

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

University of South Florida Research
Foundation, Inc., a Florida Corporation and
University of South Florida Board of
Trustees,

Plaintiffs,

v.

Hologic, Inc., a Delaware Corporation
Defendant.

C.A. No. 20-352-CFC

JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

Plaintiffs, University of South Florida Research Foundation, Inc. (“USFRF”) and University of South Florida Board of Trustees (“USF”) (collectively referred to as “Plaintiffs”), through undersigned counsel hereby bring their Complaint for patent infringement against Defendant Hologic, Inc. (“Hologic”) and allege as follows:

NATURE OF ACTION

1. This is an action by Plaintiffs for infringement of United States Patent No. 6,630,937 (“the ‘937 Patent”). Plaintiffs seek damages for violation of the United States Patent Laws, Title 35 of the United States Code.

THE PARTIES

2. Plaintiff USFRF is a not for profit corporation under Florida Statute Chapter 617, and a direct support organization of the University of South Florida pursuant to Florida Statute Section 1004.28.

3. USFRF has its principal place of business at 3802 Spectrum Boulevard, #100, Tampa, Florida 33612.

4. Plaintiff USF maintains its principal office at 4202 E. Fowler Ave, Tampa, Florida 33620.

5. On information and belief, Hologic is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts 01752.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this is a civil action for patent infringement arising under the federal patent laws of the United States.

8. Defendant is subject to personal jurisdiction in this District by virtue of the fact that: (i) it is incorporated under the laws of the State of Delaware; (ii) it has substantial and continuous contacts within the State of Delaware; (iii) it has committed acts of patent infringement in the State of Delaware.

9. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1400(b) because Hologic resides within this District as it is incorporated within this District.

FACTUAL BACKGROUND

10. In the Mid-1990's, a group of researchers working at the University of South Florida Moffitt Cancer Center began working towards creating a solution for quicker and more accurate cancer diagnosis than was currently utilized through reading of analog x-ray film. The researchers, headed by Dr. Laurence P. Clarke and Dr. Maria Kallergi, sought to create a workstation to display and manipulate digitized mammograms and their digitized images instead of the existing analog x-ray film based technology.

11. On February 22, 2002, the inventors, who were conducting research at the USF campus, filed a patent application on an invention entitled “Workstation Interface for Use in Digital Mammography and Associated Methods.” That application related to, and claimed priority from, one or more earlier provisional patent applications. The application was duly examined on the merits by the United States Patent Office and the ‘937 Patent was lawfully issued with seventeen (17) claims on October 7, 2003.

12. The inventors of the ‘937 Patent assigned their rights to USF in Tampa, Florida. USF then granted USFRF a royalty-free, exclusive license, including the right to sublicense, make, have made, develop, use, lease, sublicense, import, export, offer to sell, sell and have sold the ‘937 Patent. This included the right to stop others from using the invention.

13. After the invention of the ‘937 Patent received FDA clearance, virtually all companies started using the claimed technology of the ‘937 Patent. The ‘937 Patent represents substantial advancements in medical technology as it contributes to improved cancer diagnoses through early observing techniques.

14. The ‘937 Patent is valid and enforceable.

THE ACCUSED SYSTEM

15. Defendant Hologic manufactures, or has manufactured, and sells or offers for sale, digital displays and workstation systems for medical installations providing interface between digital mammography images and users. This workstation incorporates electronic communications, accesses and receives stored digitized mammography images, and displays images reflecting a plurality of grayscale values. These products enable display and control over the grayscale rendition and illumination state of the mammographic images of varying resolution in different

spatial configurations. The main accused system manufactured by Hologic is its Hologic SecurView DX Mammography System (“SecurView”).

Hologic SecurView

16. Hologic has infringed and continues to infringe literally and/or through the doctrine of equivalents, one or more claims of the ‘937 Patent, including but not limited to the independent claims of the ‘937 Patent by using, making, offering to sell, and/or selling without authority in the United States its SecurView.

17. For purposes of example only, and without limitation, the SecurView performs every element of the independent claims, 2, 3, and 17 of the ‘937 Patent. Hologic has also infringed and continues to infringe other claims of the ‘937 Patent, including but not limited to the various dependent claims.

18. In particular, Claim 2 of the ‘937 Patent involves “A system for interfacing a digitized mammogram to a user.” The SecurView is designed specifically to allow radiologists to manipulate and evaluate mammography images.

19. Claim 2 of the ‘937 Patent further provides for a monitor capable of displaying image data in a predetermined format, and in varying grayscale colors, said monitor having a predetermined illumination capability. Hologic’s SecurView provides a monitor for displaying a mammography image at a default illumination. The image is displayed in shades of grade, in a format that is supported for display.



20. Claim 2 of the '937 Patent further recites “an electronic storage medium with digitized mammogram image data, said digitized mammogram image data corresponding to a film mammogram image and the digitized mammogram image data having grayscale values corresponding to the optical densities of the film mammogram image.” The SecurView features an electronic storage medium system called SecurXchange Archive. SecurXchange Archive will store and retrieve physician annotations, as well as CAD markings.

21. Claim 2 of the '937 Patent further recites “a processor in circuit communication with said monitor and said electronic storage medium” The SecurView uses a processor, for example a CPU Six Core, Xeon® processor in combination with various storage mediums.

22. Claim 2 of the '937 Patent next recites “an input device in circuit communication with said processor.” The SecurView comprises several input devices such as a workflow keypad, a pointing device and a keyboard to receive user input and communicates with the workstation processor and/or the SecurXchange Archive.

23. Claim 2 of the '937 Patent next recites “said processor being adapted to receive input signals from said input device, and being responsive to a signal from said input device to transfer digitized image data from said electronic storage medium to said monitor in a way that causes the monitor to produce a display having a plurality of windows and to display a mammogram image

in a different form in each window with grayscale values that, along with the illumination characteristics of said monitor, appears to a user as a mammogram in each window under a predetermined illumination state, thereby interfacing said mammogram image in each window and in a predetermined illumination state to an operator handling said input device” SecurView provides a processor that receives input from the input devices (e.g. workflow keypad, pointing device, keyboard) and based on that input transfers images from the storage for display on the monitor. The monitor displays images in multiple windows, where the grayscale values of each image appears as a mammogram in a specified illumination state, e.g. a default illumination state.



24. Claim 2 of the ‘937 Patent finally recites “said processor being adapted to receive further input from said input device related to the mammogram image in a selected window, said further input from said input device including input that selectively controls the grayscale values of the mammogram image in the selected window, thereby enabling an operator handling said input device to selectively control the illumination state with which the mammogram image in the selected window is displayed to the operator.” SecurView’s processor can receive input device about an image in a selected window wherein the input selectively controls the grayscale values to allow a user to control the illumination state.

25. Claim 3 of the '937 Patent recites “means for establishing electronic communications with a processor for receiving a stored digitized medical image comprising data representative of a plurality of greyscale values” SecurView provides a workstation processor that has circuitry to communicate with a processor for receiving stored digitized medical images. The images comprise digital image luminance values corresponding to shades of grey from black to white.

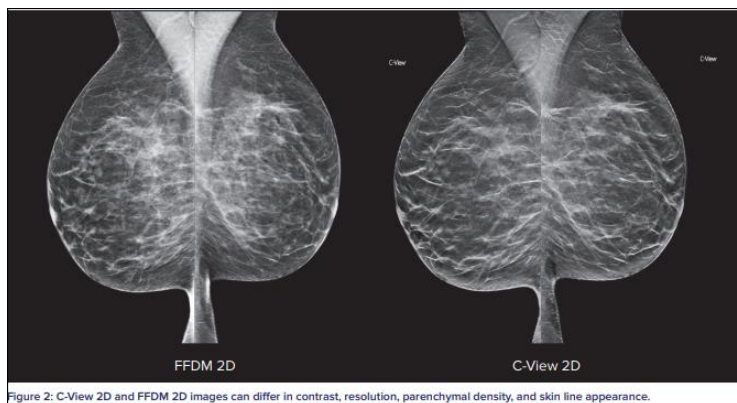
26. Claim 3 of the '937 Patent also recites a “means for communicating with a display.” The SecurView comprises several input devices such as a workflow keypad, a pointing device and a keyboard to communicate with the monitor.

27. Claim 3 of the '937 Patent also requires “software means loadable into the processor comprising:” Hologic provides software that can be installed and run on the SecurView processor. The software includes Image Analytics software which includes C-View synthesized 2D software, ImageChecker, and Qantra. The software further includes MultView™ Multimodality and Mammography Prior Enhancement™ (MPE) software.

28. Claim 3 of the '937 Patent requires “means for receiving a signal from a user-operable device.” The SecurView comprises monitors with a Graphics User Interface (GUI) that receives signals via user operable input devices that include a workflow keypad, a pointing device, and a keyboard.

29. Claim 3 of the '937 Patent requires “means controllable by a signal from the user-operable device for transforming the image into a plurality of varying-resolution forms, each form having a different set of greyscale values”. The SecurView’s software allows a user to transform images to different resolutions. For example, a user controlling an input device can transform an image of a first size into an image of a second size, or into a magnified portion of the image.

30. Claim 3 of the '937 Patent finally recites a “means for displaying the forms on the display means, each form displayed within a different sector of the display means.” The SecurView’s software provides different resolution forms of an image that are displayed in different windows of the same display.



31. Claim 17 of the '937 Patent recites “a first and a second display monitor.” The SecurView provides a first and a second display monitor.

32. Claim 17 of the '937 Patent recites “a processor having means for communicating with an image storage device and software means resident thereon, the software means comprising.” The SecurView provides a processor to communicate with an image storage device and associated software.

33. Claim 17 of the '937 Patent recites “means for receiving a signal from a user-operable device”. The SecurView’s software, when running on a workstation processor, receives user input from input devices such as a workflow keypad, a pointing device, a keyboard, and/or a modified iPad device.

34. Claim 17 of the '937 Patent recites “means controllable by a signal from the user-operable device for transforming the image into a plurality of varying-resolution forms, each form having a

different set of greyscale values” The SecurView runs software, which transforms the image into a plurality of varying-resolution forms, each form with a different shades of gray.

35. Claim 17 finally recites “means for displaying a first form on the first monitor and a second form on the second monitor.” Hologic’s software provides different versions of an image that are displayed on two different screens. For example, a first workstation monitor displays a low resolution thumbnail image, and a second workstation monitor displays the corresponding high resolution image.

COUNT I

PATENT INFRINGEMENT UNDER 35 U.S.C. § 271

36. Plaintiffs repeat and re-allege the foregoing paragraphs of the Complaint as though fully set forth fully herein.

37. The ‘937 Patent was duly and legally issued by the United States Patent and Trademark Office.

38. The ‘937 Patent is valid and enforceable.

39. USFRF is the exclusive licensee of the ‘937 Patent with the right to enforce, including the right to bring suit for infringement.

40. Hologic has been and is currently infringing, has actively induced others to infringe, and/or has contributed to the infringement of, at least Claims 2, 3, and 17 of the ‘937 Patent in violation of 35 U.S.C. § 271, by making, using, selling, and/or offering for sale, or causing or inducing others to infringe the same in connection with at least the infringing system identified herein.

41. Upon information and belief, Hologic will continue to infringe the ‘937 Patent unless and until it is enjoined by this Court.

42. Upon information and belief, Hologic’s infringement has been willful. On or around December 2017, Hologic was notified of its infringement in the form of notice letter sent to

Hologic's CEO. The letter identified the '937 Patent and provided notice that Hologic was infringing on the '937 Patent. Therefore, Hologic's infringement has been willful since at least December of 2017.

43. Hologic has caused and will continue to cause Plaintiffs irreparable injury and damages as a result of its direct and/or indirect infringement of the '937 Patent. Plaintiffs will suffer further irreparable injury, for which there is no adequate remedy at law, unless and until Hologic is enjoined from infringing the '937 Patent.

44. Plaintiffs are entitled to damages under 35 U.S.C. § 284 by virtue of Hologic's infringement of the '937 Patent, and enhanced damages by virtue of Hologic's willful infringement.

45. This is an exception case warranting an award of attorney's fees to Hologic under 35 U.S.C. § 285.

PRAYER FOR RELIEF

Wherefore, based on the foregoing, Plaintiffs pray for judgment against Hologic as follows:

- a. An entry of judgment that Hologic, its officers, agents, servants, employees and attorneys, and all persons in active concert or participation with it be found to have infringed the '937 Patent directly and /or indirectly;
- b. An order enjoining, preliminarily and permanently, Hologic, its officers, agents, servants, employees and attorneys, and all persons in active concert or participation with it, from making, using, selling, offering for sale, or importing into the United States products which infringe the '937 Patent;
- c. An award of damages adequate to compensate Plaintiffs for Hologic's infringement of the '937 Patent;

- d. A post-judgment equitable accounting of damages for the period of infringement of the '937 Patent;
- e. A finding that this case is exception pursuant to 35 U.S.C. § 285 and an award of enhanced damages;
- f. An award of prejudgment interest, costs and disbursements, and attorney fees; and
- g. Such other and further relief as the Court deems Plaintiffs may be entitled to in law and equity.

JURY DEMAND

Pursuant to Rules 38(b) and 38(c) of the Federal Rules of Civil Procedure, Plaintiffs request a trial by jury for all issues so triable.

DATE: March 26, 2020

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