

1 LATHAM & WATKINS LLP
Stephen P. Swinton (Bar No. 106398)
2 12636 High Bluff Drive, Suite 400
San Diego, CA 92130
3 Telephone: (858) 523-5400
Facsimile: (858) 523-5450
4 steve.swinton@lw.com

5 LATHAM & WATKINS LLP
Mark A. Finkelstein (Bar No. 173851)
6 650 Town Center Drive, 20th Floor
Costa Mesa, CA 92626-1925
7 Telephone: (714) 540-1235
Facsimile: (714) 755-8290
8 mark.finkelstein@lw.com

9 Attorneys for Plaintiff
GEN-PROBE INCORPORATED

FILED
OCT 19 2009
CLERK, U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
BY *gd* DEPUTY

11 UNITED STATES DISTRICT COURT
12 SOUTHERN DISTRICT OF CALIFORNIA

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

Case No. **09 CV 2 31 9 BEN NLS**
COMPLAINT FOR PATENT INFRINGEMENT
DEMAND FOR JURY TRIAL

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

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

GR

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

5 **THE PARTIES**

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

12 3. Gen-Probe is informed and believes, and based thereon alleges, that defendant
13 Becton, Dickinson and Company (hereinafter "Defendant," or "BD") is a corporation that
14 maintains its principal place of business and worldwide headquarters in Franklin Lakes, New
15 Jersey. Gen-Probe is further informed and believes that BD conducts research, manufacturing,
16 sales and/or other business activities throughout the United States, including in this judicial
17 district.

18 4. In the 1990s, Gen-Probe began development of an instrument to completely
19 automate nucleic acid testing to detect infectious diseases and screen human blood. Despite
20 previous failures by larger and better funded competitors to develop similar fully automated
21 systems, by 2003, Gen-Probe began clinical trials for use of the TIGRIS® System for blood
22 screening. After obtaining FDA approval to use the TIGRIS System for blood screening,
23 Gen-Probe then obtained FDA approval for use of the TIGRIS System in the clinical diagnosis
24 of infectious diseases, thus establishing the TIGRIS System as the first fully automated, high-
25 throughput nucleic acid testing instrument. Currently, the TIGRIS System is used to screen a
26 significant portion of the nation's blood supply and is being used in major clinical laboratories
27 around the world for clinical diagnosis of infectious disease, including sexually transmitted
28 diseases such as Chlamydia trachomatis and Neisseria gonorrhoeae. In 2005, as a direct result of

1 Gen-Probe's inventions arising from the development of the TIGRIS System, the United States
2 awarded Gen-Probe the National Medal of Technology, the nation's highest honor for
3 technological innovation, for Gen-Probe's "pioneering work in the development and
4 commercialization of new blood-testing technologies and systems for the direct detection of viral
5 infections." The Gen-Probe patents asserted herein represent some of the pioneering work
6 recognized by that award.

7 **JURISDICTION AND VENUE**

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

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

14 **BACKGROUND**

15 7. On July 14, 2009, the United States Patent and Trademark Office issued United
16 States Patent No. 7,560,256 (hereinafter "the '256 patent") entitled "Automated Process for
17 Detecting The Presence of a Target Nucleic Acid In A Sample." Gen-Probe has attached a copy
18 of the '256 patent as Exhibit A to this complaint.

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

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

27 10. On January 27, 2009, the United States Patent and Trademark Office issued
28 United States Patent No. 7,482,143 (hereinafter "the '143 patent") entitled "Automated Process

1 for Detecting The Presence of a Target Nucleic Acid In A Sample.” Gen-Probe has attached a
2 copy of the ‘143 patent as Exhibit D to this complaint.

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

7 12. On March 18, 1997, the United States Patent and Trademark Office issued United
8 States Patent No. 5,612,200 (hereinafter “the ‘200 patent”) entitled “Method and Kit for
9 Destroying Ability of Nucleic Acid to be Amplified.” Gen-Probe has attached a copy of the ‘200
10 patent as Exhibit F to this complaint.

11 13. On November 13, 2007, the United States Patent and Trademark Office issued
12 United States Patent No. 7,294,308 (hereinafter “the ‘308 patent”) entitled “Penetrable Cap.”
13 Gen-Probe has attached a copy of the ‘308 patent as Exhibit G to this complaint.

14 14. On May 17, 2005, the United States Patent and Trademark Office issued United
15 States Patent No. 6,893,612 (hereinafter “the ‘612 patent”) entitled “Penetrable Cap.”
16 Gen-Probe has attached a copy of the ‘612 patent as Exhibit H to this complaint.

17 15. Gen-Probe owns, by assignment, all right, title and interest in and to the ‘256,
18 ‘255, ‘652, ‘143, ‘892, ‘200, ‘308 and ‘612 patents.

19 **COUNT ONE**

20 **INFRINGEMENT OF THE ‘256 PATENT**

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

23 17. Gen-Probe is informed and believes, and based thereon alleges, that BD has been
24 and is directly and indirectly infringing the ‘256 patent through acts which include but are not
25 limited to the manufacture, use, distribution and sale of BD’s “Viper with XTR Technology”
26 nucleic acid testing system and companion nucleic acid diagnostic assays. Gen-Probe is further
27 informed and believes that BD’s “Viper with XTR Technology” is not a staple article or
28 commodity of commerce suitable for substantial non-infringing use; that BD has actual

1 knowledge of the '256 patent, has manufactured, distributed and sold those nucleic acid testing
2 systems and companion assays specifically for uses that practice the '256 patent, and BD has
3 provided written instructions to the users of such systems and assays with the specific intent to
4 encourage those users to practice the '256 patent. Gen-Probe is further informed and believes,
5 and based thereon alleges, that BD will continue to infringe unless enjoined by this Court.

6 18. BD's infringement of the '256 patent has caused and will continue to cause
7 Gen-Probe substantial and irreparable injury for which Gen-Probe is entitled to receive
8 injunctive relief and damages adequate to compensate it for such infringement.

9 19. Gen-Probe is informed and believes, and based thereon alleges, that BD's
10 infringement of the '256 patent has been and is being committed in a willful manner, and in
11 deliberate and intentional disregard of Gen-Probe's rights.

12 **COUNT TWO**
13 **INFRINGEMENT OF THE '255 PATENT**

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

16 21. Gen-Probe is informed and believes, and based thereon alleges, that BD has been
17 and is directly and indirectly infringing the '255 patent through acts which include but are not
18 limited to the manufacture, use, distribution and sale of BD's "Viper with XTR Technology"
19 nucleic acid testing system and companion nucleic acid diagnostic assays. Gen-Probe is further
20 informed and believes that BD's "Viper with XTR Technology" is not a staple article or
21 commodity of commerce suitable for substantial non-infringing use; that BD has actual
22 knowledge of the '255 patent, has manufactured, distributed and sold those nucleic acid testing
23 systems and companion assays specifically for uses that practice the '255 patent, and BD has
24 provided written instructions to the users of such systems and assays with the specific intent to
25 encourage those users to practice the '255 patent. Gen-Probe is further informed and believes,
26 and based thereon alleges, that BD will continue to infringe unless enjoined by this Court.

27 22. BD's infringement of the '255 patent has caused and will continue to cause
28 Gen-Probe substantial and irreparable injury for which Gen-Probe is entitled to receive

1 injunctive relief and damages adequate to compensate it for such infringement.

2 **23.** Gen-Probe is informed and believes, and based thereon alleges, that BD's
3 infringement of the '255 patent has been and is being committed in a willful manner, and in
4 deliberate and intentional disregard of Gen-Probe's rights.

5 **COUNT THREE**
6 **INFRINGEMENT OF THE '652 PATENT**

7 **24.** Gen-Probe repeats, repleads, and incorporates herein the allegations contained in
8 paragraphs 1 to 15 of this Complaint.

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

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

23 **27.** Gen-Probe is informed and believes, and based thereon alleges, that BD's
24 infringement of the '652 patent has been and is being committed in a willful manner, and in
25 deliberate and intentional disregard of Gen-Probe's rights.

26 **COUNT FOUR**
27 **INFRINGEMENT OF THE '143 PATENT**

28 **28.** Gen-Probe repeats, repleads, and incorporates herein the allegations contained in

1 knowledge of the '892 patent, has manufactured, distributed and sold those nucleic acid testing
2 systems and companion assays specifically for uses that practice the '892 patent, and BD has
3 provided written instructions to the users of such systems and assays with the specific intent to
4 encourage those users to practice the '892 patent. Gen-Probe is further informed and believes,
5 and based thereon alleges, that BD will continue to infringe unless enjoined by this Court.

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

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

12 **COUNT SIX**
13 **INFRINGEMENT OF THE '200 PATENT**

14 **36.** Gen-Probe repeats, repleads, and incorporates herein the allegations contained in
15 paragraphs 1 to 15 of this Complaint.

16 **37.** Gen-Probe is informed and believes, and based thereon alleges, that BD has been
17 and is directly and indirectly infringing the '200 patent through acts which include but are not
18 limited to the use, distribution and sale of BD's "Viper" and "Viper with XTR Technology"
19 nucleic acid testing systems and companion nucleic acid diagnostic assays. Gen-Probe is further
20 informed and believes that BD has actual knowledge of the '200 patent, and has directed users of
21 those nucleic acid testing systems and companion assays to practice the '200 patent by and
22 through written instructions supplied therewith with the specific intent to encourage those users
23 to practice the '200 patent. Gen-Probe is further informed and believes, and based thereon
24 alleges, that BD will continue to infringe unless enjoined by this Court.

25 **38.** BD's infringement of the '200 patent has caused and will continue to cause
26 Gen-Probe substantial and irreparable injury for which Gen-Probe is entitled to receive
27 injunctive relief and damages adequate to compensate it for such infringement.

28 **39.** Gen-Probe is informed and believes, and based thereon alleges, that BD's

1 infringement of the '200 patent has been and is being committed in a willful manner, and in
2 deliberate and intentional disregard of Gen-Probe's rights.

3 **COUNT SEVEN**

4 **INFRINGEMENT OF THE '308 PATENT**

5 40. Gen-Probe repeats, repleads, and incorporates herein the allegations contained in
6 paragraphs 1 to 15 of this Complaint.

7 41. Gen-Probe is informed and believes, and based thereon alleges, that BD has been
8 and is directly and indirectly infringing the '308 patent through acts which include but are not
9 limited to the manufacture, use, distribution and sale of BD ProbeTec™ Female Endocervical
10 and Male Urethral Specimen Collection Kits for Amplified Chlamydia trachomatis/Neisseria
11 gonorrhoeae (CT/GC) DNA Assays. Gen-Probe is further informed and believes that BD's
12 ProbeTec™ Female Endocervical and Male Urethral Specimen Collection Kits for Amplified
13 Chlamydia trachomatis/Neisseria gonorrhoeae (CT/GC) DNA Assays are not staple articles or
14 commodities of commerce suitable for substantial non-infringing use; that BD has actual
15 knowledge of the '308 patent, has manufactured, distributed and sold those nucleic acid testing
16 systems and companion assays specifically for uses that practice the '308 patent, and BD has
17 provided written instructions to users of those specimen collection kits with the specific intent to
18 encourage those users to practice the '308 patent. Gen-Probe is further informed and believes,
19 and based thereon alleges, that BD will continue to infringe unless enjoined by this Court.

20 42. BD's infringement of the '308 patent has caused and will continue to cause Gen-
21 Probe substantial and irreparable injury for which Gen-Probe is entitled to receive injunctive
22 relief and damages adequate to compensate it for such infringement.

23 43. Gen-Probe is informed and believes, and based thereon alleges, that BD's
24 infringement of the '308 patent has been and is being committed in a willful manner, and in
25 deliberate and intentional disregard of Gen-Probe's rights.

26 **COUNT EIGHT**

27 **INFRINGEMENT OF THE '612 PATENT**

28 44. Gen-Probe repeats, repleads, and incorporates herein the allegations contained in

1 infringement;

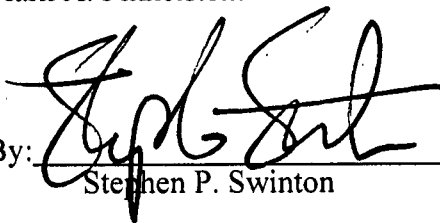
2 4. Award Gen-Probe treble damages pursuant to 35 U.S.C. § 284 as a consequence
3 of BD's willful infringement;

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

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

7 Dated: October 19, 2009

LATHAM & WATKINS LLP
Stephen P. Swinton
Mark A. Finkelstein

By: 

Stephen P. Swinton

Attorneys for Plaintiff
GEN-PROBE INCORPORATED

8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28