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GEN-PROBE INCORPORATED

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

v.

BECTON, DICKINSON AND COMPANY,

Defendant.

CASE NO. 09-CV-2319 BEN (NLS)

**FIRST AMENDED COMPLAINT FOR  
PATENT INFRINGEMENT**

**DEMAND FOR JURY TRIAL**

Plaintiff Gen-Probe Incorporated (“Gen-Probe”) alleges as follows:

**1.** Gen-Probe is a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective nucleic acid tests and corresponding equipment used primarily to detect infectious microorganisms such as *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, human papillomavirus (“HPV”), and human immunodeficiency virus (“HIV”) that cause human diseases, and to screen donated human blood. With the increasing pressure to contain health care costs, leverage the limited supply of medical professionals and technologies and the ever-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, New  
16 Jersey. Gen-Probe is further informed and believes that BD conducts research, manufacturing,  
17 sales and/or other business activities throughout the United States, including in this judicial  
18 district.

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

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

## 8 JURISDICTION AND VENUE

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

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

## 15 BACKGROUND

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

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

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

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

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

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

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

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

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1 provided written instructions to the users of such systems and assays with the specific intent to  
 2 encourage those users to practice the '256 patent. Gen-Probe is further informed and believes,  
 3 and based thereon alleges, that BD will continue to infringe unless enjoined by this Court.

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

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

10 **COUNT TWO**  
 11 **INFRINGEMENT OF THE '255 PATENT**

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

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

25 **21.** BD's infringement of the '255 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

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

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

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

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

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

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

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

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

28. Gen-Probe is informed and believes, and based thereon alleges, that BD has been and is directly and indirectly infringing the '143 patent through acts which include but are not limited to the manufacture, use, distribution and sale of BD's "Viper with XTR Technology" nucleic acid testing system and companion nucleic acid diagnostic assays. Gen-Probe is further informed and believes that BD's "Viper with XTR Technology" is not a staple article or commodity of commerce suitable for substantial non-infringing use; that BD has actual knowledge of the '143 patent, has manufactured, distributed and sold those nucleic acid testing systems and companion assays specifically for uses that practice the '143 patent, and BD has provided written instructions to the users of such systems and assays with the specific intent to encourage those users to practice the '143 patent. Gen-Probe is further informed and believes, and based thereon alleges, that BD will continue to infringe unless enjoined by this Court.

29. BD's infringement of the '143 patent has caused and will continue to cause Gen-Probe substantial and irreparable injury for which Gen-Probe is entitled to receive injunctive relief and damages adequate to compensate it for such infringement.

30. Gen-Probe is informed and believes, and based thereon alleges, that BD's infringement of the '143 patent has been and is being committed in a willful manner, and in deliberate and intentional disregard of Gen-Probe's rights.

## COUNT FIVE INFRINGEMENT OF THE '892 PATENT

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

32. Gen-Probe is informed and believes, and based thereon alleges, that BD has been and is directly and indirectly infringing the '892 patent through acts which include but are not limited to the manufacture, use, distribution and sale of BD's "Viper with XTR Technology" nucleic acid testing system and companion nucleic acid diagnostic assays. Gen-Probe is further informed and believes that BD's "Viper with XTR Technology" is not a staple article or commodity of commerce suitable for substantial non-infringing use; that BD has actual knowledge of the '892 patent, has manufactured, distributed and sold those nucleic acid testing

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

5 **33.** 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 **34.** 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 **COUNT SIX**

### 12 **INFRINGEMENT OF THE '308 PATENT**

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

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

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**COUNT SEVEN**  
**INFRINGEMENT OF THE ‘612 PATENT**

40. Gen-Probe is informed and believes, and based thereon alleges, that BD has been and is directly and indirectly infringing the '612 patent through acts which include but are not limited to the manufacture, use, distribution and sale of BD ProbeTec™ Female Endocervical and Male Urethral Specimen Collection Kits for Amplified Chlamydia trachomatis/Neisseria gonorrhoeae (CT/GC) DNA Assays. Gen-Probe is further informed and believes that BD's ProbeTec™ Female Endocervical and Male Urethral Specimen Collection Kits for Amplified Chlamydia trachomatis/Neisseria gonorrhoeae (CT/GC) DNA Assays are not staple articles or commodities of commerce suitable for substantial non-infringing use; that BD has actual knowledge of the '612 patent, has manufactured, distributed and sold those nucleic acid testing systems and companion assays specifically for uses that practice the '612 patent, and BD has provided written instructions to users of those specimen collection kits with the specific intent to encourage those users to practice the '612 patent. Gen-Probe is further informed and believes, and based thereon alleges, that BD will continue to infringe unless enjoined by this Court.

**41.** BD's infringement of the '612 patent has caused and will continue to cause Gen-Probe substantial and irreparable injury for which Gen-Probe is entitled to receive injunctive relief and damages adequate to compensate it for such infringement.

WHEREFORE, Plaintiff Gen-Probe prays that this Court:

2. Preliminarily and permanently enjoin BD, its employees and agents, and any other person(s) in active concert or participation with BD from infringing, directly or indirectly, the ‘256, ‘255, ‘652, ‘143, ‘892, ‘308 and ‘612 patents;

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

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

LATHAM & WATKINS LLP  
Stephen P. Swinton  
Dean G. Dunlavey  
Alexander E. Long

Attorneys for Plaintiff  
GEN-PROBE INCORPORATED

**DEMAND FOR JURY TRIAL**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure and Local Civil Rule 38.1, Plaintiff Gen-Probe Incorporated demands trial by jury for all issues triable of right by a jury.

Dated: April 22, 2011

LATHAM & WATKINS LLP  
Stephen P. Swinton  
Dean G. Dunlavey  
Alexander E. Long

By: s/Stephen P. Swinton  
steve.swinton@lw.com

Attorneys for Plaintiff  
GEN-PROBE INCORPORATED

**PROOF OF SERVICE**

I am employed in the County of San Diego, State of California. I am over the age of 18 years and not a party to this action. My business address is Latham & Watkins LLP, 12636 High Bluff Drive, Suite 400, San Diego, CA 92130.

On April 22, 2011, I served the following document described as:

**1. FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT  
(DEMAND FOR JURY TRIAL)**

by serving a true copy of the above-described document in the following manner:

**BY ELECTRONIC FILING**

I am familiar with the United States District Court, Southern District of California's practice for collecting and processing electronic filings. Under that practice, documents are electronically filed with the court. The court's CM/ECF system will generate a Notice of Electronic Filing (NEF) to the filing party, the assigned judge, and any registered users in the case. The NEF will constitute service of the document. Registration as a CM/ECF user constitutes consent to electronic service through the court's transmission facilities. Under said practice, the following CM/ECF users were served:

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I declare that I am employed in the office of a member of the Bar of, or permitted to practice before, this Court at whose direction the service was made and declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on April 22, 2011, at San Diego, California.

s/ Stephen P. Swinton  
steve.swinton@lw.com