Vector

MBBP Quarterly Life Sciences Newsletter

Q4 - 2009

Sean Detweiler Joins MBBP's Expanding Patent Practice

Sean D. Detweiler

In an effort to bring more of the same to our clients — senior level attention, focused expertise at a value unmatched by the downtown Boston legal market — we have continued to expand our Intellectual Property practice. Our most recent addition is Sean Detweiler, a patent attorney with experience in medical devices, hi-tech and combined technologies. Sean spent nine years at the intellectual property law firm of Lahive & Cockfield, and also brings perspective as a former in-house intellectual property attorney for a multi-billion dollar international corporation. He is the fourth IP attorney to join the MBBP team in less than a year.

Life Science Transactions on the Rebound

Mark J. Tarallo

As was the case with virtually every other industry group, merger and acquisition activity in the life sciences space fell significantly from 2007 levels during 2008 and the first part of 2009. As measured by the number of announced transactions, activity for the year ended December 31, 2008 was down almost 90% compared to the year ended December 31, 2007. Early data from the first two quarters of 2009 show that the M&A activity during this period was on a 2008 pace as well. However, the recent surge in announced transactions involving Massachusetts companies suggests that transaction activity in the life sciences space may be on the rebound.

On September 21, 2009, Inverness Medical Innovations of Waltham, MA (http://www.invernessmedical.com) announced that it would purchase Free & Clear, Inc., of Seattle, Washington, in a deal valued at as much as $130 million. Free & Clear (www.freeclear.com) is a privately-held company that designs online and phone-based programs that support smoking cessation and healthy living initiatives. This is the first deal announced by Inverness during 2009; in contrast, the company completed twelve transactions during 2007.

In addition, Biogen Idec, Inc., of Cambridge, MA (www.biogenidec.com) recently launched an all-cash tender offer for the outstanding shares of Facet Biotech Corp. (www.facetbiotech.com) of Redwood City, CA. Facet has been a development partner with Biogen on multiple sclerosis and cancer drugs. The unsolicited bid was for a price of $14.50 per share, and came after Facet's board rejected a friendly offer from Biogen. In a hostile tender offer, the buyer makes the offer to buy shares directly to the shareholders of the target, without the backing of the target's board. On October 16, Biogen extended the tender offer through December 16, 2009.

On September 28, Covidien (www.covidien.com) announced that it had agreed to acquire publicly traded Aspect Medical Systems, Inc., for a price of $12.00 per share. The total transaction is valued at approximately $210 million. Aspect Medical focuses on brain monitoring technologies, and its products will be sold through Covidien's Oximetry and Monitoring division. The transaction is expected to close on December 31, 2009.

This uptick in announced activity is a welcome departure from the slow pace of deals in 2008 and early 2009. As these deal represent a broad spectrum of industry sectors (biotech, medical devices and services), they may signal a rebound in transaction activity industry-wide.

For more information please contact Mark J. Tarallo at mtarallo@mbbp.com.

Supreme Judicial Court Decision Heightens Concern for Businesses Using Independent Contractors

Robert M. Shea

On August 21, 2009, the Massachusetts Supreme Judicial Court in *Somers v. Converged Access, Inc.* held that an employee misclassified as an independent contractor is entitled to recover damages under Massachusetts wage and

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hour laws (M.G.L. c. 149 and M.G.L. c. 151), even if the individual received more money as an independent contractor than he would have received if properly classified as an employee. More significantly, the Court also signaled that persons misclassified as independent contractors may use the Massachusetts wage act to recover "other benefits" such persons "would have received as employees," including vacation pay, holiday pay, employer contributions for employee health, dental and life insurance plans, and employer contributions for employee 401(k) and flexible spending account plans.

The Court emphasized that the wage act is a strict liability statute and that, "[g]ood faith or bad, if an employer misclassified an employee as an independent contractor the employer must suffer the consequences." Those consequences include the trebling of any damages incurred plus the recovery of attorney's fees and costs against the employer. The decision creates (or at least highlights) a dangerous and uncharted area of legal exposure and likely will lead to a further rise in misclassification claims against businesses using independent contractors.

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GUEST COLUMN

When is a Priority Claim Not a Valid Priority Claim?

Justine Muir

The English Patents Court has recently issued a decision in *Edwards Lifesciences AG vs Cook Biotech Incorporated* which calls into question the validity of some priority claims. This decision will likely have far reaching consequences, especially for Applicants claiming priority from US first filings. The full text of the case can be viewed at http://www.bailii.org/ew/cases/EWHC/Patents/2009/1304.html.

Edwards Lifesciences AG sought revocation of EP (UK) Patent 1 255 510, and Cook Biotech Incorporated counterclaimed for infringement. The issue of priority was fundamental to the case; if the priority date were held invalid, relevant prior art would become available which had the potential to invalidate the claims.

Sequence of events:

- A US patent application 60/179 195 was filed on 31st January 2000 in the names of Obermiller, Osse and Thorpe as joint inventors.
- An international application was filed on 31st January 2001 by Cooke Biotech Incorporated claiming priority from the earlier US case. Inventor Obermiller was an employee of Cooke Biotech Incorporated, and it was not disputed that Obermiller's rights in the invention belonged to Cook Biotech Incorporated.
- Osse and Thorpe were not employees of Cook Biotech Incorporated, and their rights in the invention were assigned to Cook Biotech Incorporated in September 2002, i.e., 21 months after the international application was filed but long before any patents were granted.

Cook Biotech Incorporated argued that their priority claim was valid, as they had acquired all the rights in the invention well before the date of grant.

Edwards Lifesciences AG argued that the priority claim was invalid because the right to priority can only be enjoyed by the person(s) who filed the priority application (or his successor in title) at the date the right to priority is claimed. In this case, on 31st January 2001 when the international application was filed, a valid priority claim could only be made jointly by Cook Biotech Incorporated (as the employer of Obermiller), Osse and Thorpe (as joint inventors).

The Court concluded that Article 4 of the Paris Convention requires that:

> "A person who files a patent application for an invention is afforded the privilege of claiming priority only if he himself filed the earlier application from which priority is claimed or if he is the successor in title to the person who filed the earlier application. If he is neither the person who filed the earlier application nor his successor in title then he is denied the privilege. Moreover his position is not improved if he subsequently acquires title to the invention…Any other interpretation would introduce uncertainty and the risk of unfairness to third parties."

Cook Biotech Incorporated also argued that because it always owned Obermiller's interest in the invention, this alone was sufficient to render the priority claim on 31st January 2001 valid. The Court refuted this argument, stating:

> "The US application was filed in the names of Joe Obermiller, Francisco Osse and Patricia Thorpe all as joint inventors. It was not filed by Joe Obermiller alone and therefore he is not "a person" who had "duly filed an application for a patent" within the meaning of Article 4A(1) of the Paris Convention."

Hence the patent was found not to be entitled to claim priority to the earlier US filing. Accordingly relevant prior art was introduced, and the patent was held to be invalid on the grounds of obviousness. The Court noted that its findings were consistent with those of the Board of Appeal of the EPO in J 0019/87 and T 0062/05.

Practice note:

To ensure the validity of a priority claim

it is crucial that either:

1. the initial priority-founding application and the subsequent priority-claiming application are filed using the same Applicant name(s); or
2. that all rights are transferred from the Applicant(s) of the priority founding application to the Applicant(s) of the later application before the later application is filed and a claim to priority is made.

If you find that you are not able to effect the transfer of rights before the later application is filed, to avoid jeopardising the validity of the priority claim, it is important to file the later application in the same name(s) as the priority founding application (i.e., in the name of the person(s) who enjoy "the privilege of claiming priority"), even if this does not accurately reflect the ultimate intended owner of the rights. Any discrepancy can then be rectified after the application is filed.

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H-1B Visas: Gone Until October 2010?

John J. Gallini

Normally at this time of year companies are scrambling to find other visa options beyond the H-1B "specialty worker" visa to employ and/on retain highly skilled foreign scientists and high tech workers – and they will be again at any moment because only a handful of H-1B visas are left. As of December 8, 2009 USCIS had received approximately 61,500 cap-subject petitions for new H-1B employment under the FY2010 Cap. USCIS also announced that it had received sufficient H-1B petitions to meet the exemption of 20,000 for U.S. Master's degree holders.[1]

Given this news, employers should be aware that sponsorship of a cap-subject H-1B worker is risky. While the USCIS has been providing weekly updates of the H-1B count at www.uscis.gov, there is a strong chance that the next announcement will be that the agency has received a sufficient number of petitions for FY2010. Further, any employer beginning this process now is at a serious disadvantage if they do not already have a pre- approved Labor Condition Application (LCA) with the Department of Labor (DOL) for the sponsored position. All H-1B petitions must be supported by an LCA certified by the DOL. Obtaining certification usually takes 7 days and can often take several weeks, particularly if the DOL is not able to match the employer's Tax ID (EIN) in its system.

What can employers do to ensure that they do not find themselves on a dead-end street in their recruiting/hiring efforts? When interviewing candidates who indicate that they require sponsorship, employers should try to determine whether the candidate has previously been issued an H-1B visa in the past several years. If the candidate has held H-1B status, it is also important to know whether the H-1B visa was for employment with an exempt institution. Institutions of higher education or "affiliated" employers, non-profit research organizations and governmental research organizations are exempted from H-1B numerical limitations. A candidate who has only held H-1B status through one of these "exempt" employers will be subject to the H-1B cap when moving to a non-exempt H-1B employer. If the candidate has never held H-1B visa status there may be other visa options that will allow his or her employment. For example, recent U.S. college graduates who are in F-1 status and have earned a bachelor's or higher degree in a STEM (Sciences, Technology, Engineering or Mathematics)-designated field may be able to extend their Optional Practical Training (OPT) for additional 17 months beyond their current 1 year of authorized employment. Other F-1 recent graduates may be able to later receive "cap gap" relief that will bridge their ability to remain employed. Citizens of some countries have more options available than citizens of other countries. A citizen of Australia may be eligible for an E-3 visa, citizens of Chile or Singapore may be eligible for an H-1B1 visa, and citizens of Canada or Mexico may be eligible for TN visa

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[1] The USCIS Fiscal Year runs October 1 through September 30. Congress allocates 65,000 H-1B visa per Fiscal Year under the regular quota, and reserves 6,800 of that number to Chile and Singapore under Free Trade Agreements with those countries. Congress also exempts 20,000 visas from the quota for sponsored workers who hold have graduated with a Master's or higher degree from a U.S. university or college.

status. If the individual is highly accomplished, an O-1 visa might be an option if a track record of extraordinary achievement can be documented. If you aren't sure what options are available, just ask us.

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The True Scope of a "Make-Use-Sell" License


Howard G. Zaharoff

A recent Federal Circuit case, *Corebrace v. Star Seismic*, clarifies the hidden breadth of a license to "make, use or sell" a patented invention.

The plaintiff-appellant Corebrace owned a patent for a brace used to fabricate earthquake-resistant steel-frame buildings. Star Seismic was granted a non-exclusive license to "make, use, and sell" licensed products. The license agreement, which stated that Star could not "assign, sublicense, or otherwise transfer" its rights and reserved all rights not expressly granted, did not expressly provide that Star could have licensed products made by third parties… but Star did so anyway.

> The Federal Circuit agreed that the right to "make, use and sell" inherently includes the right to have the product made by a third party "absent a clear indication of intent to the contrary."

Corebrace sent Star a notice of termination, claiming that Star breached the license by having third parties make licensed products for its own use. By doing so Corebrace ignored provisions of the agreement that allowed termination for breach *after* a 30-day notice and failure to cure. On the same day it sent the notice of termination, Corebrace also sued Star for breach, due to Star's use of third party contractors, and for patent infringement, on the grounds that the license had terminated. The district court held that Star did not breach, because a right to "make" includes a right to have others do that work, and that even if it had breached the license was not properly terminated.

The Federal Circuit agreed with the lower court's holding that the right to "make, use and sell" inherently includes the right to have the product made by a third party "absent a clear indication of intent to the contrary." This was so despite the prohibition on assignment and reservation of rights clause: since the right to "make" *inherently* includes the right to "have made," the have-made rights are included in the license and not reserved to the licensor, unless the license expressly says so. Here, nothing indicated an intent to exclude have-made rights.

As a result, Star did not breach the license by having third parties make licensed products for its own use. Since there was no breach, the question of whether Corebrace followed proper termination procedures was moot. And since the license wasn't terminated, Star could not have infringed the patent under which it was licensed. In short, complete vindication for Star.

Although the holding depends largely on state contract law – in particular, the law of Utah—it holds lessons for licensors and licensees everywhere, namely —

- For patent licensors: *If you do not want your licensee to be able to use third parties to make the licensed product, you must say so expressly.*
- For patent licensees: *If you are licensed to make, use and sell a product, absent an express provision to the contrary this generally includes the right to engage third parties to do the making for you.*
- For both licensors and licensees: As with any issue that is subject to agreement, don't leave matters to chance … or expensive litigation. Rather, *be sure the contract or license says what you mean and covers, or reserves, whatever rights you intend to cover or reserve.*

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Promises, Promises: A Cautionary Tale


Lisa M. Warren

In yet another example of the dramatic impact the assignment provision of an employment agreement can have, the Court of Appeals for the Federal Circuit recently put an end to a Stanford lawsuit alleging infringement by Roche of patents relating to PCR methods for measuring HIV virus concentration in a blood sample. The Court found that Stanford lacked standing to assert a claim of infringement against Roche because Stanford did not possess all ownership interests in the asserted patents (*Stanford v. Roche*, Fed. Cir. 2009).

Mark Holodniy was a Stanford researcher named as an inventor on all three of the patents-in-suit. Upon beginning employment as a Research Fellow at Stanford, Holodniy signed a "Copyright and Patent Agreement" which stated "I **agree to assign**…right, title, and interest…in inventions…" to Stanford. Subsequently, as part of a col-

laboration between Stanford and Cetus, Holodniy began regular visits to Cetus to learn PCR techniques and develop related assays. Holodniy signed a "Visitor's Confidentiality Agreement" with Cetus in which he agreed that he "will assign and **do hereby assign**" to Cetus his right, title and interest in each idea, invention and improvement he made as a consequence of his activities at Cetus.

A patent application naming Holodniy and two others as inventors was ultimately filed relating to PCR assays to measure the amount of HIV RNA in biological samples; after the application was filed Holodniy signed an assignment document assigning his rights in the application to Stanford. Roche acquired Cetus' business and began manufacturing HIV detection kits using RNA assays. After licensing discussions between the two parties broke down, Stanford sued Roche, alleging infringement of patents which were issued on the progeny of the initial patent application.

> Employers are well advised to review the IP transfer provisions in their standard agreements and revise them if necessary to include language which creates a present assignment of future inventions.

Applying past precedent, the Federal Circuit found the language "agree to assign" to be a mere promise to assign rights in the future, not an immediate transfer of expectant interests. As such, a subsequent written assignment was needed to actually transfer rights to Stanford. The court also found that the language "do hereby assign" created a present assignment of a future invention, and, thus, once the invention was made and the patent application filed, legal title to the application passed to Cetus by operation of law. Accordingly, by the time Holodniy signed the assignment to Stanford, he had no rights left to transfer, having already given them to Cetus.

Although Stanford may have a cause of action against Holodniy for breach of his contract promising to assign his rights to Stanford, that cause of action doesn't affect title to the application (and patents-in-suit). As a result, according to the court, Stanford could not establish ownership of Holodniy's interest. Because all co-owners must normally join as plantiffs in an infringement action, Stanford lacked standing (as lacking ownership of all rights in the patents) to assert an infringement claim against Roche.

Although it is likely that the court's decision will be appealed on a number of grounds, the decision nonetheless serves as a cautionary tale. In particular, failure to use appropriate language in agreements which transfer rights in inventions and patents/patent applications renders the transfer susceptible to intervening third party rights.

Employers are well advised to review the IP transfer provisions in their standard agreements, including IP policies and consulting and employment agreements, and revise them if necessary to include language which creates a present assignment of future inventions (e.g., "do hereby assign" such rights). If such changes are not possible (for example, due to a perceived conflict with Bayh-Dole requirements), employers should consider requiring employees to submit all agreements with third parties to the employer for review prior to execution.

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Bonus Depreciation Rules Set to Expire

Chip A. Wry

Internal Revenue Code Section 168(k) was added in 2002 in the wake of 9/11 and has since been expanded and extended. Its purpose is to stimulate growth by encouraging businesses to purchase and place in service equipment and other tangible assets. It permits a taxpayer to deduct 50% of the cost of "qualified property" as depreciation for the year in which the property is placed in service.

The definition of "qualified property" is quite broad. It includes most equipment (as long as it has a recovery period of 20 years or less), software that's either "off-the-shelf" or not acquired as part of the acquisition of a business, and certain leasehold improvements. In general, however, to qualify, the property must be (i) new and (ii) acquired and placed in service before January 1, 2010 (or, in the case of certain property with a long production period or aircraft, January 1, 2011).

Section 168(k) has not yet been further extended and may expire at the end of this year (or the end of 2010 for certain property with a long production period or aircraft). Accordingly, businesses that plan to make equipment purchases and other capital expenditures should seriously consider making the purchases and expenditures before the end of 2009 to take advantage of Section 168(k). After the provision has expired, businesses will be left to depreciate their tangible assets over the longer recovery periods prescribed by the regular depreciation rules.

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The Cure for Trademark Selection: Take Two ZANA™ Analgesics and Call Me in the Morning

Tom F. Dunn

A trademark can be a valuable asset. To develop that asset one must invest the necessary resources to select, register and enforce one's mark. This note focuses on the first step – selection.

When selecting a mark, it is useful to keep in mind the function a mark performs. Applicants too often select a mark in the belief that a strong mark immediately conveys to prospective purchasers some information about one's product or service. In fact, however, marks that are "merely descriptive" of one's product or service are weak. Absent substantially exclusive and continuous use for many years (and possibly despite such use), the trademark office will refuse registration of a "merely descriptive" mark on the Principal Register.

When selecting a mark, it is best to select a term that is at most suggestive of one's goods or services, and preferably either arbitrary or coined. Consider the following distinctiveness spectrum:

A generic term is a term for the genus itself. An example of a generic term is ASPIRIN for use with analgesics; that term has no distinctiveness, is incapable of acquiring distinctiveness even with extensive use and, therefore, cannot function as a mark for analgesics.

A descriptive term is one that forthwith conveys an immediate idea of an ingredient, quality, characteristic, feature, function, purpose or use of the goods or services. See In re Bayer Aktiengesellschaft, 82 USPQ2d 1828 (C.A.F.C. 2007) [precedential] (affirming the TTAB's holding that "ASPIRINA" is merely descriptive for analgesics). The "primary meaning" of ASPIRINA is non-distinctive; it may acquire distinctiveness only if, as a result of substantially exclusive and continuous use, consumers perceive it as having a "secondary meaning" as an indicator of source, i.e., as a mark.

A suggestive mark is one that, when applied to the goods or services at issue, requires imagination, thought or perception to reach a conclusion as to the nature of those goods or services. In registering UN-ASPIRIN for a "pharmaceutical preparation for the treatment of colds" the trademark office presumably determined that consumers would have to engage in some imagination, thought or perception to conclude the product is a non-aspirin preparation.

Arbitrary marks have a common meaning that has no relation to the goods or services being sold. For example, the registered TIGER mark for analgesics is arbitrary because a "tiger" has no relation to aspirin, much as APPLE is an arbitrary mark for computers.

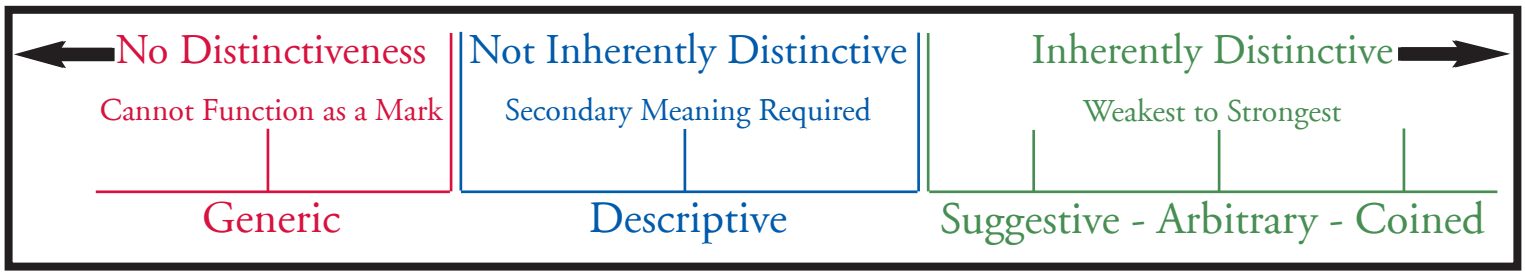
Coined (or fanciful) marks comprise terms that have been invented for the sole purpose of functioning as a trademark or service mark. ZANA is a coined term for analgesics, much like KODAK for film and XEROX for copiers.

Arbitrary and coined terms like TIGER and ZANA used with aspirin are among the strongest types of marks not because they describe (or even are suggestive of) aspirin but because they have a lasting impact on the consumer's mind. Moreover, courts afford such marks a broad scope of protection and more readily view use of a similar mark for closely related products by competitors and non-competitors alike as an infringement. Those qualities – strong consumer recognition and broad legal protection - deliver return on investment.

Where do your marks fall on the distinctiveness spectrum?

For more information, contact Tom F. Dunn at tdunn@mbbp.com.

Morse, Barnes-Brown & Pendleton represents biotechnology, medical device and pharmaceutical companies and research institutions in a wide range of legal matters that arise in connection with the development, protection and commercialization of their unique life science technologies. To discuss your company's specific legal needs, and how our experienced attorneys might meet them more efficiently and responsively, please contact us at 781-622-5930 or mbbp@mbbp.com.



CLIENT SPOTLIGHT

MBBP client Allegro Diagnostics (www.allegrodx.com) has received a $2.8 million Phase I/II Fast Track Small Business Innovation Research grant from The National Cancer Institute to be used for a clinical study of its lung cancer diagnostic test, BronchoGen™. Allegro Diagnostics, a Boston-based molecular diagnostic company, is enrolling 800 people throughout the United States to receive the BronchoGen™ test, which studies the RNA gene expression levels of patients' airway-lining cells that are accessed during bronchoscopy.

According to the Allegro Diagostics press release, BronchoGen™ uses easily accessible cells lining the airway (bronchial epithelial cells) obtained during bronchoscopy and analyzes their RNA to measure gene expression levels. Allegro's scientific team has found that specific sets of genes are over- and under-expressed in current or former smokers with lung cancer as compared to those without lung cancer. This finding was validated in a 164 patient study published in Nature Medicine in March, 2007. Importantly, the BronchoGen™ approach does not require an actual tissue sample from a suspicious nodule or lesion, which often must be accessed through highly invasive procedures that pose significant risks to the patient.

Bronchoscopy is one of the most common diagnostic modalities used to assess patients for suspicion of lung cancer. Performed over 300,000 times a year in the U.S. in such patients, bronchoscopy has relatively low sensitivity for detecting disease in those patients who have it, leading to a high number of false negative results. Guidelines from the American College of Chest Physicians state that when a bronchoscopy is non-diagnostic or negative and suspicion of lung cancer remains, a clinician should pursue additional diagnostic procedures to assess the patient's status.

"The NCI support for our trial is highly encouraging news for current or former smokers at risk for lung cancer, and will propel the development of BronchoGen™. It will also help Allegro Diagnostics extend its scientific platform into other areas," said Dan Rippy, President & CEO of Allegro. "Lung cancer patients generally have a very poor prognosis because most are diagnosed with late stage disease. BronchoGen™ may help clinicians to detect disease earlier and reduce unnecessary medical procedures in those patients who do not have lung cancer."

About Allegro Diagnostics
Allegro Diagnostics was founded in 2006 to develop and commercialize molecular diagnostics in lung cancer and other pulmonary diseases using proprietary gene expression technology originating within the Pulmonary Center at the Boston University School of Medicine. The company's initial focus is on earlier stage, more accurate diagnosis of suspected lung cancer. Allegro Diagnostics is privately funded by Kodiak Venture Partners, Catalyst Health Ventures, and Boston University. For more information, visit the website of Allegro Diagnostics at: www.allegrodx.com.