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Petition to

The Honorable Spencer Abraham
Secretary of Energy
Washington, D.C. 20585

and

Paul A. Gottlieb
Assistant General Counsel
for Technology Transfer and Intellectual Property
Department of Energy
Washington, D.C. 20585

Concerning Government Rights in Ion Mobility Analysis for
Rapid Identification of Cardiovascular Disease Indicators
Developed Under Contract No. DE-AC03-76SF00098 Between
the U.S. Department of Energy and The Regents of the
University of California for the Management and Operation of
the Lawrence Berkeley National Laboratory

Date: November 11, 2002

Petitioner:

Berkeley HeartLab, Inc.
Burlingame, California

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I. Executive Summary

Berkeley HeartLab, Inc. ("BHL") petitions the Department of Energy for relief under the Government's march-in rights or appeal process from an improper licensing decision made because of a conflict of interest. The Regents of the University of California ("Regents"), who operate Lawrence Berkeley National Laboratory ("LBNL") under a contract with the Department of Energy, have decided to license the rights to certain technology developed at LBNL to their own former employees despite having already licensed those rights exclusively to BHL and having allowed the former employees to manipulate their positions at LBNL and contacts with the Regents to skew the licensing process. The Regents reached their decision even though (i) BHL already has an exclusive license to the same intellectual property from the Regents; (ii) under a different agreement, the Regents were obligated to develop other BHL technology in the same manner as the technology they now seek to license to their former employees; (iii) the thinly-capitalized former LBNL employees that the Regents now seek to reward with a license were the very people who failed to optimize the other BHL technology, and now appear to have misused BHL's proprietary data and software in violation of BHL's contractual rights (which limited the Regents' use to non-commercial research only); and (iv) BHL was clearly the entity best-positioned to develop viable products and services from the technology at issue. BHL asks for nothing more than a level playing field, free of conflicts of interest; such fair circumstances would lead to BHL having a license to the technology at issue. Thus, BHL requests that the Department of Energy provide it a license to the technology at issue on commercially reasonable terms, whether in the form of an exclusive license, a partially exclusive license, or a nonexclusive license.

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II. Background

This petition relates to rights in work done at Lawrence Berkeley National Laboratory ("LBNL"), a research facility owned by the Government of the United States of America. The Government, through the United States Department of Energy, is a party to Contract No. DE-AC03-76SF00098 with the Regents of the University of California ("Regents"). Pursuant to that contract, the Government provides funding for research and development work at LBNL in exchange for the Regents' management and operation of LBNL. The research that the Regents carry out at LBNL includes research on certain aspects of lipoproteins. As with other contracts, the Government has reserved certain rights (including march-in rights) with regard to any Government-funded work at LBNL. As a result, the United States Department of Energy has the power to provide the relief requested in this petition.

The Petitioner, Berkeley HeartLab, Inc. ("BHL"), is a company dedicated to advanced cardiovascular informatics and disease management, including risk detection and therapy of advanced cardiovascular disease. In particular, BHL is the technology leader in analysis of lipoprotein subclasses. Indeed, BHL is the exclusive licensee of U.S. Patent No. 5,925,229 (the "'229 patent"), entitled "Low Density Lipoprotein Fraction Assay," and related technologies. Under the '229 patent, BHL is the only party entitled to commercialize segmented gradient gel electrophoresis for detection and quantitation of lipoproteins.

BHL has numerous ties to LBNL and has supported significantly the research done on lipoproteins there. First, BHL has licensed the '229 patent from the Regents ("License Agreement"; Exhibit A), whose employees conceived of the invention in the

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course of their work at LBNL. That is, the '229 patent names Ronald M. Krauss, Patricia J. Blanche, and Joseph R. Orr, all then employees of the Regents working at LBNL, as inventors. Second, BHL had a funding agreement with the Regents ("Funding Agreement"; Exhibit B), under which BHL agreed to assume the Government's payment responsibility for certain work in exchange for rights in the fruits of that work. That work by Ronald M. Krauss, Patricia J. Blanche, and others in the Clinical Laboratory Unit of the Cholesterol Research Center at LBNL eventually led to both the '229 patent and the ion mobility technology at issue in this petition. Third, BHL sponsored further research by then employees of the Regents working at LBNL (including Drs. Krauss and Blanche) in order to develop the lipoprotein assay technology licensed from the Regents to the point of commercialization. (Exhibit C). BHL's relationship with LBNL has been so productive that the Technology Transfer Department of LBNL recognizes the collaboration between BHL and LBNL as a licensing success in the promotional materials published on its website. (Exhibit D).

BHL's contractual relationship with the Regents began in November 1996 with the execution of the Funding Agreement. Over the course of the next three years, the Funding Agreement was amended four times (*See* Exhibit B), and BHL's research relationship with the Regents (and, specifically, Drs. Krauss and Blanche) then continued until July 2002. (Exhibit C). Regardless of the amendments, however, the key LBNL personnel working under the Funding Agreement and its goal remained the same. (*See* Exhibit B, Statement of Work). Dr. Krauss was the principal investigator, Dr. Blanche was the chief scientist, and the goal of the project was to develop and perfect gradient gel electrophoresis-based methods for analysis and quantitation of lipoproteins. The

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lipoproteins for analysis and quantitation included very low density lipoproteins (VLDLs), low density lipoproteins (LDLs), intermediate density lipoproteins (IDLs), and high density lipoproteins (LDLs). (See, e.g., Exhibit B, Amendment 4).

One of the products of the Regents' work under the Funding Agreement was the conception of the subject matter of the '229 patent. Under the Funding Agreement, BHL received a non-exclusive, paid-up license subject to the Government's right to revocation. (Exhibit B, ¶ V(D)). In order to obtain exclusive rights to the '229 patent and other technology, although on a royalty-bearing basis, BHL entered into the License Agreement with the Regents on April 30, 1997. (Exhibit A). Paragraph 3.1 of the License Agreement sets forth the scope of the license:

Subject to the limitations set forth in this Agreement, [the Regents and LBNL] grants to [BHL] the limited (by the terms of Sections 3.2 and 3.7) exclusive, royalty-bearing license, under the Licensed Patents and Proprietary Rights, to make, use, and sell Licensed Products and Alternative Methodology Products and to practice Licensed Methods.

(Exhibit A, ¶ 3.1). That is, the license granted rights not only in "Licensed Patents" – which include the '229 patent – but also "Proprietary Rights." Proprietary rights are defined by the License Agreement as:

[I]nformation related to the Invention, including data, drawings and sketches, designs, test results, and information of a like nature, whether patentable or not, developed by Ron Krauss, Patricia Blanche or others working under their direct supervision at Ernest Orlando Lawrence Berkeley National Laboratory. Proprietary rights also includes copyright in the foregoing, to the extent [the Regents and LBNL] obtains the right to assert copyright under its DOE Contract.

(Exhibit A, ¶ 2.8). Finally, the "Alternative Methodology Products" that BHL is licensed to make, use, and sell include:

[A]ny product or service of [BHL] that performs substantially similar functions to inventions claimed in a Licensed Patent (whether more highly

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automated or not) and whose use, approval by the Federal Drug Administration, or attractiveness to the market depends at least in a material part on Proprietary Rights. Nothing in this Agreement shall create any [Regents or LBNL] ownership interest in such Alternative Methodology Products, but such products are subject to royalties to the extent provided in Section 5.1.

(Exhibit A, ¶ 2.2). Thus, BHL is the Regents' exclusive licensee not merely under the '229 patent, but also under Proprietary Rights and for Alternative Methodology Products.

Since executing the License Agreement, BHL has invested very substantial amounts of money in the form of research and development funding for LBNL, royalties paid under the License Agreement, and money to develop the advanced lipoprotein testing market. Thus far, BHL has paid over [REDACTED] for that research and development, which was intended to allow the technology licensed under the License Agreement to be expanded in its discrimination of lipoproteins (including expansion to VLDLs and IDLs) and to be used for quantitative determination.¹ (Exhibit B). Drs. Krauss and Blanche carried out that work at LBNL between 1996 and 2002, and in doing so had access to BHL proprietary data and software to improve and expedite the BHL-sponsored work. (Exhibits B, C). However, to date, neither LBNL nor Drs. Krauss and Blanche has provided the results of the BHL-sponsored work to BHL or given contractually required reports to BHL. While it was sponsoring research at LBNL, BHL has spent over [REDACTED] million in developing the advanced lipoprotein testing market. BHL has also paid over [REDACTED] in licensing fees to the Regents under the License Agreement. As a result of its

¹ As discussed above, this work was to have been completed under the Funding Agreement. However, the Regents (through Drs. Krauss and Blanche) did not finish their work during the term of the Funding Agreement. Instead, they indicated that the work would be completed soon thereafter. In fact, Dr. Krauss indicated in e-mail communications in 2000 that he would be able to provide, and was committed to providing, this expansion and quantitation because he his work had already been funded. (Exhibit C, January 6, 2000 e-mail message). Dr. Krauss never delivered on his promise, but his written commitment kept BHL from developing the capabilities on its own.

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outlay of funds, and in part due to the lack of promised development at LBNL, BHL has not yet reported a profit.

In April 2002, the Regents provided to BHL and others a solicitation for proposals for a license to rights to technology identified as Ref. IB-1730, entitled "Ion Mobility Analysis of Biological Particles" ("Solicitation"; Exhibit E). The Regents indicated that the IB-1730 technology was, like other technology licensed to BHL, developed at LBNL using Government funding from Contract No. DE-AC03-76SF00098.² While the Solicitation appears on its face to be a neutral opportunity for any interested party to obtain rights under the IB-1730 technology, it now appears that the solicitation was part of plan to steer the fruits of Government sponsored research to a group closely associated with the Regents (including Drs. Krauss and Blanche). Furthermore, it also appears that the Regents have allowed Drs. Krauss and Blanche to misuse their offices at LBNL to further their own interests to the detriment of BHL.

The Regents, through Drs. Krauss and Blanche, had agreed to develop BHL's existing technology in a manner similar to the IB-1730 technology years ago, but never provided the results of the BHL-funded research to BHL. The Regents contractually agreed to expand the technology underlying the '229 patent to allow quantification of many different subspecies of lipoproteins, including VLDLs, LDLs, IDLs, and HDLs. (Exhibits B, C). That expansion would make the technology underlying the '229 patent quite similar to the IB-1730 technology. Dr. Krauss received (and has never returned) samples, equipment, and software from BHL; Dr. Blanche continued to profit from being

² It is unclear whether Drs. Krauss and Blanche diverted any of BHL's funds to support the development of the IB-1730 technology. It is clear, however, that they misused BHL's equipment and software, which was provided only for non-commercial research uses, for the commercial use of developing intellectual property to be licensed to CardioProfile.

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a consultant to BHL until she quit working at LBNL on July 1, 2002 and had unfettered access to BHL's proprietary data. (Exhibit C). That is, while Drs. Krauss and Blanche were being paid to do discrimination expansion and quantification research for BHL, they diverted their efforts to working on the IB-1370 technology that the Regents later decided to license back to them.

The IB-1730 technology represents a method for determining lipoprotein subclasses. According to the Solicitation, the technology was developed by Drs. Krauss and Blanche and W. Henry Benner.³ (Exhibit E). The Regents distributed the Solicitation in April 2002 so that the scheduled choice of a licensee would be made on July 1, 2002. *Id.* The timing appears not be randomly chosen – Drs. Krauss and Blanche left the Regents' employment and LBNL on the very same day as the original date for the Regents' choice of licensee. Drs. Krauss and Blanche were leaving, and did leave, to become part of a new company, CardioProfile, Inc., that had no existing intellectual property rights or other clear assets beyond the expectation that it would win the license to the IB-1730 technology.

But the IB-1730 technology appears to be more than just a "going away" present to Drs. Krauss and Blanche. One of CardioProfile's board members is Jerome Engel, the Executive Director of the Lester Center for Entrepreneurship & Innovation at the University of California's Haas School of Business. As the Executive Director of the Lester Center, Mr. Engel not only has self-admitted close ties to LBNL, he is also a direct employee of the Regents. The Lester Center, an entity associated with but not funded by the Regents, needs to enter into agreements with other entities, such as the Regents and

³ Dr. Benner remains an employee of the Regents working at LBNL, but BHL believes that he too has an ownership interest in CardioProfile.

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LBNL, to sustain its operations. Indeed, the Lester Center states on its website that “[i]ts ties with Lawrence Berkeley and Lawrence Livermore National Laboratories, the College of Engineering and with the Berkeley Center for Executive Development have provided opportunities for a variety of successful collaborations.”

Despite the Regents’ potential for mischief given their conflict of interest, BHL submitted a proposal for a license to rights to the Ref. IB-1730 technology in response to the Solicitation. (“Proposal”; Exhibit F). Apparently, BHL was the only party other than CardioProfile to submit a proposal. In compliance with the Solicitation, BHL’s Proposal included comprehensive information in each of the following sections: Company Information and Brief Introduction; Licensed Products; R&D Resources; Sales Projections; Financial Terms and Conditions; and Additional Information.

BHL’s Proposal revealed the clear truth – BHL has proven its ability to develop technology of this exact type. Under its License Agreement with the Regents, BHL has developed a reliable assay determining distribution of low-density lipoprotein (LDL) and high-density lipoprotein (HDL) subclasses and, more importantly, relating these values to cardiovascular disease and treatment. BHL has developed a database of over 60,000 patients and 500,000 metrics correlated to allow physicians to provide the most comprehensive and discriminating cardiovascular risk assessment and disease management possible. As mentioned earlier, BHL has also invested over \$40 million to develop and promote its technology. However, according to the Regents’ Solicitation, BHL’s technology suffers from one deficiency – it may produce erroneous quantitative results due to differential stain uptake. It was that very issue that Drs. Krauss and

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Blanche were supposed to be working on at LBNL for BHL in their most recent funded work but they, of course, have never provided their results.

BHL's Proposal was not merely the best proposal on the merits. In addition, BHL's Proposal indicated that the IB-1730 technology was believed to fall within the scope of the Funding Agreement and License Agreement. That is because the IB-1730 technology was not only within the scope of the nonexclusive license under the Funding Agreement, but also constituted Proprietary Rights under the License Agreement. As a result, the Regents knew that they were contractually obligated to license the IB-1730 technology to BHL.

Despite these circumstances, the Regents advised BHL by an October 21, 2002 electronic mail message that they had decided to initiate negotiations with another party in relation to the IB-1730 technology. (Exhibit G). The chosen party was later confirmed to be CardioProfile, the company founded by Drs. Krauss and Blanche. In informing BHL that they had chosen not to provide a license to BHL, the Regents indicated that they had analyzed BHL's position that the IB-1730 technology fell within the scope of the Funding Agreement and License Agreement and had concluded that they "do not have any legal or ethical obligation to license IB-1730 to Berkeley HeartLab." Explaining the selection process, the Regents simply stated that they "completed a review of the competing proposals on the merits," providing no additional details. Thus, it appears that Drs. Krauss and Blanche have used their positions at LBNL on behalf of the Regents, as well as BHL's funding and confidential information, to position themselves to capitalize on a new method for determining the same LDL and HDL subclasses that

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BHL determines and harmed BHL in the process by not satisfying the Regents' contractual obligations.

In further correspondence, the Regents have taken the position that their decision is final and that they have no formal mechanisms to address reconsideration of Berkeley Lab licensing decisions. That is, the Regents appear to have allowed their close ties to Drs. Krauss and Blanche, as well as others at CardioProfile, to cloud their decision making process. They are not merely allowing CardioProfile to piggyback on BHL's work (which would itself be improper), but even allowing Drs. Krauss and Blanche both to obtain rights with no track record of success or prior market development efforts and to misuse their positions at LBNL to gain a competitive advantage over BHL by taking BHL's money and withholding the discrimination expansion and quantification results funded by that money. A neutral observer would see clearly that BHL's only disadvantage in the bidding process was that it was attempting to play on a level playing field, not one intentionally slanted against it. But the Regents instead ignored the conflicts in interest and allowed Drs. Krauss and Blanche to take advantage of their positions at LBNL. Accordingly, BHL hereby petitions the Department of Energy for a license as a remedy.

III. Grounds for Petition

A. March-in Rights Under 35 U.S.C. §§ 202 and 203 and 37 § C.F.R. 401.6

35 U.S.C. § 202 provides for the disposition of patent rights in inventions made with federal assistance. Section 202(a) states: "Each nonprofit organization or small business firm may, within a reasonable time after disclosure [of the invention to the Government] . . . , elect to retain title to any subject invention" In this case, it

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appears likely that the Regents have made such an election, since they have solicited proposals for licensing the IB-1730 technology and have filed a U.S. patent application covering the IB-1730 technology which indicates that the assignee of the application is The Regents of the University of California.

Notwithstanding the probable election of the Regents to retain title to the IB-1730 technology, the federal government retains "march-in rights" under 35 U.S.C. § 203, which states: "the Federal agency under whose funding agreement the subject invention was made shall have the right . . . to require the contractor . . . to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself." 37 C.F.R. § 401.6 prescribes formal procedures for the exercise of march-in rights under 35 U.S.C. § 203.

As provided by statute, the operation contract between the Department of Energy and the Regents includes the standard Technology Transfer Mission clause set forth in 48 CFR § 970.5227-3. Part (d) of the Technology Transfer Mission clause pertains to conflicts of interest, and states: "The Contractor shall have implementing procedures that seek to avoid employee and organizational conflicts of interest, or the appearance of conflicts of interest, in the conduct of its technology transfer activities." In this case, the Regents violated this contractual provision by selecting a company founded by their own former employees – Drs. Krauss and Blanche – as the exclusive licensee of the IB-1730 technology, rather than the Petitioner, while providing no reasons whatsoever for its choice. At the very least, this decision creates the appearance of a conflict of interest, if

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not an actual conflict of interest, and amounts to a breach of the operation contract between the Department of Energy and the Regents. But the Regents have steadfastly refused to explain (i) why they awarded the right to negotiate an exclusive license to their own former employees despite the obviously greater merit of BHL's operation as an on-going enterprise, (ii) how they can commercialize an invention developed and compared to BHL's methodology using BHL's equipment and software despite having agreed that the equipment, software, and BHL proprietary data would be used for non-commercial research purposes only, or (iii) why they have failed to provide to BHL the discrimination expansion and quantification methodology for which BHL has already paid and which would allow BHL to compete more forcefully in the market and be more competitive with the projected benefits of the IB-1730 technology.

BHL's Proposal shows that BHL is in the best position to develop the IB-1730 technology for the public benefit. Its financial strength, scientific expertise in lipoprotein analysis, and management commitment to developing the technology, combined with its proven commercial success in the field of lipoprotein analysis, make BHL the logical choice to develop the IB-1730 technology. Furthermore, as noted, BHL is amenable to a co-exclusive or non-exclusive arrangement. The superiority of BHL's Proposal, coupled with the lack of any explanation for the denial of a license to BHL, indicates that the Regents' decision was arbitrary and capricious. For these reasons, the Department of Energy should exercise its march-in rights in this case and require the Regents to grant a license to the Petitioner.

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B. Appeal Under 35 U.S.C. § 208 and 37 C.F.R. § 404.11

If the Regents have not, in fact, made an election to retain title to the IB-1730 technology under 35 U.S.C. § 203, then it follows that the government owns the rights to the invention. Accordingly, BHL has a right to appeal the denial of a license to the IB-1730 technology under 37 C.F.R. § 404.11, which was promulgated under the authority of 35 U.S.C. § 208. Paragraph 404.11 states: "the following parties may appeal to the agency head or designee any decision or determination concerning the grant, denial, interpretation, modification, or termination of a license: (a) A person whose application for a license has been denied" Furthermore, if the government owns the rights to the IB-1730 technology, then it was inappropriate for the Regents to complete a review of the proposals to license the IB-1730 technology. Hence, the Department of Energy should conduct its own review of the proposals *de novo*. If the Department of Energy were to conduct such a review, the Petitioner is confident that its own proposal would be selected as the most meritorious.

IV. Relief Sought

The Petitioner seeks a license agreement for the IB-1730 technology with commercially reasonable terms. The petitioner would be amenable to negotiating for a nonexclusive, partially exclusive, or exclusive license for the IB-1730 technology. 35 U.S.C. §§ 203 and 207 give the Department of Energy the authority to grant such relief.

BHL, which has invested [REDACTED] developing the advanced lipoprotein testing market, paid over \$ [REDACTED] in royalties, and provided over \$ [REDACTED] for research and development at LBNL in order to make the '229 patent's technology more competitive, is eminently qualified to bring the IB-1730 technology to market at the

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earliest possible time. BHL's Proposal demonstrates that BHL is in the best position to develop the IB-1730 technology for the benefit of the public. The denial of a license to BHL, without explanation, reflects the arbitrary and capricious nature of the Regents' decision.

By awarding a license to the Petitioner in this case, the Department of Energy would fulfill "the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research," as articulated in 35 U.S.C. § 200. By denying BHL a license and, instead, allowing the thinly-capitalized CardioProfile to have exclusive rights to the technology, the Department of Energy would run the risk that the technology would go forever undeveloped or developed only by foreign competitors. Therefore, the Department of Energy should exercise its statutory rights and cause a license to the IB-1730 technology to be granted to the Petitioner.

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TABLE OF EXHIBITS

- Exhibit A License Agreement for Measurement of Lipoprotein Subspecies Between Berkeley HeartLab, Inc. and The Regents of the University of California through the Ernest Orlando Lawrence Berkeley National Laboratory
- Exhibit B Agreement Between The Regents of the University of California as Management and Operation Contractor of the Lawrence Berkeley National Laboratory and Berkeley HeartLab, a California Corporation, with four Amendments
- Exhibit C Correspondence and Software License Agreement relating to ongoing relationship between The Regents of the University of California as Management and Operation Contractor of the Lawrence Berkeley National Laboratory and Berkeley HeartLab, Inc. during the period from 1999 to 2002
- Exhibit D Web page from the LBNL Technology Transfer website, recognizing Berkeley HeartLab, Inc. as a Licensing Success
- Exhibit E Berkeley Lab Technology Transfer Department Solicitation for Berkeley Lab Ref. IB-1730— Ion Mobility Analysis of Biological Particles
- Exhibit F Berkeley HeartLab, Inc. Proposal for Berkeley Lab Ref. IB-1730—Ion Mobility Analysis of Biological Particles, with Attachments
- Exhibit G Electronic mail message correspondence between Frank Ruderman, CEO of Berkeley HeartLab, Inc. and Viviana Wolinsky, Licensing Manager at Lawrence Berkeley National Laboratory dated October 29, 2002, October 24, 2002, and October 21, 2002