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10 Attorneys for Plaintiff
 Advanced Biological Laboratories S.A.

11 UNITED STATES DISTRICT COURT
 12 NORTHERN DISTRICT OF CALIFORNIA
 13 SAN FRANCISCO DIVISION

14 ADVANCED BIOLOGICAL
 15 LABORATORIES S.A., a Luxembourg limited
 liability company,

16 Plaintiff,

17 vs.

18
 19 THE BOARD OF TRUSTEES OF THE
 LELAND STANFORD JUNIOR
 20 UNIVERISTY, and ROBERT W. SHAFER,
 M.D.

21 Defendants.

CASE NO. CV 08 5399 JCS

**FIRST AMENDED COMPLAINT FOR:
 DEFAMATION**

DEMAND FOR JURY TRIAL

22
 23 **FIRST AMENDED COMPLAINT**

24 Plaintiff Advanced Biological Laboratories S.A. (“Plaintiff” or “ABL SA”), files this
 25 complaint against Robert W. Shafer, M.D. (“Dr. Shafer” or “Defendant”), alleging as follows:

26 **JURISDICTION AND VENUE**

27 1. This is an action for defamation and is a civil action over which
 28 this Court has original jurisdiction under 28 U.S.C. 1332. The amount in controversy exceeds

1 \$75,000.00 USD and there is diversity of citizenship between Plaintiff and the remaining
2 Defendant. All allegations against The Board of Trustees of the Leland Stanford Junior University
3 (“Stanford”) have been dismissed.

4 2. Venue is proper in this court as Shafer resides in this District.

5 **THE PARTIES**

6 3. Plaintiff Advanced Biological Laboratories, S.A. is a limited liability company
7 organized under the laws of Luxembourg, having its principal place of business at 2, rue des
8 Dalhias, L-1411 Luxembourg, Luxembourg.

9 4. Defendant, Robert M. Shafer, M.D. is an individual. He can be served at his place of
10 business Division of Infectious Diseases, Room S-101, Stanford University Medical Center, 300
11 Pasteur Drive, Stanford, CA 94301.

12 **FACTS**

13 5. Plaintiff hereby incorporates each and every paragraph set forth above, as though
14 fully set herein.

15 6. Dr. Shafer is the self-described principal investigator and scientific curator behind the
16 HIVdb website. The HIVdb website located at <http://hivdb.stanford.edu/> is maintained on the
17 Stanford website.

18 7. On information and belief, resolution of litigation between Stanford and ABL SA led
19 to the development of strong feelings from Dr. Shafer against ABL SA, dating from at least March
20 10, 2008.

21 8. On information and belief, Dr. Shafer has noted and shared his antagonism towards
22 ABL SA within the HIV community on numerous occasions, including but not limited to the
23 statements enumerated below.

24 9. On information and belief, Dr. Shafer is the developer and author of the website
25 harmfulpatents.org. A true and correct copy of this website as of the date of filing is attached as
26 Exhibit A. The aim of this website is to: “combat harmful patents”¹ specifically ABL SA’s U.S.
27 Patent Nos. 6,081,786 and 6,188,988 (“the ABL SA Patents”). Dr. Shafer accuses the ABL SA

28

¹ All quotations have been taken from Dr. Shafer’s website, harmfulpatents.org.

1 patents of claiming “a monopoly on the very concept of developing software to help physicians
2 make treatment decisions.” This statement is false. On information and belief, he has expressed
3 this view in written and oral communications to a wide variety of HIV researchers, as well as any
4 person or persons with access to the internet, indicating that ABL SA wishes to keep physicians
5 from effecting the best treatment for their patients. Further, he has solicited letters from other
6 researchers, to include on his website, that express negative opinions toward ABL SA and its
7 patents. On information and belief, he has obtained such letters by falsely stating that ABL SA
8 seeks to shut down the HIVdb website.

9 10. On October 10, 2008, Dr. Shafer filed an Ex Partes reexamination request for the
10 ‘988 patent and an Ex Parte reexamination request for the ‘786 patent.

11 11. Dr. Shafer claims “In March 2008, Stanford chose to negotiate with ABL because of
12 their concern about the potential expense of litigation and the potential for the HIV Drug
13 Resistance Database being shutdown as a result of the litigation.”

14 12. Dr. Shafer further asserts that ABL SA and Stanford entered into “a licensing
15 agreement intended to limit the use of the free HIV database created by one of its faculty.” This
16 statement is false.

17 13. In reference to his website, and his allegations against ABL SA, Dr. Shafer also
18 claims “If you use the freely available Stanford HIV Drug Resistance Database and want to
19 continue to use it without fear of being sued – you should care.” ABL SA has not threatened to
20 sue users of the HIVdb.

21 14. Dr. Shafer further claims “If you are developing a medical expert system and do not
22 want to pay licensing fees to a company claiming a monopoly on such systems – you should care.”
23 ABL SA has never claimed a monopoly on medical expert systems.

24 15. ABL SA has not, and will not, attempt to shut down the HIVdb, as it, and the entire
25 HIV community, believes it is an important tool in the fight against HIV. False accusations that
26 ABL SA has threatened to shut down the HIVdb threaten and impair ABL SA’s professional
27 reputation, and are responsible for the loss of several potential business deals for ABL SA with
28 several members of the HIV community.

1 16. Further, Dr. Shafer indicates that the ABL SA Patents are “undeserved obvious
2 patents” and ABL SA engages in “abusive patent litigation.” These false assertions have been
3 cited to ABL SA as reasons that potential business partners have chosen not to work with ABL
4 SA. ABL SA has not engaged in abusive litigation practices, nor has it been accused of such by
5 opposing counsel.

6 17. Dr. Shafer further describes ABL SA’s patents as “obstacles to the development of
7 educational and medically useful web-based programs.” One of ABL SA’s stated goals is to
8 improve healthcare, thus describing ABL SA’s intellectual property as “obstacles” to ABL SA’s
9 own stated goals damages ABL SA’s reputation.

10 18. Dr. Shafer further implies that ABL SA is a “litigious (sic) owner of undeserved
11 obvious patents.” This statement is false.

12 19. Dr. Shafer has publicly stated his accusation that a substantial amount of prior art
13 was not made available to the USPTO at the time the patents were filed. On information and
14 belief, Dr. Shafer has reiterated this belief via written communications to a number of leading
15 members of the HIV community. This statement is false.

16 20. Such references to the ABL SA patents as “undeserved” and its litigation as
17 “abusive” indicate some sort of inequitable conduct by ABL SA during the acquisition or
18 litigation of the ABL SA patents.

19 21. ABL SA has reason to believe that Shafer has made additional defamatory comments
20 about ABL SA, specifically in written communications to a variety of HIV researchers. ABL SA
21 has been unable to obtain a copy of these communications despite repeated requests.

22
23 **COUNT I: DEFAMATION**

24 22. Plaintiff hereby repeats and realleges each and every allegation stated in
25 Paragraphs 1- 38, as if stated fully herein.

26 23. On information and belief, starting shortly after the signing of the
27 Agreement, and continuing to the present, Dr. Shafer has made derogatory and
28 untrue statements, both written and oral, regarding ABL SA, its patents, and its

1 litigation practices. These statements tended to injure ABL and as a natural and
2 proximate cause of those statements, ABL has suffered injury to its professional
3 reputation.

4 24. The material that Dr. Shafer placed, and continues to place, on his
5 harmfulpatents.org website wrongly disparages ABL's business and conduct, and,
6 as a result of the inequitable conduct allegations, effectively accuses ABL of
7 fraud. These false statements tended to injure ABL and as a natural and proximate
8 cause of those statements, ABL has suffered injury to its professional reputation.
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11 **DEMAND FOR JURY TRIAL**

12 25. ABLSA hereby demands a jury trial on all claims and issues triable of right by a jury.

13 **PRAYER FOR RELIEF**

14 WHEREFORE, Plaintiff prays for judgment that:

- 15 a. Defendant Shafter be held to have Defamed ABL SA;
16 b. Defendant account for and pay to ABLSA all damages caused by Defamation;
17 c. Plaintiff be awarded its costs and prejudgment interest on its damages,
18 d. Defendant be required to pay ABLSA's attorneys' fees and court costs;
19 e. Punitive damages and that
20 f. Plaintiff be granted such other and further relief as the Court may deem just and proper

21 under the current circumstances.
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Dated: April 6, 2009

Respectfully submitted,
/s/ Edward W. Goldstein
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ATTORNEY FOR PLAINTIFF

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all claims that are triable by jury.

Dated: April 6, 2009

Respectfully submitted,
/s/ Edward W. Goldstein
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ATTORNEY FOR PLAINTIFF

Exhibit A

harmfulpatents.org

How could the USPTO have issued two patents on the mere concept of using computers to help physicians choose medical treatments more than 20 years after medical expert systems were first developed?

How could the company that purchased these patents expect to license them to diagnostic companies, diagnostic service providers and therapeutic manufacturers, file five patent infringement lawsuits against seven companies, and threaten to sue a university for hosting a widely used freely available HIV database?

How could a university, particularly one that had performed much of the seminal research on artificial intelligence in medicine, enter into a licensing agreement intended to limit the use of the free HIV database created by one of its faculty?

Who should care?

If you use the freely available Stanford HIV Drug Resistance Database and want to continue to use it without fear of being sued - you should care.

If you are developing a medical expert system and do not want to pay licensing fees to a company claiming a monopoly on such systems - you should care.

If you are a diagnostic company, diagnostic service provider, or therapeutic manufacturer - you should care.

If you are disgusted by undeserved obvious patents and abusive patent litigation - you should care.

If you are concerned about how the dense web of licensing and cross-licensing raises the cost of health care - you should care.

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1. Aims of This Site

1. To inform biomedical researchers about two patents that appear to claim *a monopoly on the very concept of developing software to help physicians make treatment decisions*.
2. To inform the HIV clinical and research community about the litigation surrounding these patents.
3. To raise funds to defray my legal costs and to support my ongoing efforts to invalidate the '786 and '988 patents.
4. To demonstrate that a clinical / research community with shared interests can act in concert to combat harmful patents and patent litigation.

People

[Robert Shafer MD](#)
Division Infectious Diseases
Department of Medicine
Stanford University
rshafer stanford.edu

[HIV Drug Resistance Database](#): A free publicly available online resource to help those performing HIV drug resistance surveillance, interpreting HIV drug resistance tests, and developing new HIV drugs. It contains HIV sequences linked to HIV drug treatment histories, drug susceptibility experiments, and clinical response data. Users are provided with graphical query interfaces for retrieving data and with interactive programs for analyzing HIV sequences. The database is used by researchers, clinicians, and laboratories from more than 100 countries.

Publications

[Science News](#)
Jon Cohen, February 2009

Letters

[Professor Mark Wainberg](#)
Director McGill University AIDS Center,
Former President Interantional AIDS Society, March 2009

[Professor Gio Wiederhold](#)

2. Background Information

1. 1998-2001: The US Patent and Trademark Organization (USPTO) issues two broad patents on the concept of using computers to help physicians make treatment decisions

- US patents 6,081,786 ('786) and 6,188,988 ('988) are two patents that describe the "invention" of using computers to help physicians make treatment decisions. Both patents were continuations of single patent filed in 1998 by TherapyEdge, a spin-off of the North Carolina-based company Triangle Pharmaceuticals.
- During the '786 patent's prosecution, the patent examiner allowed the 66 claims of the patent based on one distinguishing feature stating "The specific allowable feature, which distinguishes the present invention over the prior art is the generation of a ranked listing of available therapeutic treatment regimens for the patient."
- The '988 patent disclosure is identical to the '786 patent. And its claims are nearly identical to the '786 claims. Despite the fact that the patent examiner had determined that the sole novel feature of the TherapyEdge patent application was the ranked listing of available therapeutic treatment regimens, the '988 patent was allowed to issue without the ranked listing requirement.

2. 2004-2007: ABL acquires the '786 and '988 patents and sues Hoffman La Roche, Virco Laboratories, Applera, Celera Diagnostics, Abbott Laboratories, SmartGene, and Ameripath for patent infringement

- Advanced Biological Laboratories (ABL), a Luxembourg-based company, acquires majority control of TherapyEdge.
- ABL and [Evidence Medical LLC](#) (a holding company) issue the following [press release](#):

"Control of these patents was at the heart of our business strategy. We believe the patents will prove seminal to the diagnosis and treatment of most chronic diseases. The patents broadly cover the computer analysis of multiple databases which lead to a report meant to guide physicians towards the optimal therapy for a given patient. Historically, such reports were principally associated with the treatment of HIV, but *we envision that eventually the diagnosis and treatment of most chronic diseases will fall under the claims of these patents as well.* We intend to widely license the patents to diagnostic companies, diagnostic service providers and therapeutic manufacturers."

- ABL announces the formation of "ABL Patent Licensing Technologies SARL" and states "ABL owns US patents (US 6,081,786 and US 6, 188,988) and their foreign equivalents and is currently in the business of licensing intellectual property to diagnostic manufacturers, therapeutic companies, and diagnostic service providers."
- In 2004, ABL sues Hoffman La Roche, Virco Laboratories, Applera, Celera Diagnostics, and Abbott Laboratories for patent infringement. The lawsuits are voluntarily withdrawn for unstated reasons.
- In 2007, ABL sues Ameripath and SmartGene in the Eastern District of Texas

3. 2007-2008: ABL sues Stanford University and the principal investigator of the [HIV Drug Resistance Database](#)

- ABL threatens to sue Stanford University claiming that the HIV Drug Resistance Database infringes the '786 and '988 patents because it provides - at no cost -

Stanford University (CS, IEEE, Medicine),
April 2008

[Professor W. Jeffrey Fessel](#)

Emeritus Clinical Professor (UCSF), Director
Clinical Research San Francisco Unit, Kaiser
Permanente Medical Care Program -
Northern California, March 2009

Documents

[US Patent No. 6,081,786](#)

[US Patent No. 6,188,988](#)

[European Patent Office Rejection of ABL Patents](#)

[ABL Press Release](#)

[ABL vs Roche](#)

[ABL vs Virco](#)

[ABL vs Applera](#)

[ABL v. Viralliance \(Ameripath\)](#)

[ABL v. SmartGene](#)

[Stanford Complaint for Declaratory Relief](#)

[Stanford-ABL Agreement](#)

[1st Reexamination Petition \(6,081,786\)](#)

[1st Reexamination Petition \(6,188,988\)](#)

['786 Order Granting Reexamination](#)

(D. Hughes Examiner 571-272-6982)

['988 Order Granting Reexamination](#)

(D. Hughes Examiner 571-272 6982)

[ABL lawsuit vs Stanford and Shafer](#)

Non-Profit Organizations

[Public Patent Foundation](#)

"Our work is based on the concept of protecting freedom from illegitimate restraint. The patents we seek to have the Patent Office reexamine are those that have a chilling effect on some conduct that would otherwise be permissible."

[Patent Fairness Coalition](#)

"Modernization and reform of the current patent system will spur job creation by allowing American businesses to focus on innovation instead of unjustified patent litigation."

"An industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees" - Supreme Court Justice Kennedy (Ebay v. Mercantile).

[Patients not Patents](#)

"To reduce the barriers to affordable healthcare and to educate the public about the effects of intellectual property laws on the availability of healthcare for all."

[Electronic Frontier Foundation](#)

"Now some patent holders have begun to set their sights on the new class of technology users - small organizations and individuals who cannot afford to retain lawyers. Faced with million-dollar legal demands, they have no choice but to capitulate and pay license fees - fees that often fund more threat letters and lawsuits."

[Public Knowledge Foundations"](#)

"The quality of patents issued has reduced over the past decade, especially in the

several programs to help researchers and clinicians interpret HIV-1 drug resistance information.

- In October 2007, Stanford University sues ABL for [Declaratory Relief](#) (PDF) stating that the HIV Drug Resistance Database does not infringe the ABL patents and that Stanford has sufficient grounds to seek patent invalidation.
- In March 2008, Stanford chose to negotiate with ABL because of their concern about the potential expense of litigation and the potential for the HIV Drug Resistance Database being shutdown as a result of the litigation. Stanford and ABL quickly negotiated, without my knowledge or participation, a [licensing agreement](#) which would require me to place a statement on the Database website and which according to ABL's interpretation would

"put the HIV community on notice about ABLs patents".

- When I learned of the signed Stanford-ABL agreement, I would not agree to place ABL's statement on the Database website. The Database depends on contributions of data by hundreds of medical researchers and has been funded primarily by National Institutes of Health (NIH) grants and by unrestricted funding from multiple pharmaceutical and diagnostic companies. Using the Database to advertise patents that I believed to be broad, obvious, and contentious would betray the trust of those who made the database possible. I also believed that ABL's patents were obstacles to the development of educational and medically useful web-based programs, and that any agreement with ABL over the patents would make it more difficult for future targets of ABL to defend themselves.
- In May 2008, I hired the firm of Day Casebeer to petition the USPTO to re-examine and invalidate the ABL patents asserting that the patents were broad and obvious and that an extensive amount of prior art was not made available to the USPTO at the time the patents were filed. The petitions were filed with the USPTO in October 2008.
- In December 2008, ABL filed a lawsuit against Stanford University for breach of contract and against me for "inducing a breach of contract", "negligent interference with prospective business advantage", and "defamation."

software and business method areas. These low quality patents discourage innovation because follow on inventors will not innovate based on a technology covered by a patent. Because certain key courts tend to favor patent owners in litigation, many competitors license these patents rather than challenge them, thus unfairly raising the cost of products containing these patents."

Bibliography

3. US Patents 6,081,786 and 6,188,988

"Systems, methods and computer program products for guiding selection of a therapeutic treatment regimen for a known disease such as HIV infection are disclosed. The method comprises (a) providing patient information to a computing device (the computer device comprising: a first knowledge base comprising a plurality of different therapeutic treatment regimens for the disease; a second knowledge base comprising a plurality of expert rules for selecting a therapeutic treatment regimen for the disease; and a third knowledge base comprising advisory information useful for the treatment of a patient with different constituents of the different therapeutic treatment regimens; and (b) generating in the computing device a listing (preferably a ranked listing) of therapeutic treatment regimens for the patient; and (c) generating in the computing device advisory information for one or more treatment regimens in the listing based on the patient information and the expert rules."

The 66 claims of each patent on the USPTO website: [US Patent No. 6,081,786](#) [US Patent No. 6,188,988](#).

4. European Patent Office (EPO) Rejection of the ABL Patents

1. The EPO rejected the European counterpart to the TherapyEdge patent applications because the patent claims were considered to be obvious: [EPO Refusal](#) (PDF), [Additional web documents](#) (EPO website).

5. Petitions to the USPTO for Patent Reexamination and Invalidation

1. Request for ex parte reexamination of [6,081,786](#) (PDF) filed by the law firm of [Day Casebeer](#) on my behalf
2. Request for inter partes reexamination of [6,188,988](#) (PDF) filed by the law firm of Day Casebeer on my behalf.

6. ABL's Lawsuits Related to the '786 and '988 Patents

1. Lawsuit against [Virco Laboratories](#) (PDF) 2004 for patent infringement. This lawsuit was dismissed without prejudice (i.e., without abandonment of ABL's claims) for unstated reasons.
2. Lawsuit against [Hoffman La Roche](#) 2004 (PDF). This lawsuit was voluntarily dismissed for unstated reasons.
3. Lawsuit against [Applera, Celera Diagnostics, Abbott Laboratories](#) (PDF) 2004. This lawsuit was voluntarily dismissed without prejudice (i.e., without abandonment of ABL's claims) for unstated reasons.
4. Lawsuit against [Ameripath](#) (PDF) in the [Eastern District of Texas](#) 2007 - 2008
 - The Docket for this case contains 69 documents filed between January 2007 and June 2008. ABL's complaint appears to have been related to the fact that Ameripath offered an HIV drug resistance test developed by the French company Viralliance. This test was designed to help physicians make treatment decisions. The case was "settled" in June 2008. A [press release](#) announced that "ABL Patent Licensing Technologies, SARL, a subsidiary of Advanced Biological Laboratories SA (ABL) entered into a patent licensing agreement with Viralliance Inc. (VI). As per the scope of the patent license agreement, ABL has granted a non-exclusive, royalty-bearing license to VI to use the ABL patent portfolio for guiding and ranking the selection of a therapeutic regimen for a given patient. The other terms of the agreement are confidential.". Viralliance has gone out of business. Former members of Viralliance are not permitted to speak about ABL or the licensing agreement.
5. Lawsuit against [SmartGene](#) (PDF) initiated in the [Eastern District of Texas](#) 2007 -
6. Lawsuit against Stanford University and Robert Shafer: [ABL lawsuit](#) (PDF) 2008. March 20, 2009 Stanford notifies Shafer that Stanford will be paying ABL a cash settlement in exchange for ABL dropping their charges against Stanford. ABL's lawsuit vs Shafer will continue, bankrolled in part by the settlement with Stanford.

7. Donations

1. To file with the USPTO two additional petitions for patent reexamination. These will complement the arguments presented in the first two petitions I filed in October 2008.
2. To pay my legal fees in ABL's lawsuit against me
3. To turn *Harmful Patents* into a 501c3 designed to protect individuals and small companies performing useful public health functions from litigious owners of undeserved obvious patents. The *Harmful Patents* Board will marshal the collective actions of the broader community affected by specific harmful patents through publicity and fund raising in a manner similar to what I am doing here.

Contributions

Option 1 \$25.00

Pay Now

