

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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CYTYC CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 03-11142-DPW
)	[Consolidated Action – Lead Case]
TRIPATH IMAGING, INC.,)	
)	
Defendant.)	
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TRIPATH IMAGING, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 03-12630-DPW
)	
CYTYC CORPORATION,)	
)	
Defendant.)	
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SECOND AMENDED COMPLAINT
(Jury Trial Demanded)

Cytc Corporation (“Cytc”) brings this action to obtain a declaratory judgment that (i) United States Patent Nos. 5,257,182; 5,715,327; 5,793,969; and 6,327,377 (collectively, the “TriPath patents”) are invalid; and (ii) Cytc’s manufacture, use, offer for sale, and sale of its ThinPrep® Imaging System does not infringe any valid claim of any of the TriPath patents.

THE PARTIES

1. Cytc is a Delaware corporation with its principal place of business at 85 Swanson Road, Boxborough, Massachusetts.

2. TriPath Imaging, Inc. (“TriPath”) is a Delaware corporation with its principal place of business at 780 Plantation Drive, Burlington, North Carolina. Upon information and belief, TriPath regularly conducts business in Massachusetts.

JURISDICTION AND VENUE

3. This Court has jurisdiction over Cytoc’s claims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

4. Venue is proper in the District of Massachusetts pursuant to 28 U.S.C. § 1391.

FACTUAL ALLEGATIONS

Cytoc’s ThinPrep® Imaging System

5. Since Dr. George Papanicolaou introduced his test for cervical cancer (the “Pap smear”) in the 1940s, scientists and clinicians have sought to improve the technology and ease the laborious nature of the work. Founded in 1987, Cytoc has dedicated its scientific resources to addressing the limitations of the conventional Pap smear test.

6. In the late 1980s, Cytoc began working on a system for automated computer image analysis of Pap smears. However, it became apparent that the main obstacle to computer imaging was the poor quality of conventional Pap smears. As a result, Cytoc’s scientists and engineers developed a way to prepare slides for cervical screening that would be clearer, more accurate, and easier to read. Cytoc’s slide preparation system is known as the ThinPrep® Pap Test, a semi-automated system for preparing a monolayer slide from a cervical cell sample preserved in a liquid preservative. Since 1996, when the product was approved by the United States Food and Drug Administration (“FDA”), the ThinPrep Pap Test has become the standard of care in cancer screening of cervical cell samples. After introducing the ThinPrep Pap Test,

Cytc developed and introduced a fully automated batch sample preparation system, the ThinPrep® 3000 Processor.

7. To realize its initial goal of automated computer image analysis of Pap test samples, Cytc also developed the ThinPrep Imaging System. The ThinPrep Imaging System is a device that uses computer imaging technology to assist cytotechnologists in screening of Pap test slides for the presence of atypical cells, cervical neoplasia, including its precursor lesions, and carcinoma, as well as certain other cytologic criteria. The ThinPrep Imaging System is designed to assist in improving both diagnostic accuracy and the work environment and productivity of cytotechnologists. The ThinPrep Imaging system analyzes Pap test slides and identifies a number of fields of view within a microscope for a cytotechnologist to review in making a diagnosis.

8. On June 6, 2003, the FDA approved Cytc's ThinPrep Imaging System for commercial use. Immediately following FDA approval, Cytc began actively marketing and selling the ThinPrep Imaging System in the United States.

The Controversy Between Cytc and TriPath

9. In May 2000, an attorney representing TriPath sent Cytc a letter stating that Cytc might be introducing an "automated Pap smear screening system" and also stating that TriPath had an "extensive patent portfolio ... covering multiple aspects of automated cytological screening systems." The attorney enclosed a list of TriPath's patents, and further stated that "[n]othing in this letter should be construed as an offer to license any of TriPath's patents."

10. The list of patents attached to the attorney's letter included patents generally relating to automated systems for scanning pap smear slides and identifying areas most likely to contain malignancies, such as United States Patent No. 5,257,182 ("the 182 patent"), attached

hereto as Exhibit 1; United States Patent No. 5,715,327 (“the ‘327 patent”), attached hereto as Exhibit 2; United States Patent No. 5,793,969 (“the ‘969 patent”), attached hereto as Exhibit 3. More recently, TriPath has accused Cytoc of infringing United States Patent No. 6,327,377 (“the ‘377 patent”), attached hereto as Exhibit 4.

11. Cytoc does not believe that its ThinPrep Imaging System infringes any of the TriPath patents, or that the TriPath patents are valid.

12. During the week since Cytoc received FDA approval for its ThinPrep Imaging System, TriPath has stated that it plans to file a patent infringement lawsuit against Cytoc as soon as Cytoc sells an imaging system. Upon information and belief, TriPath has made such statements to the investment community, as well as to Cytoc’s customers. Cytoc has sold an imaging system.

13. Based on the foregoing, there is an actual, immediate and justiciable controversy between Cytoc and TriPath as to the infringement and validity of the TriPath patents.

COUNT I

14. Cytoc repeats and incorporates paragraphs 1-13 above as if set forth fully herein.

15. Each of the claims of the ‘182 patent is invalid for failure to comply with the conditions of patentability of, *inter alia*, 35 U.S.C. §§ 101, 102, 103 and 112.

16. Cytoc has not infringed, directly, indirectly, or otherwise any valid claim of any of the ‘182 patent.

17. To resolve the legal and factual questions raised by TriPath and to afford relief from the uncertainty and controversy which TriPath's accusations have precipitated, Cytoc is

entitled to a declaratory judgment that it does not infringe the '182 patent and that the '182 patent is invalid.

COUNT II

18. Cytoc repeats and incorporates paragraphs 1-17 above as if set forth fully herein.

19. Each of the claims of the '327 patent is invalid for failure to comply with the conditions of patentability of, *inter alia*, 35 U.S.C. §§ 101, 102, 103 and 112.

20. Cytoc has not infringed, directly, indirectly, or otherwise any valid claim of any of the '327 patent.

21. To resolve the legal and factual questions raised by TriPath and to afford relief from the uncertainty and controversy which TriPath's accusations have precipitated, Cytoc is entitled to a declaratory judgment that it does not infringe the '327 patent and that the '327 patent is invalid.

COUNT III

22. Cytoc repeats and incorporates paragraphs 1-21 above as if set forth fully herein.

23. Each of the claims of the '969 patent is invalid for failure to comply with the conditions of patentability of, *inter alia*, 35 U.S.C. §§ 101, 102, 103 and 112.

24. Cytoc has not infringed, directly, indirectly, or otherwise any valid claim of any of the '969 patent.

25. To resolve the legal and factual questions raised by TriPath and to afford relief from the uncertainty and controversy which TriPath's accusations have precipitated, Cytoc is entitled to a declaratory judgment that it does not infringe the '969 patent and that the '969 patent is invalid.

COUNT IV

26. Cytoc repeats and incorporates paragraphs 1-25 above as if set forth fully herein.

27. Each of the claims of the '377 patent is invalid for failure to comply with the conditions of patentability of, *inter alia*, 35 U.S.C. §§ 101, 102, 103 and 112.

28. Cytoc has not infringed, directly, indirectly, or otherwise any valid claim of any of the '377 patent.

29. To resolve the legal and factual questions raised by TriPath and to afford relief from the uncertainty and controversy which TriPath's accusations have precipitated, Cytoc is entitled to a declaratory judgment that it does not infringe the '377 patent and that the '377 patent is invalid.

WHEREFORE, Cytoc respectfully requests that this Court:

Determine and declare that the claims of the '182 patent are invalid;

Determine and declare that the claims of the '182 patent are not infringed by Cytoc;

Determine and declare that the claims of the '327 patent are invalid;

Determine and declare that the claims of the '327 patent are not infringed by Cytoc;

Determine and declare that the claims of the '969 patent are invalid;

Determine and declare that the claims of the '969 patent are not infringed by Cytoc;

Determine and declare that the claims of the '377 patent are invalid;

Determine and declare that the claims of the '377 patent are not infringed by Cytoc;

Award Cytyc costs of this action, including reasonable attorneys fees; and

Grant such other further relief as the Court deems appropriate.

DEMAND FOR JURY TRIAL

Cytyc demands trial by jury on all issues so triable.

CYTYC CORPORATION,

By its attorneys,

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Dated: May 19, 2004

CERTIFICATE OF SERVICE

I hereby certify that on May 19, 2004 I caused a true and accurate copy of this document to be delivered to counsel for the Defendant:

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