incorporated by reference, as if set forth fully herein.

68. Prior to the filing of the instant Complaint, GenMark had both actual and constructive knowledge about the existence and the claims of the '206 Patent. In the alternative, GenMark has been willfully blind to the existence and the claims of the '206 Patent in this period.

69. As of the filing of the instant Complaint, GenMark has actual and constructive knowledge of the existence and the claims of the '206 Patent.

70. Use of GenMark's eSensor RVP system by third party end-users according to GenMark's instructions and as directed in other ways by GenMark constitutes direct infringement of at least one claim of the '206 Patent.

71. GenMark knew and continues to know that such use of the RVP system by third party end-users constitutes direct infringement of at least one claim of the '206 Patent.

72. GenMark specifically intended that its customers infringe at least one claim of the '206 Patent.

73. GenMark's knowing, deliberate activities in inducing infringement have caused, and will continue to cause, one or more third party end users to directly infringe one or more claims of the '206 Patent.

74. GenMark is thus actively inducing infringement of the '206 Patent.

75. GenMark's infringing activities entitle ViroNovative to an award of damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by GenMark, together with interest and costs.

76. GenMark's induced infringement of ViroNovative's rights in the '206 Patent is causing ViroNovative irreparable injury and will cause further irreparable injury unless Defendant is preliminarily and permanently enjoined under 35 U.S.C. § 283.

77. This case is an exceptional case justifying an award of attorneys' fees and treble damages against Defendant. 35 U.S.C. §§ 284 & 285.

PRAYER FOR RELIEF

WHEREFORE, ViroNovative prays for judgment against Genmark as follows:

a. That GenMark directly infringed one or more claims of the '206 Patent;

b. That GenMark induced infringement of one or more claims of the '206 Patent;

c. For compensatory and prejudgment interest thereon for Defendant's acts of infringement;

d. For temporary, preliminary and permanent injunctive relief prohibiting Defendant, and its officers, directors, agents, servants, or anyone working for, in concert with or on behalf of Defendant from infringing the '206 Patent or from inducing others to infringe the '206 Patent;

e. For immediate preliminary injunctive relief prohibiting Defendant, and its officers, directors, agents, servants, or anyone working for, in concert with or on behalf of Defendant from making, using, selling, offering for sale, or importing into the United States its eSensor RVP product in conjunction with hMPV testing;

f. A finding that this case is an exceptional case justifying an award of attorneys' fees against Defendant. 35 U.S.C. § 285.

g. A finding that this case is an exceptional case justifying an award of treble damages against Defendant. 35 U.S.C. § 284.

h. For costs of court.

i. Restitutionary relief against GenMark and in favor of ViroNovative, including disgorgement of wrongfully-obtained profits and any other appropriate relief.

j. For such further equitable and legal relief that this Court deems reasonable and appropriate under the circumstances.

Dated: January 6, 2015

SULLIVAN, HILL, LEWIN, REZ & ENGEL
A Professional Law Corporation

By: */s/Donald G. Rez*
Donald G. Rez
Attorneys for Plaintiff, ViroNovative, B.V.

DEMAND FOR JURY TRIAL

Plaintiff, ViroNovative, B.V., hereby demands trial by jury.

Dated: January 6, 2015

SULLIVAN, HILL, LEWIN, REZ & ENGEL
A Professional Law Corporation

By: */s/Donald G. Rez*
Donald G. Rez
Attorneys for Plaintiff, ViroNovative, B.V.

Index of Exhibits

A U.S. Patent 8,927,206;

B FDA 510(k) Substantial Equivalence Determination Decision Summary ("Decision Summary");

C January 2, 2015 Notice of Allowed Claims;

D. Complaint for Declaratory Judgment, GenMark Diagnostics, Inc., v. ViroNovative B.V., Case No. '14CV1140-JAH-NLS, filed May 6, 2014 (Docket 1);

E. ARUP Poster Presentation – Evaluation of GenMark RVP.