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Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

THOMAS AVERY and KURT STABEL, Plaintiffs, v. SANFORD BARSKY, M.D., Defendant.	CASE NO.: **COMPLAINT AND JURY DEMAND**

Plaintiffs Thomas Avery and Kurt Stabel ("Plaintiffs") bring this Complaint against Sanford Barsky, M. D. ("Dr. Barsky") and allege as follows:

NATURE OF THE ACTION

1. This action arises out of an agreement between the three parties to jointly a) pursue a patent related to their invention of i) high-resolution image recognition in the microscopical analysis of pathological materials and ii) methods for transmitting microscopical images over a network for diagnostic and other purposes and b) develop Imaging Insight as the company that

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would utilize the patent to deliver products to end-users through a dedicated, high-speed Internet connection.

2. Instead of honoring that agreement, Dr. Barsky removed Plaintiffs as co-inventors from the patent application, developed BioImagene, Inc. (herein "BioImagene") as a company to fill the role the parties agreed Imaging Insight would fill, developed spin-off patents for the automated detection of cell patterns to be used by BioImagene, and then participated in the sale of BioImagene (with the spin-off patents) to the company, Roche, for about one hundred million dollars ($100,000,000) without any compensation to Plaintiffs.

PARTIES

3. Plaintiff Thomas Avery ("Avery") is an individual residing in Orange County, California.

4. Plaintiff Kurt Stabel ("Stabel") is an individual residing in Long Beach, California.

5. On information and belief, Defendant Dr. Barsky is an individual residing at 2670 Lake Ridge Shores, Reno, Nevada 89519.

JURISDICTION AND VENUE

6. This action arises in part under the patent laws of the United States, 35 U.S.C. § 1 et seq. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Furthermore, there is a complete diversity of the parties and the amount in controversy exceeds the sum of $75,000.00, exclusive of interest and costs. 28 U.S.C. § 1332.

7. Dr. Barsky is subject to the jurisdiction of this Court because he is a citizen of the State of Nevada where he maintains his primary residence.

8. Venue is proper under 28 USC 1391 (b) in the District of Nevada-Reno, as Dr. Barsky maintains his primary residence in Reno.

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FACTUAL ALLEGATIONS

9. In 1999, Avery and Stabel collaborated to conceive an idea that would change the face of medicine. In short, their idea was to create a searchable database of digital images of known pathology specimens and then use pattern recognition software to compare images of unknown pathology specimens to the known pathology specimens to identify similar specimens and use that information to help diagnose a condition.

10. Avery and Stabel teamed up with Dr. Barsky, who was affiliated with UCLA, to develop the idea, turn it into a patentable invention, and develop a business that would bring the invention to market.

11. Dr. Barsky used his connections at UCLA to introduce Avery and Stabel to Emily Waldron at the UCLA office of technology transfer. Plaintiffs and Dr. Barsky negotiated with and arranged for UCLA to advance the expenses associated with pursuing the patent at least initially. UCLA then directed Jerry Sewell, Esq and James Hill, Esq. of Knobbe, Martens, Olson & Bear to "prepare and file" the appropriate U.S. patent application. UCLA further directed as follows:

> Although there is no immediate publication date, the inventors are anxious to get an application filed as soon as possible, as there may be other inventors doing work in this area. Please contact the inventors immediately for details.

Additionally, UCLA directed as follows:

> Disclosure of the invention, pertinent prior art, and other materials are enclosed. Additional technical information may be obtained from the inventors who can be reached at:

Sanford H. Barsky, MD (Lead)
University of California,
Los Angeles
Dept/Pathology & Lab Med.
13-262 Factor Building
Los Angeles, CA 90095
T: (310) 825-5588
F: (310) 441-1248
E-mail: sbarsky@ucla.edu

Mr. Kurt Stabel, President
Imaging Insight, Inc.
101 Seal Beach Way, #A
Seal Beach, CA 90740
T: (562) 598-5752
E-mail:
kstabel@pacbell.net

Mr. Thomas W. Avery
c/o Sanford H. Barsky, MD
University of California,
Los Angeles
Dept/Pathology & Lab Med.
13-262 Factor Building
Los Angeles, CA 90095

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12. Mr. Sewell and Mr. Hill did as instructed and on August 10, 2000, Provisional Patent Application 60/224,252 was filed for a United States patent. That application was substantially developed by Avery and Stabel with assistance provided by Mr. Hill. The application accurately identifies Dr. Barsky and Plaintiffs as co-inventors of high-resolution digital image processing in the analysis of pathological materials as follows:

PROVISIONAL APPLICATION FOR PATENT
COVER SHEET

Case No. UCLA016.001PR
Date: August 10, 2000
Page 1

08/10/00 JC667 U.S. PTO

Jc666 U.S. PTO 60/224252 08/10/00

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

ATTENTION: PROVISIONAL PATENT APPLICATION

Sir:

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR § 1.53(c).

For: **HIGH-RESOLUTION DIGITAL IMAGE PROCESSING IN THE ANALYSIS OF PATHOLOGICAL MATERIALS**

Name of First Inventor: Sanford H. Barsky
Residence Address: 10422 Lindbrook
Los Angeles, CA 90024

Name of Second Inventor: Kurt Stabel
Residence Address: 1101 Seal Way, #A
Seal Beach, CA 90740

Name of Third Inventor: Thomas W. Avery
Residence Address: 14392 Silverbrook
Tustin, CA 92780

00010250 252209

A significant portion of the *Detailed Description of a Preferred Embodiment* found on pages one through six of the application as well as the *Company Plan*, *Business Plan*, *Executive Summary*, *Detailed Plan of the Work*, *Diagrams*, *Disclosure of the Invention*, and other parts of the application were prepared by Stabel and Avery on their personal computers.

13. As set forth in the application, the parties agreed to jointly a) pursue a patent related to their invention of i) high-resolution image recognition in the microscopical analysis of pathological materials and ii) methods for transmitting microscopical images over a network for diagnostic and other purposes and b) develop Imaging Insight as the company that would use the

patent to deliver products to end-users through a dedicated, high-speed Internet connection. More specifically, the application provides as follows:

HIGH-RESOLUTION DIGITAL IMAGE RECOGNITION IN THE ANALYSIS OF PATHOLOGICAL MATERIALS

Background of the Invention

Field of the Invention

The present invention relates to high-resolution image recognition in the microscopical analysis of pathological materials. The invention further relates to systems and methods for transmitting microscopical images over a network for diagnostic and other purposes.

Detailed Description of a Preferred Embodiment

Imaging Insight ("the Company") plans to use a streamlined product pricing structure and delivery model, and to offer two levels of service. Each will be targeted at two different groups of end-users. Both products will be focused on accessing the Company's proprietary database and the information it contains through a dedicated, high-speed Internet connection.

14. Ideas were exchanged and these documents were prepared only after the parties entered into an agreement to keep confidential the ideas and information exchanged. In connection therewith, the parties essentially agreed to divide equally between them any proceeds derived from the pursuit of the business and/or the development of the related patent.

15. Dr. Barsky did not honor that agreement and instead individually pursued the patent and development of the business without regard to Plaintiffs or their rights and interests therein.

16. In January of 2003, Dr. Barsky, without Plaintiffs' knowledge, helped form a company called BioImagene to function as Avery and Stabel envisioned Imaging Insight would function. Indeed, an article published by Drug Discovery News provides as follows:

> Sanford Barsky, M.D., professor and Senhauser Chair in the Department of Pathology, teamed with BioImagene to develop digital pathology as both a research and diagnostic tool.

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17. On August 9, 2001, Dr. Barsky submitted a new patent application for the subject invention and this time identified only himself as the inventor despite copying most of the language from the original application word for word. That application provides in pertinent part as follows:

02-06-03 10/343952 PCT

U.S. Application No. | International Application No. PCTUS/01/25026 | Attorney Docket No. UCLA016.001NP

Date: February 4, 2003

DT03 Rec'd PCT/PTO 04 FEB 2003

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 USC 371

International Application No.:	PCTUS/01/25026
International Filing Date:	August 9, 2001
Priority Date Claimed:	August 10, 2000
Title of Invention:	HIGH-RESOLUTION DIGITAL IMAGE PROCESSING IN THE ANALYSIS OF PATHOLOGICAL MATERIALS
Applicant(s) for DO/EO/US:	Sanford H. Barsky

18. On July 21, 2003, Dr. Barsky, without providing any notice to Plaintiffs, made a declaration that is completely false. More specifically, he stated in pertinent part as follows:

> I believe I am the original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled HIGH-RESOLUTION DIGITAL IMAGE PROCESSING IN THE ANALYSIS OF PATHOLOGICAL MATERIALS; the specification of which was filed as International Application No. PCTUS/01/02526, the U.S. national phase of which was assigned U.S. Application Serial No. **10/343,952**.
>
> I hereby claim the benefit under Title 35, United States Codes § 119(e) of any United States provisional application(s) listed below.
>
> Application No.: 60/224,252 Filing Date: 08-10-00

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole inventor: **Sanford H. Barsky**

Inventor's signature Sanford H Barsky Date 07/21/03

19. In connection therewith, Dr. Barsky executed an Assignment to the Regents of the University of California and caused the filing of an Establishment of Right of Assignee to Take Action and Revocation and Power of Attorney. That document states that the Assignment represents "the entire chain of title of the invention from the Inventor(s) to the Assignee."

20. Over the next two years, Dr. Barsky and others related to BioImagene filed applications for spin-off patents for the automated detection of cell patterns to be used by BioImagene. Those spin-off patents are infringements of the original patent, but Dr. Barsky as the "sole inventor" did nothing to protect the original patent.

21. In 2008 Dr. Barsky convinced the Regents of the University of California to assign their contrived rights in the invention to Ohio State University. In early 2011 he convinced Ohio State University to assign to him, without consideration, their contrived rights in the invention.

22. Dr. Barsky's efforts then culminated in the issuance of Patent No. US 7,894,645 B2 on February 22, 2011. As a result of his numerous false filings, the documentation reflects that Dr. Barsky is the sole inventor so that he may individually take credit for an idea and work that did not individually belong to him. The following is an excerpt from the first page:

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(12) **United States Patent**
Barsky

(10) **Patent No.: US 7,894,645 B2**
(45) **Date of Patent: Feb. 22, 2011**

(54) **HIGH-RESOLUTION DIGITAL IMAGE PROCESSING IN THE ANALYSIS OF PATHOLOGICAL MATERIALS**

(75) Inventor: **Sanford H. Barsky**, Los Angeles, CA (US)

(73) Assignee: **Ohio State University**, Columbus, OH (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 748 days.

(21) Appl. No.: **10/343,952**

(22) PCT Filed: **Aug. 9, 2001**

(86) PCT No.: **PCT/US01/25026**

§ 371 (c)(1),
(2), (4) Date: **Aug. 1, 2003**

(87) PCT Pub. No.: **WO02/15559**

PCT Pub. Date: **Feb. 21, 2002**

(65) **Prior Publication Data**

US 2004/0030232 A1 Feb. 12, 2004

Related U.S. Application Data

(60) Provisional application No. 60/224,252, filed on Aug. 10, 2000.

5,797,130	A		8/1998	Nelson et al.
5,828,776	A		10/1998	Lee et al.
5,865,745	A		2/1999	Schmitt et al.
5,868,669	A		2/1999	Iliff
5,876,926	A		3/1999	Beecham
5,878,746	A	*	3/1999	Lemelson et al. 600/407
5,933,519	A		8/1999	Lee et al.
5,939,278	A		8/1999	Boon et al.
5,940,535	A		8/1999	Huang
5,960,435	A		9/1999	Rathmann et al.
5,978,497	A		11/1999	Lee et al.
5,980,096	A		11/1999	Thalhammer-Reyero
5,982,917	A		11/1999	Clarke et al.
5,987,094	A		11/1999	Clarke et al.
5,987,158	A		11/1999	Meyer et al.
6,014,451	A	*	1/2000	Berry et al. 382/110
6,014,452	A		1/2000	Zhang et al.
6,021,220	A		2/2000	Anderholm
6,031,929	A		2/2000	Maitz et al.
6,033,076	A		3/2000	Braeuning et al.
6,075,879	A		6/2000	Roehrig et al.
6,081,612	A		6/2000	Gutkowicz-Krusin et al.
6,095,989	A		8/2000	Hay et al.
6,134,354	A		10/2000	Lee et al.

(Continued)

FOREIGN PATENT DOCUMENTS

WO	WO 91/14202	9/1991

(Continued)

OTHER PUBLICATIONS

Despite those changes, application 60/224,252 is still identified on the face of the patent and the patent contains the precise language that Plaintiffs first crafted on their personal computers and included in application 60/224,252. Indeed, even the identification of Imaging Insight to operate as the company to deliver products to the end-user was left unchanged even though Dr. Barsky helped start up BioImagene in 2003 to essentially replace Imaging Insight.

23. A number of the publically available documents regarding BioImagene incorporate much of the same language that Plaintiffs first crafted on their personal computers for Imaging Insight. While using the Invention (and the work product of Plaintiffs) to develop BioImagene, Dr. Barsky reaped substantial rewards and became recognized as a "pioneer of digital pathology." Dr. Barsky used that success to become a professor and the Chair of the Department of Pathology at

University of Nevada School of Medicine. Dr. Barsky then participated in the sale of BioImagene (with the transfer of the spin-off patents) to Roche for about $100,000,000.00. Dr. Barsky continued to try to keep his distance from Plaintiffs and they only learned of his conduct well after the sale of BioImagene to Roche.

24. According to a *Division of Proceeds Agreement*, Dr. Barsky was required to provide Plaintiffs written notice of all proceeds granted to Dr. Barsky within ten days of receipt thereof. Pursuant to that agreement, Dr. Barsky was further obligated to provide each of them one third of any proceeds granted to him no later than twenty days from the date of receipt thereof; provided, however, that if such proceeds consisted of tangible objects which cannot be divided, Dr. Barsky was obligated to provide them with cash or cash equivalents in an amount equal to one third of the fair market value on the date of receipt of such proceeds.

25. Dr. Barsky failed to provide Plaintiffs written notice of the proceeds he received and Dr. Barsky failed to provide them their share of those proceeds. These failures constitute breaches of Dr. Barsky's agreement with them. Moreover, Dr. Barsky's conduct as set forth above also gives rise to claims for theft of intellectual property.

COUNT I – PATENT INFRINGEMENT

26. Plaintiffs repeat, re-allege, and incorporate by reference Paragraphs 1 through 25 of this Complaint as through fully set forth herein.

27. Provisional Patent Application 60/224,252 was duly and legally filed for an invention entitled "High-Resolution Digital Image Processing in the Analysis of Pathological Materials." A true and correct copy of the application is attached hereto as **Exhibit A.**

28. Dr. Barsky did and continues to directly infringe the High-Resolution Digital Image Processing in the Analysis of Pathological Materials. In addition, Dr. Barsky did and continues to contributorily infringe by inducing infringement by others. Dr. Barsky has infringed either literally or under the doctrine of equivalents, although discovery may show that Dr. Barsky infringes still other

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claims, in which case Plaintiffs will seek to amend this Complaint. The infringing acts include, but are not limited to, making, using, selling, or offering for sale the High-Resolution Digital Image Processing in the Analysis of Pathological Materials and/or services offered in relation to the High-Resolution Digital Image Processing in the Analysis of Pathological Materials. Accused features and functionality of the High-Resolution Digital Image Processing in the Analysis of Pathological Materials include, but are not limited to, the delivery of the specified product to end-users in the manner set forth in the application. Dr. Barsky is liable for infringement of the High-Resolution Digital Image Processing in the Analysis of Pathological Materials.

29. Dr. Barsky's infringement caused Plaintiffs damage in a substantial sum in excess of $75,000.00, the exact amount of which will be set forth at the time of trial in this matter.

30. As a direct result of Dr. Barsky's aforementioned conduct, Plaintiffs have been forced to retain the services of the undersigned counsel to pursue this matter and are thus entitled to an award of their reasonable attorneys' fees and costs associated herewith.

COUNT II- BREACH OF CONTRACT

31. Plaintiffs repeat, re-allege, and incorporate by reference Paragraphs 1 through 30 of this Complaint as through fully set forth herein.

32. As set forth above, Dr. Barsky entered into a contract with Plaintiffs regarding the joint development of the invention and the business to bring it to market.

33. Plaintiffs fully performed their obligations under the contract.

34. Dr. Barsky's failure to fulfill the terms of the contract and to split the proceeds with Plaintiffs as agreed upon constitutes Dr. Barsky's breach of his agreement with Plaintiffs.

35. Dr. Barsky's breach caused Plaintiffs damage in a substantial sum in excess of $75,000.00, the exact amount of which will be set forth at the time of trial in this matter.

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36. As a direct result of Dr. Barsky's aforementioned conduct, Plaintiffs have been forced to retain the services of the undersigned counsel to pursue this matter and are thus entitled to an award of their reasonable attorneys' fees and costs associated herewith.

COUNT III – FRAUD

37. Plaintiffs repeat, re-allege, and incorporate by reference Paragraphs 1 through 36 of this Complaint as through fully set forth herein.

38. On or about March 28, 2001, in Los Angeles, California, Dr. Barsky told Plaintiffs that he intended to develop the patent with Plaintiffs and to pay them a certain percentage of the proceeds.

39. On information and belief, at the time Dr. Barsky made the false statement, he knew the statement was false or had reckless disregard of the falsity.

40. On information and belief, Dr. Barsky made the false statement with the intention that Plaintiffs would rely on the statement.

41. Plaintiffs relied on Dr. Barsky's false statement.

42. Dr. Barsky's fraudulent conduct caused Plaintiffs damage in a substantial sum in excess of $75,000.00, the exact amount of which will be set forth at the time of trial in this matter.

43. As a direct result of Dr. Barsky's aforementioned conduct, Plaintiffs have been forced to retain the services of the undersigned counsel to pursue this matter and are thus entitled to an award of their reasonable attorneys' fees and costs associated herewith.

COUNT IV – MISAPPROPRIATION OF TRADE SECRETS

44. Plaintiff repeats, re-alleges, and incorporates by reference Paragraphs 1 through 43 of this Complaint as through fully set forth herein.

45. The parties entered into a confidentiality agreement with regard to ideas and information related to further development of the patent.

46. The ideas and information comprised a valuable trade secret.

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47. Dr. Barsky misappropriated the trade secret through use of the secret to develop the BioImagene patents.

48. The misappropriation was wrongful because it was made in breach of an agreement not to disclose.

49. Dr. Barsky's misappropriation caused Plaintiffs damage in a substantial sum in excess of $75,000.00, the exact amount of which will be set forth at the time of trial in this matter.

50. As a direct result of Dr. Barsky's aforementioned conduct, Plaintiffs have been forced to retain the services of the undersigned counsel to pursue this matter and are thus entitled to an award of their reasonable attorneys' fees and costs associated herewith.

COUNT V – CONVERSION

51. Plaintiffs repeat, re-allege, and incorporate by reference Paragraphs 1 through 50 of this Complaint as through fully set forth herein.

52. Dr. Barsky has exerted wrongful dominion over Plaintiffs' intellectual property for Dr. Barsky's own benefit, all without first having paid Plaintiffs the value thereof.

53. Dr. Barsky's act was in denial of, or inconsistent with, his rights with respect to the aforementioned intellectual property, as this property did not belong to Dr. Barsky.

54. Dr. Barsky's acts are in defiance of Plaintiffs' rights in their aforementioned property.

55. Dr. Barsky has failed or refused to return any of the aforementioned property.

56. As a direct and proximate cause of Dr. Barsky's aforementioned conduct, Plaintiffs have been damaged in a substantial sum in excess of $75,000.00, the exact amount of which will be set forth at the time of trial in this matter.

57. As a direct result of Dr. Barsky's aforementioned conduct, Plaintiffs have been forced to retain the services of the undersigned counsel to pursue this matter and are thus entitled to an award of their reasonable attorneys' fees and costs associated herewith.

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COUNT VI – UNJUST ENRICHMENT

58. Plaintiffs repeat, re-allege, and incorporate by reference Paragraphs 1 through 57 of this Complaint as though fully set forth herein.

59. Dr. Barsky unjustly retained Plaintiffs' intellectual property and used said property for Dr. Barsky's own benefit all without having first paid Plaintiffs the value whereof.

60. Plaintiffs conferred a benefit upon Dr. Barsky, as Dr. Barsky used Plaintiffs' intellectual property for Dr. Barsky's own benefit, though Plaintiffs did not know of, and did not consent to, such use.

61. Dr. Barsky accepted and retained the benefit of using Plaintiffs' property.

62. Dr. Barsky's unjust retention of Plaintiffs' property is inequitable.

63. Dr. Barsky should be required to disgorge his unjust enrichment.

64. As a direct and proximate cause of Dr. Barsky's aforementioned conduct, Plaintiffs have been damaged in a substantial sum in excess of $75,000.00, the exact amount of which will be set forth at the time of trial in this matter.

65. As a direct result of Dr. Barsky's aforementioned conduct, Plaintiffs have been forced to retain the services of the undersigned counsel to pursue this matter and are thus entitled to an award of their reasonable attorneys' fees and costs associated herewith.

COUNT VII – BREACH OF THE IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

66. Plaintiffs repeat, re-allege, and incorporate by reference Paragraphs 1 through 65 of this Complaint as though fully set forth herein.

67. Dr. Barsky directly contravened the terms of the agreement between Plaintiffs and Dr. Barsky to develop the Imaging Insight patent.

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68. As a direct and proximate cause of Dr. Barsky's aforementioned conduct, Plaintiffs have been damaged in a substantial sum in excess of $75,000.00, the exact amount of which will be set forth at the time of trial in this matter.

69. As a direct result of Dr. Barsky's aforementioned conduct, Plaintiffs have been forced to retain the services of the undersigned counsel to pursue this matter and are thus entitled to an award of their reasonable attorneys' fees and costs associated herewith.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment and seek relief against Dr. Barsky as follows:

(a) For Judgment that the High-Resolution Digital Image Processing in the Analysis of Pathological Materials has been and continues to be infringed by Dr. Barsky;

(b) For an accounting of all damages sustained by Plaintiffs as the result of the acts of infringement by Dr. Barsky, but not less than a reasonable royalty under 35 U.S.C. § 284;

(c) For actual damages together with prejudgment interest;

(d) For enhanced damages pursuant to 35 U.S.C. § 284;

(e) For an award of attorneys' fees pursuant to 35 U.S.C. § 284 or as otherwise permitted by law;

(f) For all costs of suit; and

(g) For such other and further relief as the Court may deem just and proper.

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Las Vegas, Nevada 89102

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues triable by jury.

DATED: December 11, 2012

Respectfully submitted,

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Troy L. Isaacson, Esq., NV Bar No. 6690
Norberto J. Cisneros, Esq., NV Bar No. 8782
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anava@anglawfirm.com

Attorneys for Plaintiffs

Exhibit "A"

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

Bib Data Sheet

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
60/224,252	08/10/2000 RULE _	–	–	UCLA016.001PR

APPLICANTS

Sanford H. Barsky, Los Angeles, CA ;
Kurt Stabel, Seal Beach, CA ;
Thomas W. Avery, Tustin, CA ;

** CONTINUING DATA **********

** FOREIGN APPLICATIONS **********

IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 11/02/2000 –

Foreign Priority claimed	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ yes ☐ no	CA	–	–	–
35 USC 119 (a-d) conditions met ☐ yes ☐ no ☐ Met after Allowance				
Verified and Acknowledged _____ Examiner's Signature Initials				

ADDRESS

–

James W Hill MD
Knobbe Martens Olson & Bear LLP
620 Newport Center Drive
16th FLoor
Newport Beach ,CA 92660

TITLE

High-resolution digital image processing in the analysis of pathological materials

FILING FEE RECEIVED	FEES: Authority has been given in Paper	
150	No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

08/21/2000 ETULU1 00000019 60224252
01 FC:114 150.00 OP

PTO-1556
(5/87)

*U.S. GPO: 1999-459-082/19144

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

Case No. UCLA016.001PR
Date: August 10, 2000

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

ATTENTION: PROVISIONAL PATENT APPLICATION

Sir:

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR § 1.53(c).

For: **HIGH-RESOLUTION DIGITAL IMAGE PROCESSING IN THE ANALYSIS OF PATHOLOGICAL MATERIALS**

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Name of Third Inventor: Thomas W. Avery
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Tustin, CA 92780

Enclosed are:

(X) Specification in eight (8) pages.

(X) A check in the amount of $150 to cover the filing fee.

(X) A return prepaid postcard.

The Commissioner is hereby authorized to charge any additional fees, which may be required, now or in the future, or credit any overpayment to Account No. 11-1410. A duplicate copy of this sheet is enclosed.

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Was this invention made by an agency of the United States Government or under a contract with an agency of the United States Government?

(X) No.

( ) Yes. The name of the U.S. Government agency and the Government contract number are:

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Respectfully submitted,

James W. Hill, M.D.
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Applicants	:	Sanford H. Barsky, et al.
For	:	HIGH-RESOLUTION DIGITAL IMAGE PROCESSING IN THE ANALYSIS OF PATHOLOGICAL MATERIALS
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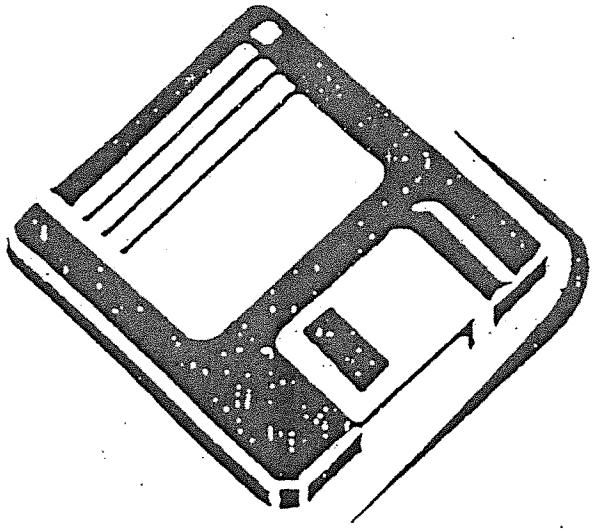

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HIGH-RESOLUTION DIGITAL IMAGE RECOGNITION IN THE ANALYSIS OF PATHOLOGICAL MATERIALS

Background of the Invention

Field of the Invention

The present invention relates to high-resolution image recognition in the microscopical analysis of pathological materials. The invention further relates to systems and methods for transmitting microscopical images over a network for diagnostic and other purposes.

Detailed Description of a Preferred Embodiment

Imaging Insight ("the Company") plans to use a streamlined product pricing structure and delivery model, and to offer two levels of service. Each will be targeted at two different groups of end-users. Both products will be focused on accessing the Company's proprietary database and the information it contains through a dedicated, high-speed Internet connection.

The first level of service (level I) will be offered to working hospitals, pharmaceutical companies, and others that must ensure a high level of accuracy when identifying pathology samples. This service will allow the user to submit specimens that have been converted to a digital format, engage our search engine, which will compare the submission to all samples in the database, and return a positive match. Our system will permit both computer-assisted diagnosis and computer-independent diagnosis on the basis of digital comparisons of unknown images with the company reference library of digital images.

At the user's location, a specialized Personal Computer (PC) resides on the desktop. A digital microscope resides alongside the PC that will allow the user to convert the specimen to a digital image. Both the PC and the digital microscope can be leased from the Company to the end user, which will allow us to maintain the integrity of the data coming into the system for analysis.

After the specimen has been submitted, the user will also be able to run a report characterizing the matched sample. This report can detail the specific characteristics of the sample, like who is likely to be afflicted with the pathogen in question, their age,

race, gender, etc. Further, this report may outline the etiology of the sample, what kind of cancer, how aggressive is the disease, and importantly which treatments may be employed to cure the affliction. End-users will have the ability to "search and query" the database based on text characteristics specified by the user. This first level of service will be the most desirable because of the ability to submit a digital image and have a positive match returned.

Our product will be extremely beneficial to the medical community and will take much of the guesswork out of diagnosing certain cancers and other pathogens that otherwise may be misdiagnosed. Accuracy and integrity of our data will foster an extremely high confidence level among practitioners and will allow all users to "harness processing power" in their diagnosis.

The level II product will be targeted at universities and teaching hospitals, where students, interns, or professors will be able to access our database. Users in this environment will be able to run simple to complex searches of our system based on a wide range of user-specified fields. This may include morphological features, i.e., size of nuclei, degree of blood vessel formation, etc. Level II service will be nearly identical to level I service with one main exception: Level II service will not have the ability to submit digitized specimens and have a positive match returned. The rationale behind this is that universities are not interested in the service as a diagnostic tool but as learning and teaching tool. We envision our products becoming a powerful learning tool for students. If a student wants to learn about a specific cancer, whom it is likely to affect, and related mortality rates, this information will be just a simple query away.

Level II users can have the same PC that level I users have. Both levels of service can have the same advanced search and querying abilities.

All images in our database will be tagged with certain characteristics that can be called qualitative characteristics. These characteristics may include the general appearance of the sample under the microscope, who is likely to contract the disease, what are the statistical characteristics of who is affected, etc. Current technology will allow researchers and students to perform very advanced studies of different diseases and whom they affect and ultimately how they may be treated.

Another site feature allows the user to "drill down" on a specific topic. The Company has a tool whereby results to a user's query not only shows matches to the query and its related characteristics, but shows related links to other web sites with information related to the user's request. For example, if a customer submits a sample of a melanoma and the system returns a match of malignant melanoma, users can access a list of websites with subject-related information. Links to accredited sites can be displayed (e.g., American Cancer Institute, Journal of American Medicine). We can employ filtering software to ensure that customers can only access approved websites through our portal.

Imaging Insight is building its reference database of digital images, first pertaining to pathology, and then branching out to biology and almost every aspect of the medical field that relies on data interpreted in a visual medium. The first pathological images being cataloged include all of the cancer slides residing in the UCLA medical library. Images are saved in a standardized, extremely high-resolution imaging format. After thorough evaluation of different imaging formats has been completed, the lead IT implementation team determines the specific format to be employed.

Once the slide is digitized, it is categorized and placed into the Imaging Insight data farm. Only Imaging Insight and its agents will be allowed to manipulate the database, ensuring its integrity. Server technology is state-of-the-art, allowing high-speed customer access to the system from any remote location. Preliminary study suggests the company will use SUN Microsystems Solaris Servers, which can be provided by, for example, Paracel.

The Company's database can be accessible from a secure link over high-speed lines (either DSL or fractional TI), via a router, to our customers. From the customer's onsite interface they can research, compare, and access any data residing on our servers. Front end access will be provided through a custom-designed graphical user interface (GUI). The interface is preferably Windows-based, point-and-click driven, simple, and easy to use, and will work and appear similar to an Internet Web browser. Management has preliminarily selected Andersen Consulting (AC) to build this interface and the

website it will run on. AC will act as the company's main technology integrator to oversee the implementation of all Information Technology based systems.

Imaging Insight will provide a leased computer and digital microscope/camera as a package to each licensed end user. The company's goal is to provide its service to customers in a similar manner to Bloomberg, a company that has been very successful in providing dedicated data feeds to its customers. The customer will have a secure data connection that will have authentication software residing on the client-side that will ensure a secure connection. After a customer enters a service agreement, a technician will respond to the customer's location and perform the final installation of the PC and related equipment, making the final connection between the customer and the company's database. This process will help ensure the integrity of our product and assure there will be no piracy of our services.

Customers that subscribe to level I service will have the ability to submit specimens to the database, which will return a positive match. The method for comparing a submitted sample to the company database will be based on the same technology used by other bio-identity matching systems. Great strides have been made in the biocomputing industry in the past few years. Management has researched companies that provide hardware and software to companies in the biocomputing industry. Management has preliminarily found Paracel, a company headquartered in Pasadena, CA, which can provide Imaging Insight with the most advanced hardware and software currently available.

Methods of processing and analysis of the digitized images can be performed using existing technology, as will be apparent to those of skill in the art. Such methods can include or otherwise incorporate all or part of the disclosure of image-pattern-recognition and database-comparison programs from any or all of the following U.S. Patents, which are hereby incorporated in their entirety by reference: Patent No. 5,331,550 to Stafford et al., issued July 19,1994; Patent No. 5,586,160 to Mascio, issued December 17, 1996; Patent No. 5,761,334 to Nakajima et al., issued June 2, 1998; Patent No. 4,907,156 to Doi et al., issued March 6, 1990; Patent No. 4,769,850 to Itoh et al., issued September 6, 1998; Patent No. 5,980,096 to Thalhammer-Reyero, issued November 9, 1999; Patent No. 5,133,020 to Giger et al., issued July 21, 1992; Patent

No. 5,291,560 to Daugman et al., issued March 1, 1994; and Patent No. 6,014,452 to Zhang et al., issued January 11, 2000;

With the continued improvement of worldwide data services, Imaging Insight can provide digital medical data to virtually anyone in the world. It is our intent to modernize the medical field and provide a valuable resource to doctors, students, researchers, and medical professionals worldwide.

A system and method involving artificial intelligence-driven recognition based on high resolution digital image analysis has been developed which permits archiving, storage, and identification of anatomical and pathological images (gross, microscopic, and immunocytochemical). This system and method of high-resolution digital image analysis allows for the creation of a library of pathological images which serves as a reference data base for assisted diagnosis, teaching, education, and research. The library of pathological images is all-inclusive, consisting of every anatomical disease process, and all of its protean manifestations, known to man. The library of pathological images is assigned addresses which can readily be retrieved and archived.

Our system of high-resolution digital image analysis allows for artificial intelligence-driven image recognition different from existing technologies but by way of principle, analogous to voice-recognition, retinal-recognition and fingerprint-recognition technologies. Our system permits both computer-assisted diagnosis and computer-independent diagnosis on the basis of digital comparisons of unknown images with the library of pathological images existing in memory. Our system of pathological image recognition and diagnosis is useful as a diagnostic, educational, teaching, and research resource. The latter claim derives from the ability to further analyze the stored images for whatever morphological feature is desired, e.g., size of nuclei, degree of blood vessel formation, etc. This system of image recognition involves proprietary methods of image storage, retrieval, and analysis. The commercial aspects of this invention are myriad and therefore it is our wish to form a company based on this invention and technology, called Imaging Insight, Inc.

We intend to use a Natural Language Retrieval System to retrieve, categorize, and locate histopathological slides and their paraffin blocks, from which we will produce standard and uniform histopathological sections and staining. We will proceed,

organ system by organ system, retrieving and categorizing every pathological disease process known to man and all of their histopathological nuances and variations. We will produce images of each histological section. We envision entering at least 10-100 examples of each disease process in our database. In every organ system we estimate that there are between 100–1,000 separate disease processes. So what we are talking about is a large scale: 1,000–100,000 data entry for each organ system. There are approximately 20 different organ systems in the human body. Each image entered will be categorized and identified. For example, if we wanted 100 examples of a benign process of the breast called sclerosing adenosis, we will index these and retrieve them instantaneously. The data entered can be used as a visual database of cases, a database of histopathological comparisons or a database from which digital image analyses could be performed to render diagnoses on unknown slides or their images produced. For this work, we use state-of-the-art equipment, including a microscope (or two) with attached video camera (e.g., laser capture microscope).

WHAT IS CLAIMED IS:

1. A method of ascertaining diagnostic information concerning a pathological specimen over a network, comprising:

transmitting a digitized image of a pathological specimen to a central location over a network;

receiving diagnostic information over the network from the central location concerning the pathological specimen after an analysis of an image of the pathological specimen has been performed at the central location.

2. The method of Claim 1, wherein the analysis comprises comparing an image of the pathological specimen to a database of known pathological images.

3. The method of Claim 1, wherein the pathological specimen comprises a microscopical slide preparation.

4. The method of Claim 3, wherein the microscopical slide preparation is selected from the group consisting of a cytological preparation and an immunohistochemical preparation.

5. The method of Claim 1, wherein the diagnostic information is selected from the group consisting of a diagnosis, a grade of cellular abnormality, a diagnostic classification based on a known classification scheme, and related epidemiological data.

6. The method of Claim 5, wherein the related epidemiological data is selected from the group consisting of known disease risk factors, age information, race information, gender information, and probabilistic information.

7. The method of Claim 1, further comprising receiving a treatment recommendation over the network from the central location based on the diagnostic information.

HIGH-RESOLUTION DIGITAL IMAGE RECOGNITION IN THE ANALYSIS OF PATHOLOGICAL MATERIALS

Abstract of the Disclosure

A method and system of ascertaining diagnostic information concerning a pathological specimen over a network is disclosed. The method comprises transmitting a digitized image of a pathological specimen to central location, and then receiving diagnostic information from the central location concerning the pathological specimen after an analysis of the digitized image has been performed at the central location.

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