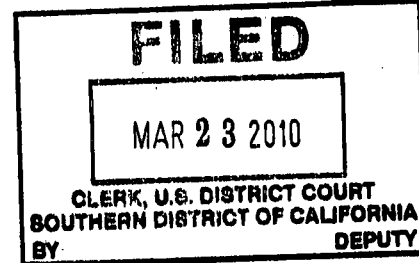


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11 GEN-PROBE INCORPORATED

12 UNITED STATES DISTRICT COURT
13 SOUTHERN DISTRICT OF CALIFORNIA
14 '10 CV 0602 JM POR

15 GEN-PROBE INCORPORATED,
16 Plaintiff,
17 v.
18 BECTON, DICKINSON AND COMPANY,
19 Defendant.

Case No.
COMPLAINT FOR PATENT INFRINGEMENT
DEMAND FOR JURY TRIAL

20
21 Plaintiff Gen-Probe Incorporated ("Gen-Probe") alleges as follows:

22 1. Gen-Probe is a global leader in the development, manufacture and marketing of
23 rapid, accurate and cost-effective nucleic acid tests and corresponding equipment used primarily
24 to detect infectious microorganisms such as Chlamydia trachomatis, Neisseria gonorrhoeae,
25 human papillomavirus ("HPV"), and human immunodeficiency virus ("HIV") that cause human
26 diseases, and to screen donated human blood. With the increasing pressure to contain health care
27 costs, leverage the limited supply of medical professionals and technologies and the ever-
28 increasing need to provide more accurate and reliable diagnostic tools, Gen-Probe's proprietary

1 technologies and patents that cover its nucleic acid tests and equipment provide it with a
2 significant competitive advantage in the global market. In this action, Gen-Probe seeks damages
3 and injunctive relief for infringement of a portfolio of Gen-Probe's patents that encompass and
4 facilitate the use of fully automated, high-throughput systems useful for detecting infectious
5 microorganisms and diagnosing human diseases.

6 **THE PARTIES**

7 2. Gen-Probe was founded in San Diego in 1983 as a small "start up" company,
8 seeking to develop products based on the discoveries of a local research scientist. Over time,
9 Gen-Probe has become one of the largest biotechnology companies in San Diego. Gen-Probe
10 maintains its principal offices and research facilities at 10210 Genetic Center Drive, San Diego,
11 CA 92121, where it employs over 1000 scientists and staff. Gen-Probe is a corporation
12 organized under the laws of the State of Delaware.

13 3. Gen-Probe is informed and believes, and based thereon alleges, that defendant
14 Becton, Dickinson and Company (hereinafter "Defendant," or "BD") is a corporation that
15 maintains its principal place of business and worldwide headquarters in Franklin Lakes,
16 New Jersey. Gen-Probe is further informed and believes that, on or about November 20, 2009,
17 BD completed the acquisition of HandyLab, Inc., an Ann Arbor, Michigan-based company.
18 Gen-Probe is further informed and believes that BD conducts research, manufacturing, sales
19 and/or other business activities throughout the United States, including in this judicial district.

20 4. In the 1990s, Gen-Probe began development of an instrument to completely
21 automate nucleic acid testing to detect infectious diseases and screen human blood. Despite
22 previous failures by larger and better funded competitors to develop similar fully automated
23 systems, by 2003, Gen-Probe began clinical trials for use of the TIGRIS® System for blood
24 screening. After obtaining FDA approval to use the TIGRIS System for blood screening,
25 Gen-Probe then obtained FDA approval for use of the TIGRIS System in the clinical diagnosis
26 of infectious diseases, thus establishing the TIGRIS System as the first fully automated, high-
27 throughput nucleic acid testing instrument. Currently, the TIGRIS System is used to screen a
28 significant portion of the nation's blood supply and is being used in major clinical laboratories

1 around the world for clinical diagnosis of infectious disease, including sexually transmitted
2 diseases such as Chlamydia trachomatis and Neisseria gonorrhoeae. In 2005, as a direct result of
3 Gen-Probe's inventions arising from the development of the TIGRIS System, the United States
4 awarded Gen-Probe the National Medal of Technology, the nation's highest honor for
5 technological innovation, for Gen-Probe's "pioneering work in the development and
6 commercialization of new blood-testing technologies and systems for the direct detection of viral
7 infections." The Gen-Probe patents asserted herein represent some of the pioneering work
8 recognized by that award.

9 **JURISDICTION AND VENUE**

10 5. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1, *et*
11 *seq.*, and more particularly 35 U.S.C. §§ 271 and 281.

12 6. Jurisdiction in this court is founded upon 28 U.S.C. §§ 1331 and 1338(a). Venue
13 is established in this judicial district pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).
14 Defendant BD has a regular place of business and transacts substantial business, either directly
15 or through its agents, on an ongoing basis in this judicial district.

16 **BACKGROUND**

17 7. On July 14, 2009, the United States Patent and Trademark Office issued United
18 States Patent No. 7,560,255 (hereinafter "the '255 patent") entitled "Automated Process for
19 Detecting The Presence of a Target Nucleic Acid In A Sample." Gen-Probe has attached a copy
20 of the '255 patent as Exhibit A to this complaint.

21 8. On April 28, 2009, the United States Patent and Trademark Office issued United
22 States Patent No. 7,524,652 (hereinafter "the '652 patent") entitled "Automated Process for
23 Detecting The Presence of a Target Nucleic Acid In A Sample." Gen-Probe has attached a copy
24 of the '652 patent as Exhibit B to this complaint.

25 9. On January 27, 2009, the United States Patent and Trademark Office issued
26 United States Patent No. 7,482,143 (hereinafter "the '143 patent") entitled "Automated Process
27 for Detecting The Presence of a Target Nucleic Acid In A Sample." Gen-Probe has attached a
28 copy of the '143 patent as Exhibit C to this complaint.

1 **10.** On October 10, 2006, the United States Patent and Trademark Office issued
2 United States Patent No. 7,118,892 (hereinafter “the ‘892 patent”) entitled “Automated Process
3 for Preparing and Amplifying a Target Nucleic Acid Sequence.” Gen-Probe has attached a copy
4 of the ‘892 patent as Exhibit D to this complaint.

5 **11.** Gen-Probe owns, by assignment, all right, title and interest in and to the ‘255,
6 ‘652, ‘143, and ‘892 patents.

7 **COUNT ONE**

8 **INFRINGEMENT OF THE ‘255 PATENT**

9 **12.** Gen-Probe repeats, repleads, and incorporates herein the allegations contained in
10 paragraphs 1 to 11 of this Complaint.

11 **13.** Gen-Probe is informed and believes, and based thereon alleges, that BD has been
12 and is directly and indirectly infringing the ‘255 patent through acts which include but are not
13 limited to the manufacture, use, distribution and sale of the BD MAX System™ nucleic acid
14 testing system (formerly known as the HandyLab “Jaguar System”) and companion nucleic acid
15 diagnostic assays. Gen-Probe is further informed and believes that the BD MAX System™ is
16 not a staple article or commodity of commerce suitable for substantial non-infringing use; that
17 BD has actual knowledge of the ‘255 patent, has manufactured, distributed and sold those
18 nucleic acid testing systems and companion assays specifically for uses that practice the
19 ‘255 patent, and BD has provided written instructions to the users of such systems and assays
20 with the specific intent to encourage those users to practice the ‘255 patent. Gen-Probe is further
21 informed and believes, and based thereon alleges, that BD will continue to infringe unless
22 enjoined by this Court.

23 **14.** BD’s infringement of the ‘255 patent has caused and will continue to cause
24 Gen-Probe substantial and irreparable injury for which Gen-Probe is entitled to receive
25 injunctive relief and damages adequate to compensate it for such infringement.

26 **15.** Gen-Probe is informed and believes, and based thereon alleges, that BD’s
27 infringement of the ‘255 patent has been and is being committed in a willful manner, and in
28 deliberate and intentional disregard of Gen-Probe’s rights.

COUNT TWO

INFRINGEMENT OF THE '652 PATENT

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3 16. Gen-Probe repeats, repleads, and incorporates herein the allegations contained in
4 paragraphs 1 to 15 of this Complaint.

5 17. Gen-Probe is informed and believes, and based thereon alleges, that BD has been
6 and is directly and indirectly infringing the '652 patent through acts which include but are not
7 limited to the manufacture, use, distribution and sale of the BD MAX System™ nucleic acid
8 testing system (formerly known as the HandyLab "Jaguar System") and companion nucleic acid
9 diagnostic assays. Gen-Probe is further informed and believes that the BD MAX System™ is
10 not a staple article or commodity of commerce suitable for substantial non-infringing use; that
11 BD has actual knowledge of the '652 patent, has manufactured, distributed and sold those
12 nucleic acid testing systems and companion assays specifically for uses that practice the
13 '652 patent, and BD has provided written instructions to the users of such systems and assays
14 with the specific intent to encourage those users to practice the '652 patent. Gen-Probe is further
15 informed and believes, and based thereon alleges, that BD will continue to infringe unless
16 enjoined by this Court.

17 18. BD's infringement of the '652 patent has caused and will continue to cause
18 Gen-Probe substantial and irreparable injury for which Gen-Probe is entitled to receive
19 injunctive relief and damages adequate to compensate it for such infringement.

20 19. Gen-Probe is informed and believes, and based thereon alleges, that BD's
21 infringement of the '652 patent has been and is being committed in a willful manner, and in
22 deliberate and intentional disregard of Gen-Probe's rights.

COUNT THREE

INFRINGEMENT OF THE '143 PATENT

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25 20. Gen-Probe repeats, repleads, and incorporates herein the allegations contained in
26 paragraphs 1 to 19 of this Complaint.

27 21. Gen-Probe is informed and believes, and based thereon alleges, that BD has been
28 and is directly and indirectly infringing the '143 patent through acts which include but are not

1 limited to the manufacture, use, distribution and sale of the BD MAX System™ nucleic acid
2 testing system (formerly known as the HandyLab “Jaguar System”) and companion nucleic acid
3 diagnostic assays. Gen-Probe is further informed and believes that the BD MAX System™ is
4 not a staple article or commodity of commerce suitable for substantial non-infringing use; that
5 BD has actual knowledge of the ‘143 patent, has manufactured, distributed and sold those
6 nucleic acid testing systems and companion assays specifically for uses that practice the
7 ‘143 patent, and BD has provided written instructions to the users of such systems and assays
8 with the specific intent to encourage those users to practice the ‘143 patent. Gen-Probe is further
9 informed and believes, and based thereon alleges, that BD will continue to infringe unless
10 enjoined by this Court.

11 **22.** BD’s infringement of the ‘143 patent has caused and will continue to cause
12 Gen-Probe substantial and irreparable injury for which Gen-Probe is entitled to receive
13 injunctive relief and damages adequate to compensate it for such infringement.

14 **23.** Gen-Probe is informed and believes, and based thereon alleges, that BD’s
15 infringement of the ‘143 patent has been and is being committed in a willful manner, and in
16 deliberate and intentional disregard of Gen-Probe’s rights.

17 **COUNT FOUR**

18 **INFRINGEMENT OF THE ‘892 PATENT**

19 **24.** Gen-Probe repeats, repleads, and incorporates herein the allegations contained in
20 paragraphs 1 to 23 of this Complaint.

21 **25.** Gen-Probe is informed and believes, and based thereon alleges, that BD has been
22 and is directly and indirectly infringing the ‘892 patent through acts which include but are not
23 limited to the manufacture, use, distribution and sale of the BD MAX System™ nucleic acid
24 testing system (formerly known as the HandyLab “Jaguar System”) and companion nucleic acid
25 diagnostic assays. Gen-Probe is further informed and believes that the BD MAX System™ is
26 not a staple article or commodity of commerce suitable for substantial non-infringing use; that
27 BD has actual knowledge of the ‘892 patent, has manufactured, distributed and sold those
28 nucleic acid testing systems and companion assays specifically for uses that practice the

1 '892 patent, and BD has provided written instructions to the users of such systems and assays
2 with the specific intent to encourage those users to practice the '892 patent. Gen-Probe is further
3 informed and believes, and based thereon alleges, that BD will continue to infringe unless
4 enjoined by this Court.

5 26. BD's infringement of the '892 patent has caused and will continue to cause
6 Gen-Probe substantial and irreparable injury for which Gen-Probe is entitled to receive
7 injunctive relief and damages adequate to compensate it for such infringement.

8 27. Gen-Probe is informed and believes, and based thereon alleges, that BD's
9 infringement of the '892 patent has been and is being committed in a willful manner, and in
10 deliberate and intentional disregard of Gen-Probe's rights.

11 **PRAYER FOR RELIEF**

12 WHEREFORE, Plaintiff Gen-Probe prays that this Court:

13 1. Adjudge that BD has infringed, and does currently infringe, directly and/or
14 indirectly, the '255, '652, '143, and '892 patents;

15 2. Preliminarily and permanently enjoin BD, its employees and agents, and any
16 other person(s) in active concert or participation with BD from infringing, directly or indirectly,
17 the '255, '652, '143, and '892 patents;

18 3. Award Gen-Probe its damages adequate to compensate Gen-Probe for BD's
19 infringement;

20 4. Award Gen-Probe treble damages pursuant to 35 U.S.C. § 284 as a consequence
21 of BD's willful infringement;

22 5. Declare this case exceptional pursuant to 35 U.S.C. § 285 and award Gen-Probe
23 its costs and attorneys' fees; and

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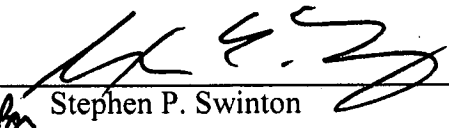
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6. Grant Gen-Probe such other and further relief as is just and proper.

Dated: March 23, 2010

LATHAM & WATKINS LLP

By: 
for Stephen P. Swinton

Attorneys for Plaintiff
GEN-PROBE INCORPORATED