NEUROMEDICAL SYSTEMS, INC., Plaintiff, -against- NEOPATH, INC., Defendant.

96 Civ. 5245 (JFK)

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

1998 U.S. Dist. LEXIS 7718

May 26, 1998, Decided
May 26, 1998, Filed

DISPOSITION: [*1] Plaintiff NSI's motion for a preliminary injunction denied.

COUNSEL: For Plaintiff: Jay R. Campbell, Of Counsel, RENNER, OTTO, BOISSELLE & SKLAR, PLL, Thomas H. Shunk, Of Counsel, BAKER & HOSTETLER, LLP, Cleveland, OH.

For Plaintiff: Maxim H. Waldbaum, Of Counsel, FRIED, FRANK, HARRIS, SHRIVER & JACOBSON, New York, NY.

For Defendant: M. Margaret McKeown, Jerry Riedinger, Michael Broaddus, William McGrath, Of Counsel, PERKINS & COIE, Seattle, WA.

For Defendant: David L. Just, Donald C. Lucas, Of Counsel, LUCAS & JUST, Dennis P. Orr, Of Counsel, MAYER BROWN & PLATT, New York, NY.

JUDGES: JOHN F. KEENAN, United States District Judge.

OPINION BY: JOHN F. KEENAN

OPINION

OPINION and ORDER

JOHN F. KEENAN, United States District Judge:

Before the Court is Plaintiff's motion for a preliminary injunction, pursuant to *35 U.S.C. § 283* and *Fed. R. Civ. P. 65*, enjoining Defendant to "maintain the status quo until the eventual trial on the merits" with respect to further manufacture, sales and expansion of use of Defendant's AutoPap 300 QC System. For the reasons discussed below, the Court denies the motion.

The Parties

Plaintiff Neuromedical Systems, Inc. ("NSI") is a [*2] Delaware corporation with its principal place of business in Suffern, New York. NSI manufactures a medical device called the Papnet Testing System ("Papnet system"), which is a computer-based system that supplements the manual screening and rescreening of pap smear slides performed by cytotechnologists and pathologists in laboratories.

Defendant NeoPath, Inc. ("NeoPath") is a Washington corporation with its principal place of business in Redmond, Washington. NeoPath manufactures a medical device called the AutoPap 300 QC System ("AutoPap QC system"), which is also a computer-based system that supplements the manual screening and rescreening of pap smear slides performed by cytotechnologists and pathologists in laboratories.

Background

The instant lawsuit arises out of Plaintiff NSI's patented technology for detecting the presence of cancerous and precancerous conditions in women through a computer-based system known as the Papnet system. According to Plaintiff, Defendant NeoPath has infringed that patented technology by incorporating it into NeoPath's computer-based system which also detects the presence of cancerous and precancerous conditions in women.

NSI manufacturers [*3] and markets an automated system, the Papnet system, which screens Pap smears for the presence of abnormalities. The Papnet system incorporates inventions set out in two NSI patents: *U.S. Patent No. 4,965,725* entitled "Neural Network Based Automated Cytological Specimen Classification System and Method" (" *'725 patent*") which issued October 23, 1990, and *U.S. Patent No. 5,287,272* entitled "Automated Cytological Specimen Classification System And Method" (" *'272 patent*") which issued February 15, 1994. In May of 1995, Defendant NeoPath, through a third party,

challenged the validity of NSI's two patents by filing a request with the U.S. Patent and Trademark Office ("PTO") to reexamine those patents. The PTO conducted reexaminations of both patents, and in May and August of 1996, the PTO confirmed the validity of every claim of the *'725* and *'272 patents* over NeoPath's arguments to the contrary. *See* Campbell Decl., Exs. 21-22.

On July 15, 1996, NSI filed this lawsuit alleging, among other things, that Defendant NeoPath directly infringed NSI's two patents by incorporating NSI's patented technology into its AutoPap QC system, which is also an automated system for screening Pap smear [*4] specimens. NSI asserts that NeoPath not only uses NSI's patented technology in the AutoPap QC system, but that NeoPath sought to hide this infringement by writing the AutoPap software code in such a way as to mask the infringement and by giving NSI's patented technology a different name in the AutoPap QC system--"fuzzy decision tree."

After an extensive discovery period, Plaintiff NSI made the instant motion for a preliminary injunction in an effort to maintain the status quo with respect to the manufacture, sale and use of Defendant's AutoPap QC system pending a trial on the merits of this lawsuit. Specifically, the proposed injunction would preclude further sales and manufacture of NeoPath's AutoPap QC systems and services in the United States, or any similar device by NeoPath that incorporates the same slide screening technology, but the proposed injunction would allow the continued use of the AutoPap QC systems now in the field at the current slide processing rate, as well as allow for NeoPath to service these systems and continue to collect revenue on their use. No expansion of the AutoPap QC system's current use would be allowed, and any excess slide screening work above the [*5] AutoPap QC systems' current slide processing rate would be handled by NSI's Papnet system pending a trial on the merits. NSI's vice-president of processing operations, Zeev Hadass, submitted an affidavit in which he stated that NSI has the capacity to handle this potential excess slide screening. *See* Hadass Decl. PP 3-5. For purposes of this preliminary injunction motion, NSI relies on two claims in the '725 and the *'272 patents* and argues that NeoPath's AutoPap QC system directly infringes those two claims: claim 19 of the *'725 patent* and claim 24 of the *'272 patent*. The parties briefed the motion and provided extensive documentation to support their respective positions on the patent infringement allegations. Shortly thereafter, for two days this Court conducted an evidentiary hearing on the preliminary injunction motion. By order of this Court, only cross-examination of witnesses was permitted at the hearing, and direct testimony was presented in the form of declarations prior to the hearing. Following the hearing, both sides submitted proposed findings of fact and conclusions of law.

Facts

A. Pap Smear Screening

Cervical cancer is a serious ailment worldwide [*6] and the second most common form of cancer afflicting women, with more than 15,000 new cases each year in the United States, and approximately 4,800 deaths annually. The disease is preceded by a precancerous, curable stage that progresses without symptoms over several years until it reaches an invasive stage that often leads to death. Thus, most deaths due to cervical cancer could be prevented with early detection and treatment.

The most common screening procedure for the early detection of cervical cancer and related precancerous conditions is the Pap test, developed in the 1940s by Dr. George N. Papanicolaou. A Pap smear is obtained by scraping the surface of a woman's cervix to collect a sample of cells that are then smeared onto a microscope slide and fixed with a preservative. The slide is then sent to a laboratory and viewed manually through a laboratory microscope by a cytotechnologist to determine if the sample includes cells, such as premalignant or malignant cells, bearing evidence of abnormality.

The work of cytotechnologists can be tedious, tiring and difficult. A single pap smear slide may contain a few hundred thousand cells that may be arranged in an overlapping manner, [*7] and only a dozen of those cells may have indications of cancerous or precancerous conditions. Indeed, a sizable percentage of slides that are initially classified by cytotechnologists as normal actually contain cells with indications of cancerous or precancerous conditions. Such slides, mistakenly diagnosed as normal, are known as "false negatives." The 1996 Cervical Cancer Consensus Conference reported that as many as 20% of all Pap smear reports are false negatives, and some laboratories have had false negative rates as high as 50%. *See* Nelson July 25, 1997 Decl. ("Nelson I Decl.") P 7; Campbell Decl., Ex. 4. Thus, while the manual Pap smear test has increased the detection of cervical cancer, this test has also been plagued by a high false negative rate in the manual screening process. For several decades, efforts were under way to utilize computers in screening Pap smears in order to improve significantly the detection of abnormal Pap smears so that abnormalities could be diagnosed early and women could be treated before an abnormality progressed into a life threatening condition. Until the very recent development of the two devices manufactured by the Plaintiff and the Defendant [*8] in this case, those efforts were not successful. Currently, the Papnet system and the AutoPap QC system are the two competing products in the market

for computerized/automated screening of Pap smear slides. As NSI puts it, "NSI and NeoPath are the only two true competitors in a newly developing field, both companies have only one product, and the companies are fighting for the same pool of customers." NSI's Mem. in Supp. at 23-24; *see also* tr. at 167 ("There are really only two rescreeners approved by the FDA, NeoPath's AutoPap QC system and NSI's Papnet system.").

Automated Pap smear screening systems are generally divided into three different applications: (1) supplemental or adjunctive; (2) quality control; and (3) primary screener. Supplemental or adjunctive use of an automated screening system means that the automated screening is not the initial or primary screening, and that the automated screening serves as a back-up or additional test. The Pap smear is first manually screened by a cytotechnologist and then screened again, typically at the request of a doctor or a patient, by an automated device. In this mode, the automated screener does not in any way replace primary [*9] manual screening. Quality control use of an automated screening system is done to meet the 10% quality control rescreening requirement mandated by federal law. Specifically, the Clinical Laboratory Improvement Amendment of 1988 ("CLIA") requires all laboratories that conduct Pap smear screening to perform quality control rescreening of at least 10% of all slides classified as normal during the initial manual screening process. Because this law does not mandate how to select which 10% of those slides classified as normal should be rescreened by the laboratory, most laboratories randomly select the 10% of their negative slides for rescreening. Primary screener use means that the automated system is used as a first line or primary screener and replaces conventional human manual rescreening. *See* Nelson Sept. 18, 1997 Decl. ("Nelson II Decl.") P 2.

B. NSI's Papnet System and the Patents at Issue on this Motion

NSI was founded in 1988 to develop and market the Papnet system, a computerized system for screening Pap smear specimens for the presence of abnormalities, such as cancer. In November of 1995, the U.S. Food and Drug Administration ("FDA") approved the Papnet system [*10] for use in the rescreening of Pap smears. The Papnet system is used primarily as a supplemental or adjunctive screener that rescreens slides upon the request of the patient or her doctor. While the Papnet system is also approved by the FDA for use as a quality control screener, "virtually none dollar-wise of the NSI business on a relative basis is in the quality control arena." Tr. at 175.

The Papnet system is not installed at laboratories. Rather, upon the request of the patient or doctor for rescreening by the Papnet system, the Pap smear slide is sent from the doctor's office to the laboratory, and then the laboratory forwards the slide to a central screening location in New York where the Papnet system is located and screens the slides. During the automated screening process, the Papnet system identifies the 128 images on an individual slide which are most likely to contain abnormalities. The slide, and the 128 images identified by the Papnet system, are then sent back to the laboratory for evaluation by a cytotechnologist to determine if any of those 128 images contain abnormalities. *See* Tench Sept. 18, 1997 Decl. ("Tench II Decl.") PP 9, 29. Following the cytotechnologist's [*11] review of the 128 images, and perhaps a manual rescreening of the slide if any of those 128 images indicate an abnormality, the slide and results are sent back to the doctor's office. The cost of having a single slide analyzed by the Papnet system runs "somewhere between 35 and 45 dollars." Tr. at 175.

The Papnet system incorporates the inventions set out in NSI's *'725* and *'272 patents*. Claim 19 of the *'725 patent* and claim 24 of the *'272 patent* are the only portions of those patents relevant to the instant motion.

1. Claim 19 of the *'725 Patent* and Claim 24 of the *'272 Patent*

NSI's *'725 patent* relates to a method of screening cytological specimens, such as Pap smears, using a primary classifier to determine locations of interest followed by a secondary classification of those locations using a neural network. Claim 19 of the *'725 patent* describes the following invention:

> A method of classifying cytological specimens, comprising using a primary classifier apparatus primarily classifying a specimen which is generally randomly arranged and can include other than in a single layer to determine locations of interest, and secondarily classifying such locations of interest using [*12] a *neural network* computer apparatus.

Campbell Decl., Ex. 1 (emphasis added). The *'725 patent* provides the following description of the preferred embodiment of a "neural network":

> A neural network is a highly parallel distributed system with the topology of a directed graph. The nodes in neural networks are usually referred to as "processing elements" or "neurons" while the links are generally known as "interconnects." Each processing element accepts multiple inputs and generates a single output signal which branches into

> multiple copies that are in turn distributed to the other processing elements as input signals. Information is stored in the strength of connections known as weights. In an asynchronous fashion, each processing element computes the sum of products of the weight of each input line multiplied by the signal level (usually 0 or 1) on that input line. If the sum of products exceeds a preset activation threshold, the output of the processing element is set to 1, if less, it is set to 0. Learning is achieved through adjustment of the values of the weights.

Id. at col. 4, lines 19-35.

The *'272 patent* is a continuation-in-part of the *'725 patent*. [*13] Claim 24 of the *'272 patent* describes the following invention:

> A method of classifying objects in a cytological specimen, comprising the steps of:
>
> a) obtaining a view of a cytological specimen,
>
> b) creating an image of such view,
>
> c) producing a digital representation of such image,
>
> d) primarily classifying objects in such digital representation of a cytological specimen based on a detectable feature, and
>
> e) secondarily classifying cells having features atypical of cells expected in the specimen among the objects identified in the primary classification step using *adaptive processing*.

Campbell Decl., Ex. 2 (emphasis added).

According to NSI, NeoPath's AutoPap QC system utilizes "neural networks" and "adaptive processing," as defined in claim 19 of the *'725 patent* and claim 24 of the *'272 patent*, and therefore unlawfully infringes NSI's patents. Thus, the question of infringement for this preliminary injunction motion comes down to whether NeoPath implemented "neural networks" or "adaptive processing," as recited in NSI's two patents, in the AutoPap QC system's software code.

C. NeoPath's AutoPap QC System

NeoPath was founded in 1989 to develop and market [*14] a Pap smear automated screening system. The FDA approved the use of the AutoPap QC System in September of 1995 for use in rescreening Pap smears. The primary intended use of the AutoPap QC system is as an automated screening device for quality control. The AutoPap QC system looks at 100% of Pap smears initially screened and classified by cytotechnologists as normal and then selects the 10% of those slides most likely to contain abnormal cells, which thus meets the CLIA's 10% minimum rescreening requirement for quality control. Therefore, rather than a 10% randomly selected sample from all of those slides manually screened and initially determined to be negative, the AutoPap QC system provides laboratories with a 10% sample of those initially screened slides most likely to contain abnormal cells--an "enriched" sample that also meets the federally mandated 10% rescreening requirement. This enriched sample of slides is then rescreened by a cytotechnologist. Some laboratories set the AutoPap QC system "sort" rate at higher than 10%, such that instead of selecting a 10% enriched sample of the slides most likely to contain abnormalities, the system will select the 20% of all supposedly negative [*15] slides that are most likely to contain abnormalities. *See* Tench II Decl. PP 16, 28.

In contrast to the Papnet system, laboratories purchase the AutoPap QC system and therefore the system is used directly in laboratories that perform Pap smear screening. This allows for the slides to be analyzed immediately by the AutoPap QC system after the initial manual screening, and, if a manual rescreen is indicated by the AutoPap QC system, it can be carried out either the same or the next day. The cost of having a single slide screened by the AutoPap QC system costs about five dollars.

NeoPath concedes that it considered the use of "neural networks" in developing the AutoPap QC system, but abandoned any use of "neural networks" once it became aware that NSI obtained a patent covering the use of a neural network to perform secondary cell classification. *See* Nelson July 25, 1997 Decl. ("Nelson I Decl.") PP 12-14. Upon learning of NSI's patents sometime in 1992, Alan Nelson, president of NeoPath, stated that he "gave express instructions to our algorithm development team that all investigation of neural network classification was to cease and that our classifiers were to be designed and [*16] implemented in a method that did not use a neural network." *Id.* at P 14. Rather than using neural networks or adaptive processing, NeoPath argues that its AutoPap QC system's "Add-On classifiers" use "fuzzy decision trees," which employ algorithms in screening Pap smear slides. *See* Marks July 25, 1997 Decl. ("Marks I Decl.") PP 5, 12; Nelson I Decl. P 14; Campbell Decl., Ex. 3 § 1.3. According to NeoPath, the

basic difference between the AutoPap QC system's fuzzy decision tree and the Papnet system's neural network, is that a decision tree takes an input, makes a decision at each non-terminal node, and then produces an output or outputs at the terminal nodes. In the neural network, there is an input and an output but no decisions are made at any nodes between the inputs and the outputs. Rather, the neural network is a "black box" where reasoning for the neural network's decision cannot be traced through the neural network to explain its decision rationale. *See* Marks I Decl. PP 5-6.

On August 28, 1997, NeoPath requested approval from the FDA for use of the AutoPap System--Primary Screener as a primary screener and quality control screener of Pap smear slides. This new [*17] device will review 100% of all of the slides, but 25% of the slides deemed to be within normal limits will have no human rescreening and the remaining 75% will be prioritized according to risk of disease and manually screened. The AutoPap System--Primary Screener contains the same technology utilized by the AutoPap QC system that is at issue in this litigation. *See* Nelson II Decl. PP 5, 7.

Discussion

The law of the Federal Circuit governs the grant or denial of a motion for a preliminary injunction in a patent case, pursuant to *35 U.S.C. § 283*. *See Hybritech, Inc. v. Abbott Lab., 849 F.2d 1446, 1451 n.12 (Fed. Cir. 1988)*. To obtain a preliminary injunction in a patent infringement case, the patentee must establish a right to such relief in light of four factors: (1) reasonable likelihood of success on the merits; (2) irreparable harm if the injunction were not granted; (3) the balance of hardships tipping in its favor; and (4) the impact of the injunction on the public interest. *See Bio-Technology Gen. Corp. v. Genentech, Inc., 80 F.3d 1553, 1558 (Fed. Cir.), cert. denied, 519 U.S. 911, 136 L. Ed. 2d 197, 117 S. Ct. 274 (1996)*. Before denying a motion for a preliminary [*18] injunction, "an analysis of each of the four factors is 'generally appropriate' for reasons of judicial economy and greatly aids appellate review." *Polymer Tech., Inc. v. Bridwell, 103 F.3d 970, 973-74 (Fed. Cir. 1996)*. While the decision whether to grant a preliminary injunction rests within the discretion of the district court, *see Bio-Technology Gen. Corp., 80 F.3d at 1558*, the Federal Circuit has cautioned that "a preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted." *Intel Corp. v. ULSI Sys. Tech., Inc., 995 F.2d 1566, 1568 (Fed. Cir. 1993), cert. denied, 510 U.S. 1092, 127 L. Ed. 2d 216, 114 S. Ct. 923 (1994).*

A. Likelihood of Success on the Merits

In seeking a preliminary injunction pursuant to *35 U.S.C. § 283*, a patent holder has the burden of making a "clear showing" of likelihood of success on the merits, both with respect to validity of its patent and with respect to infringement of its patent. *See Nutrition 21 v. United States, 930 F.2d 867, 869-70 (Fed. Cir. 1991)*; *see also Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1578, 1581 (Fed. Cir.), cert. denied, 464 U.S. 996, 78 L. Ed.* [*19] *2d 687, 104 S. Ct. 493 (1983).*

1. Validity of the Patents

"A patent shall be presumed valid. . . . The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." *35 U.S.C. § 282*. Thus, the determination of whether NSI has demonstrated a likelihood of success on the merits with respect to the validity of its patents must be made in the context of the presumption of validity that the patents will enjoy at trial and NeoPath's burden of establishing invalidity by clear and convincing proof. *See Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1570 (Fed. Cir. 1986)*; *Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549, 1555 (1985)*.

While NeoPath argues that the *'725* and *'272 patents* are invalid, the Court places great weight upon the fact that the PTO upheld validity of these two patents, despite NeoPath's arguments to the contrary, during the respective reexaminations requested by NeoPath. Indeed, on the instant motion NeoPath makes many of the same arguments for invalidity that it made to the PTO during the reexaminations. While NeoPath asserts that it has identified additional information not [*20] considered during the reexaminations of the patents that casts doubt on the validity of both patents, i.e., the testimony by Dr. Willard Rodman Taber and the "Wied reference," upon review of those arguments, NSI's counterarguments, and Dr. Taber's testimony, the Court is not persuaded that NeoPath has set forth enough evidence at this time to support a finding that this factor weighs against NSI on the instant motion. Accordingly, the Court concludes that, with regard to the likelihood of success on the merits, NSI has made the necessary showing with regard to the validity of its *'725* and *'272 patents*.

2. Infringement of the Patents

a. "Neural Networks" in Claim 19 of the *'725 Patent*

In support of its claim that NeoPath's AutoPap QC system infringes NSI's *'725 patent* by using neural networks, NSI relies primarily on the testimony of Dr. Willard Rodman Taber. Dr. Taber, who submitted a declaration and testified at the preliminary injunction hearing, is without question an expert in the field of artificial intelligence specializing in adaptive processing, fuzzy logic and neural networks. Dr. Taber has researched, lectured

and published extensively in this field. *See* Taber [*21] April 23, 1997 Decl. ("Taber I Decl."), Ex. A. Dr. Taber spent about 300 hours analyzing NeoPath's software code for the AutoPap QC system, reviewing documentation, attending and reviewing depositions relevant to this case, and preparing his declaration. Based upon the foregoing and his experience, Dr. Taber opined that the AutoPap QC system performs the steps listed in claim 19 of the *'725 patent*.

While conceding that there is no trade-association or industry-approved definition for the phrase "neural network," Dr. Taber testified that the term still has a generally understood meaning to those skilled in the art, *see* tr. at 51-56; Taber I Decl. P 3, and NSI relies on this testimony in arguing that the term "neural network," as used in the *'725 patent*, is to be given its generally understood meaning to those skilled in the art. Drawing from his experience and recognized texts in the field, Dr. Taber gave what he believed to be a generally understood definition of a neural network: "a dynamical system comprised of a directed graph, said graph having nodes and edges, and the whole apparatus having inputs and outputs. The inputs are given to the network. The output is some desired [*22] function and the apparatus is adaptively trained to perform that task." Tr. at 50. Dr. Taber explained that "adaptively trained" means to mold the network through its training so that it approximates the correct answer and that a "dynamical system" is one in which data is actually transferred between the nodes. *See* tr. at 51-52, 73. Using these definitions, Dr. Taber concluded that the AutoPap QC system's purported "fuzzy decision tree" is in reality a neural network and that the AutoPap QC system does in fact use neural networks in the secondary classification process as specified in claim 19 of the *'725 patent*. *See* tr. at 47-50; Taber I Decl. PP 6-7. At the hearing, Dr. Taber was particularly forceful in relaying his view that the AutoPap QC system uses neural networks, despite NeoPath's claim that its system is based on a fuzzy decision tree: "In their deceptive diagrams over there, [NeoPath] draw[s] them to look like trees, but they are not trees because they fail to put in the real data lines. And if this were a federal contract for the [Department of Defense], [NeoPath's officers] would be in jail right now for contract fraud, because that specification is false, [*23] demonstrably false." Tr. at 72. According to Dr. Taber, NeoPath's software code is written in such a way as to "mislead" a casual reader and cause the reader "to believe that a tree structure rather than a neural network was being employed as part of the classification method." Taber I Decl. P 10.

In addition to relying upon Dr. Taber's testimony in support of its assertion that the AutoPap QC system infringes the *'725 patent* by using neural networks, NSI points to a September 1990 NeoPath document in which NeoPath purportedly describes the AutoPap QC system's hardware as having a neural network embedded therein. The document provides: "Unique image processing algorithms that expand current state-of-the-art neural networks and artificial intelligence are implemented in hardware." Pl.'s Suppl. Mem in Supp. at 4, Ex. 7 at 2. This document was issued about one year after NeoPath purportedly finalized the hardware used in the AutoPap QC system. *See* Wilhelm Dep. at 58-59, 63.

In opposition to NSI's evidence on infringement, NeoPath argues that Dr. Taber's conclusion that the AutoPap QC systems uses neural networks is essentially meaningless to this case because Dr. Taber relied on [*24] his own definition of a neural network in arriving at this conclusion, as opposed to conducting his analysis based upon how that term is defined in the *'725 patent*. To counter Dr. Taber's testimony NeoPath offers the declaration and testimony of Robert J. Marks, III. Like Dr. Taber, Dr. Marks is an authority in the field of neural networks and has an impressive curriculum vitae. However, Dr. Marks' conclusions as to whether the AutoPap QC system uses neural networks stand in direct opposition to Dr. Taber's.

Dr. Marks disagreed with Dr. Taber's view that the term "neural network" has a generally understood meaning. Dr. Marks testified that there is no "standard accepted definition" or "general understanding" of the term neural network in the field and that therefore the term must be strictly construed as it is defined in the two patents at issue--as NeoPath asserts on this motion. Tr. at 210, 213; Marks September 18, 1997 Decl. ("Marks II Decl.") PP 14, 17. As Dr. Marks stated, "I disagree with Dr. Taber's statement [that there is a generally understood definition of neural network] because, yes, there are definitions of neural networks contained in those books, but there would [*25] be controversy in the general community on the accuracy of those definitions." Tr. at 210; *see also* tr. at 257-59 (indicating that there is more than one definition or interpretation of a neural network). Dr. Marks testified that during the time he was president of the neural network council of the Institute of Electronics Electrical Engineers ("IEEE"), [1] the council recognized the lack of uniformity of definitions for the term neural network and appointed a committee to formulate definitions "for not only what a neural network was, but also some of the related terms. That task force appointed in 1991 is still working and there is not really still a working list as of yet." Tr. at 211. Consequently, Dr. Marks analyzed the AutoPap QC system's software code for the use of any neural networks only as that term is specifically defined in the *'725 patent* specification. *See* Marks II Decl. PP 14-16, 17. Dr. Marks asserted that Dr. Taber did not apply the neural network definition in the patent and that Dr. Taber's "broad" definition ignored the

various characteristics of a neural network set forth in the patent. *See id.* PP 16, 18. Based upon his analysis of the neural network [*26] definition set forth in the *'725 patent*, *see id.* P 15 (table comparing the *'725 patent*'s description of neural network and NeoPath's fuzzy decision tree structure), Dr. Marks strongly disagreed with Dr. Taber's opinion that the AutoPap QC system's "fuzzy decision tree" is a neural network as defined in the *'725 patent*. *See* Marks I Decl. PP 5, 11-12, 16-17; Marks II Decl. P 15. Dr. Marks also disagreed with Dr. Taber's assessment that the AutoPap QC system's software code was written in such a way as to hide the presence of neural networks. *See* Marks I Decl. P 20. According to Dr. Marks, "I have . . . studied NeoPath's actual source code . . . . Nowhere do I find implementation of a neural network . . . ." *Id.* P 19; *see id.* P 5 ("NeoPath does not have a neural network as that term is used in the patents-in-suit and its algorithms were not trained adaptively and do not operate adaptively as those terms are used in the patents-in-suit."). Moreover, Dr. Marks asserted that Dr. Taber's conclusions are based on a "flawed software analysis." Marks I Decl. P 18. According to Dr. Marks, to analyze the purported NeoPath software code Dr. Taber created his own software code [*27] that purported to replicate NeoPath's code, but that Dr. Taber's code differed in language and in structure from NeoPath's code and, therefore, no meaningful comparison can be drawn from Dr. Taber's code. *Id.* P 18; *see* tr. at 94-95; Taber I Decl. PP 9-10; Taber Dep. 86-87, 110-11, 114.

> 1 The IEEE "is the largest professional society in the world and is generally recognized as the leading organization in the field of electrical and electronics matters, including subjects such as neural networks." Marks II Decl. P 3.

The Court has carefully reviewed the hearing testimony and declarations of both experts, the parties' arguments on the issue of the experts' conclusions concerning Neopath's alleged use of "neural networks," and the documentation offered by the parties to support of positions espoused by their respective experts. The Court is very much struck by the fact that Dr. Marks and Dr. Taber, whom the Court recognizes to be reliable authorities in the area of "neural networks," and whom the parties [*28] place the heaviest reliance upon in support of their respective positions on this infringement issue, have diametrically opposed views as to whether there is a generally accepted definition of the term neural network and whether the AutoPap QC system utilizes neural networks as specified in the *'725 patent*. If there is a generally understood meaning in the field of the term neural network, the Court would tend to agree with NSI that the *'725 patent* does not necessarily abandon that general meaning when that patent is construed. *See In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994)* ("when interpreting a claim, words of the claim are given their ordinary and accustomed meaning, unless it appears from the specification or the file history that they were used differently by the inventor"). The problem is that these two experts disagree on that issue and the Court believes that, on the current record, that disagreement is central to whether there is a likelihood of success on the merits as to infringement of the *'725 patent*. These two experts analyzed the AutoPap QC system code in accordance with their own definition of "neural network"--Dr. Taber using a broader definition of neural [*29] network in accordance with a purported generally understood meaning and Dr. Marks using a more limited definition of neural network as defined in the *'725 patent* specification--and these two experts came up with opposite conclusions as to whether neural networks were used by the system. While NSI makes much of the fact that Dr. Taber spent a great deal more time analyzing the AutoPap QC system software code than Dr. Marks, [2] the Court does not believe that this makes Dr. Taber's conclusions more accurate than Dr. Marks' at this juncture. Indeed, the Court found that (1) at the hearing both experts testified quite credibly in support of their respective positions and (2) these experts' respective declarations made a great deal of sense in offering support to their various conclusions and in pointing out the flaws in the analysis of the opposing expert. While NSI argues that the NeoPath document purportedly stating that neural networks are used in the AutoPap QC system supports Dr. Taber's analysis, the Court has reviewed that document and concludes that the context in which that term is used does not necessarily mean that the AutoPap QC system uses neural networks as defined in the [*30] *'725 patent*. This is especially true in light of Dr. Marks' testimony as to whether the term neural network has a generally understood meaning and whether the AutoPap QC system uses neural networks as they are defined in the *'725 patent*. Moreover, the Court notes that during cross-examination Dr. Taber stated "there's a number of definitions for neural network." Tr. at 87. Accordingly, the Court cannot find at this time NSI has made a "clear showing" of likelihood of success on the merits with respect to infringement of the *'725 patent*.

> 2 Dr. Taber claims to have some spent some 300 hundred hours analyzing the AutoPap QC system software code, reviewing documentation, attending and reviewing depositions and preparing his declaration. *See* Taber I Decl. P 6. In his original deposition, Dr. Marks stated that he spent "approximately 40 hours" total working on this case, and only seven hours reviewing the AutoPap QC system software code. *See* Pl.'s Reply Mem. at 7 (citing Marks Dep. at 5-6). Dr. Marks

later claimed that he erred in this statement and asserted that the "40" should be "140."

[*31] **b. "Adaptive Processing" in Claim 24 of the *'272 Patent***

Not surprisingly, the parties also dispute the construction of claim 24 of the *'272 patent* and whether NeoPath's AutoPap QC system uses "adaptive processing" as set forth in claim 24. NSI asserts that "adaptive processing" has a generally understood core meaning in the field, which is incorporated into the *'272 patent*, and that under this meaning of "adaptive processing" the AutoPap QC system infringes claim 24 of the *'272 patent*. *See* Pl.'s Proposed Findings PP 12-17, 21-23, 41. NeoPath argues that "adaptive processing" has no generally understood meaning and that its meaning must be defined as it is used in the patents and their prosecution histories. Under a definition appropriately derived from the patents and their prosecution histories, NeoPath asserts that the AutoPap QC system does not use adaptive processing as that phrase is used in the *'272 patent* and that NSI has failed to make a clear showing to the contrary because Dr. Taber used an improper definition of "adaptive processing" in analyzing NeoPath's software code. *See* Def.'s Proposed Findings PP 31, 37-39, 42.

In support of its argument that there [*32] is a generally understood definition of "adaptive processing" that is logically incorporated into that phrase as used in the *'272 patent*, NSI relies primarily on the testimony of Dr. Taber. Recognizing that there is no trade-association or industry-approved definition of "adaptive processing," Dr. Taber stated that the phrase does have a generally understood meaning to those skilled in the art. *See* tr. at 53-55; Taber I Decl. P 3. Dr. Taber thus provided what he believed to be a generally understood definition of adaptive processing: "It is recognized in the adaptive processing field that a classifier which has been adaptively trained is by definition an adaptive classifier and uses adaptive processing." Taber I Decl. P 12; *see also* Taber II Decl. P 7. Dr. Taber testified that the "adaptively trained" means to mold the network through its training so that it approximates the correct answer. *See* tr. at 51-52. He further explained, "In this context, what [adaptation means] is you take an initial structure and you mold it, that is, you train the network so that you get the correct or nearly approximate correct answer." *Id.* Using what he stated to be a generally understood [*33] meaning of the phrase adaptive processing, Dr. Taber concluded that the AutoPap QC system "primarily classifies objects based on detectable features and secondarily classifies cells among the objects identified by the primary classifier using adaptive processing as specified in claim 24 of the *'272 patent*." Taber I Decl. P 8; *see id.* P 14 (stating that the AutoPap QC system's "Add-on classifier . . . uses adaptive processing").

In addition to Dr. Taber's testimony, NSI also relies on documentary evidence to support its assertion that the AutoPap QC System infringes the *'272 patent* by using adaptive processing. For example, the Operator's Manual for the AutoPap QC system states that "adaptive pattern recognition techniques" are used by the system. Campbell Decl., Ex. 18 § 3.3. In another document entitled, "Device Description for Health Protection Branch, Health and Welfare Canada" which NeoPath submitted to the Canadian government in an effort to have the AutoPap QC system approved in Canada, NeoPath stated that "many adaptive processing . . . strategies are incorporated" into the system. Campbell Decl., Ex 17 § 5.1. In an internal NeoPath document entitled, "Application Software [*34] Requirement Specification (SRS)" drafted for the "Algorithm group that must design, implement and train the algorithms" NeoPath stated that the "software development process is based upon adaptive training of the processing regime." Campbell Decl., Ex. 16 § 2.5. Finally, NSI points to an internal NeoPath document discussing developmental classifiers for the AutoPap QC system in which NeoPath described an "adaptive binary decision tree classifier." Taber I Decl., Ex. B.

NeoPath attacks Dr. Taber's analysis and conclusions about the AutoPap QC system's alleged use of "adaptive processing" in the same manner in which it attacked his analysis and conclusions regarding NeoPath's alleged use of neural networks. Specifically, NeoPath asserts that there is no generally understood meaning of the phrase "adaptive processing" and therefore Dr. Taber's analysis is irrelevant because he construed that phrase in the *'272 patent* in accordance with his personal view of its generally understood meaning, thereby giving that phrase too broad a meaning. Dr. Marks testified that there is no generally understood meaning of the phrase "adaptive processing" and that there would be controversy in the field [*35] as to its meaning. *See* tr. at 210, 212-13; Marks II Decl. PP 14, 17. Moreover, Dr. Marks attacked the definition set forth by Dr. Taber in his declaration and stated that Dr. Taber's definition "is just plain wrong." Marks I Decl. P 21. Consequently, NeoPath argues that the meaning of "adaptive processing" must be derived from the patent references and their prosecution histories and NeoPath offers such a definition consistent with those sources. According to NeoPath, the *'272 patent* and its prosecution history support only the following definition of "adaptive processing": "a cell classification process that undergoes a self-organizing or self-changing procedure and through that process learns the appropriate way to classify. In other words, a classifier is only adaptive if the weights

are altered in response to each new piece of information received." Def.'s Proposed Findings P 37; *see* Hall Dep. at 138-39; Armitage Decl. PP 14-18, 25, 52-55. Because Dr. Marks concluded that the AutoPap QC system does not undergo a learning process where the program adjusts itself, or is self-organizing, *see* Marks II Decl. PP 30, 50, NeoPath argues that the AutoPap QC system does not use [*36] "adaptive processing" as that term is appropriately defined by the patents and their prosecution histories.

Upon review of both experts' testimony and the documentary evidence submitted by the parties, the Court concludes that NSI has failed to make a "clear showing" of a likelihood of success on the merits of the *'272 patent* infringement claim. NeoPath has offered evidence that calls into serious question (1) what the term "adaptive processing" means in claim 24 of the *'272 patent* and (2) the accuracy of the definition of "adaptive processing" upon which Dr. Taber relied in coming to his conclusion that the AutoPap QC system uses "adaptive processing" as covered by the *'272 patent*. Indeed, the Court observes that during his deposition Dr. Taber testified that the term was "ill defined." Taber Dep. at 138-39. Further, if the term "adaptive processing" has no generally understood meaning, and there is controversy in the field about its meaning, as Dr. Marks contends, then the NeoPath documents referring to that term do not necessarily mean that the AutoPap QC system uses "adaptive processing" as defined in claim 24 of the *'272 patent*.

B. Irreparable Harm

Irreparable harm [*37] is presumed when a clear showing has been made of patent validity and infringement. *See Smith Int'l, Inc., 718 F.2d at 1581*. Insofar as the Court has concluded that NSI has failed to make a "clear showing" of a likelihood of success as to patent infringement, NSI is not entitled to a presumption of irreparable injury. In the absence of such a presumption, NSI claims that the irreparable harm it will suffer is loss of market share. *See* Pl.'s Mem. at 24; Pl.'s Proposed Findings P 47. Specifically, NSI points out that these two companies are the only two true competitors in a developing field, have only one product, and compete for the same pool of customers. In support of this irreparable harm argument, NSI relies primarily on the testimony of David Duncan, NSI's vice president and chief financial officer.

Upon review of the testimony and declaration of Mr. Duncan, the Court concludes that NSI has failed to demonstrate that it is facing any immediate harm as a result of the alleged infringement that is not compensable through money damages. While Mr. Duncan stated that money damages "do not reflect that damage done to the market place" by sales of the AutoPap QC system, Duncan [*38] Decl. P 5, the Court finds that he failed to specifically describe what that damage might be or why it would be so difficult to calculate in money damages. Additionally, during cross-examination Mr. Duncan stated that NSI and NeoPath each have about 2% of the available market, that is, of the 50 million women who have Pap smears each year, and he agreed that the remaining 98% of the Pap smear screening market is open to NSI. *See* tr. at 165-66.

The Federal Circuit has held that "neither the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial." *Nutrition 21, 930 F.2d at 871*. Moreover, the Federal Circuit has rejected the argument "that potential lost sales alone could demonstrate 'manifest irreparable harm' because acceptance of that position would require a finding of irreparable harm to every patentee, regardless of the circumstances." *Reebok In'l, Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1558 (Fed. Cir. 1994)* (quoting *Illinois Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679, 683 (Fed. Cir. 1990))*. Based upon the record, [*39] the Court finds that NSI has failed to show that money damages cannot adequately compensate it for any harm it will suffer from the alleged patent infringement.

C. Balance of Hardships

With regard to the balance of hardships factor, "the district court must balance the harm that will occur to the moving party from the denial of the preliminary injunction with the harm that the non-moving party will incur if the injunction is granted." *Hybritech, 849 F.2d at 1457*. The Court concludes that this factor weighs in NeoPath's favor. As discussed above, in the absence of an injunction, the evidence indicates that NSI will not suffer any future harm for which monetary damages cannot suffice. As for NeoPath, however, the Court believes that the issuance of a preliminary injunction may very well sound a death knell. The AutoPap QC System is the only product NeoPath currently has available for commercial sales and distribution, and it is NeoPath's sole source of revenue. *See* Nelson I Decl. PP 3, 32. For a start-up company, such as NeoPath, in a healthcare field where the two products on the market are literally a matter of life and death for women in this country and, therefore, [*40] for whom good client relationships are critical, the issuance of a preliminary injunction in a patent infringement suit will likely have a devastating impact in terms of loss of good will. *See id.* PP 32, 34. While NSI offered the testimony of David Duncan in support of its claim that the proposed injunction would impose no hardship on NeoPath, the Court found that Mr. Duncan's analysis failed to adequately take into account the effect of an

injunction on NeoPath's international revenues, *see* tr. at 138, 154-57, on its marketing costs, *see* tr. at 160, and on its client relationships in terms of the loss of the good will and the fact that customers in this particular field may very well be deterred from continuing to use a product that a Court has determined to be a likely infringer of patented technology and may not be on the market much longer. *See* tr. at 158. Moreover, Dr. Duncan did testify that NeoPath has been recording losses and that if NeoPath continued to lose money at its current rate, NeoPath would run out of money in about 16 months. *See* tr. at 129, 130-31. Accordingly, the Court finds that the balance of hardships weighs in NeoPath's favor.

[*41] **D. Public Interest**

The Federal Circuit has instructed that "although there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief." *Hybritech, 849 F.2d at 1458.*

There is no question that NSI's Papnet system and NeoPath's AutoPap system are effective in serving a vital public interest--the early detection of cervical cancer through computerized screening of Pap smears. NSI and NeoPath produce the only two products in this market for which many women's lives hang in the balance. While NSI argues that the public interest will not be harmed by the issuance of a limited injunction tailored to maintaining the status quo and directing that NSI's Papnet system handle any excess slide screening workload pending resolution of these claims after a full trial on the merits, this Court is not so convinced on the record before it.

In support of its argument that the Papnet system is not a substitute for the AutoPap QC system, and therefore the public interest will be negatively impacted by the [*42] proposed injunction, NeoPath submitted declarations from four doctors who serve as medical directors of laboratories that use the AutoPap QC system. The Court observes that at the hearing NSI chose not to cross-examine any of the doctors who submitted declarations in support of NeoPath's opposition to the preliminary injunction motion. Dr. William D. Tench, M.D., associate laboratory director and chief of anatomic services for Palomar Pomerado Health Systems Laboratory at the Palomar Medical Center in Escondido, California, pointed out that the Papnet system, which was designed and is used primarily as a supplemental or adjunctive test, plays a different role in screening than the AutoPap QC system, which was designed and is used primarily for quality control rescreening. Dr. Tench stated that at his lab the AutoPap QC system reviews all slides initially classified as negative and then selects for manual rescreening the 20% of those slides most likely to contain abnormalities (as opposed to the random 10% quality control sample required by law). Dr. Tench described how the AutoPap QC system is an integral part of his lab's quality control process. *See* Tench II Decl. PP 13-29. With [*43] regard to the Papnet system, he opined that "is not at all suited for use in a [quality control] capacity." *Id.* P 29. Dr. Tench reasoned,

> It appears that [Papnet] was designed to be used in an adjunctive mode--that is, on a case by case basis. Papnet does not permit a laboratory to know which slides in the group initially classified as "negative" are most likely to contain abnormalities [as the AutoPap QC system permits]. Rather, [Papnet] provides the laboratory with 128 images from an individual slide which are most likely to contain a representation of the significant abnormalities on that slide. This is the fundamental difference. All 128 images, none of which may be truly abnormal, must be evaluated by a trained individual and that evaluation obviously applies only to that individual slide. From the perspective of a laboratory trying to conduct effective quality control, this information is relevant to that individually selected only and does not provide useful information for the entire laboratory case load. . . . I don't think any laboratory would or could use it realistically for [quality control] that was directed at patient benefit rather than laboratory [*44] evaluation.

Id. P 29. Dr. Tench also pointed out that while the Papnet system could rescreen 100% of the negative slides, it served no real benefit over 100% manual rescreening. *See id.* P 30. He quoted from a recent study in the professional literature that called into question the Papnet system's effectiveness as a rescreener or quality control device:

> In a fairly large study testing the rescreening ability of PAPNET . . . demonstrated that when used prospectively to perform negative rescreening, the system offers no benefit over manual rescreening. In this study, Papnet detected 5 missed cases out of 2,238 consecutive negative smears, whereas manual rescreening of 2,000 cases picked up 6 missed cases; that is not a statistically significant benefit.

Id. P 30. In addition to questions about the Papnet system's effectiveness as a rescreener or quality control device, *see* Kaufman Decl. P 8(a), the doctors also raised concerns about the fact that using Papnet would add significantly, as much as perhaps two weeks, to the amount of time it takes a laboratory to complete its review of a Pap smear and the fact that this time lapse would be unacceptable [*45] to the clinicians and patients with whom they work. *See* Marshall Decl. P 9; *see also* Kaufman Decl. P 8(d); Franquemont Decl. P 5. Moreover, the doctors expressed concerns about the fact that screening under the Papnet system calls for the Pap smear slides to be transferred to an another location. Dr. Tench summed up this concern in the following manner: "Papnet requires laboratories to send their slides outside the laboratory--or, more precisely, it requires laboratories to surrender custody and control of the slides for up to a week or longer, entrusting them first to the delivery company, and then to Papnet. For sound medical and legal reasons, laboratories are understandably reluctant to subject their slides to such an opportunity for mishandling, breakage, and outright loss." Tench II Decl. P 10; *see also* Marshall Decl. P 9; Kaufman Decl. P 8(d). Another concern expressed by the doctors was the difference in cost between the two products. The doctors pointed out that the increased cost of the Papnet system (about $ 40-45 per slide) as compared to the AutoPap QC system (about $ 5 per slide), presents an obstacle to substituting the Papnet system for the AutoPap QC. [*46] *See* Kaufman Decl. P 8(e); Marshall Decl. P 8; Franquemont Decl. PP 5, 8. Dr. Tench pointed out that some patients and clinicians might not be able or willing to pay the extra cost for the Papnet automated review, thereby indicating that some clinicians and patients might opt for a manual rescreen with a lower accuracy rate than automated rescreening. *See* Tench July 23, 1997 Decl. ("Tench I Decl.") P 6; Tench II Decl. PP 25-27; *see also* Franquemont Decl. P 8. Finally, the doctors expressed concern about their laboratories' ability to effectively incorporate use of the Papnet system into their labs. The Court notes that the evidence indicated that incorporation of the Papnet system would take some time, most notably in terms restructuring the work flow to account for use of a new system and of having to hire trained cytotechnologists to screen the 128 images identified by the Papnet system, etc. *See* Tench I Decl. P 6; Marshal Decl. P 9; Franquemont Decl. P 5-6, 8.

While the Court is aware that NSI disagrees with NeoPath's assertions that the Papnet system is not a substitute for the AutoPap QC system in terms of effectiveness as a quality control device, especially in [*47] light of the fact that about 150 labs currently use the Papnet system, *see* Tr. at 194, the Court concludes that NeoPath has offered evidence to raise very serious questions as whether the public interest will be harmed by issuance of the proposed preliminary injunction. Based on the current record, the Court cannot say that the public interest will not be harmed by issuance of the proposed injunction where laboratories have integrated the AutoPap QC system into their quality control process. *Cf. Ethicon Endo-Surgery v. United States Surgical Corp., 855 F. Supp. 1500, 1517 (S.D. Ohio 1994)* (denying preliminary injunction: "Although the relative merits of the two competing lines of cutters is disputed, unquestionably a large number of surgeons are familiar with and have been trained to use the U.S. Surgical cutters. To suddenly withdraw these devices from the market could have a serious disruptive effect on surgical practice."). The issue of early detection of cervical cancer is of grave national concern. Failure to detect and begin treatment in a timely fashion is the difference between life and death. In a case where the medical directors of four laboratories that use the AutoPap [*48] QC system have offered testimony that the Papnet system is not a substitute for the AutoPap system and that the quality of care provided by these laboratories would take a step backward if they were forced to use the Papnet system at this time, *see* Franquemont Decl. P 8; Kaufman Decl. P 9; Marshall Decl. P 10; Tench II Decl. PP 32-33, the Court believes that there may very well be a negative impact on the public interest by the issuance of the proposed injunction. Accordingly, the Court believes that the public interest is best served at this time by the unhindered availability of both the Papnet and AutoPap QC computerized Pap smear screening systems, the only two such systems approved by the FDA for automated rescreening, pending a trial on the full merits of this case.

Conclusion

Upon consideration of the four factors relevant to the issue of whether a preliminary injunction should issue, the Court believes that this is not an appropriate case for the "extraordinary and drastic remedy" of a preliminary injunction. Accordingly, the Court denies Plaintiff NSI's motion for a preliminary injunction. The Court directs the parties to complete discovery by August 28, 1998 [*49] and to appear before the Court for a pre-trial conference on August 31, 1998 at 9:45 a.m.

SO ORDERED.

Dated: New York, New York

May 26, 1998

JOHN F. KEENAN

United States District Judge