Vector

MBBP Life Sciences Newsletter

Summer 2016

MBBP Firm Highlights

Recent Digital Health Financing

MBBP represented client **Persivia Holdings, Inc.** in its acquisition of digital health company Alere Analytics, Inc. from Alere in May 2015, and in the acquisition of IHM Services Inc. and a $5 million venture capital and angel financing in staged tranches between August 2015 and March 2016. MBBP had also represented the predecessor of Alere Analytics, DiagnosisOne, Inc., which was acquired by Alere in 2012, and the co-founders of DiagnosisOne and Persivia, Mansoor and Fauzia Khan.

MBBP Adds Two Attorneys

Morse, Barnes-Brown & Pendleton, PC expanded its litigation group and enhanced its PIFA team with the addition of two attorneys.

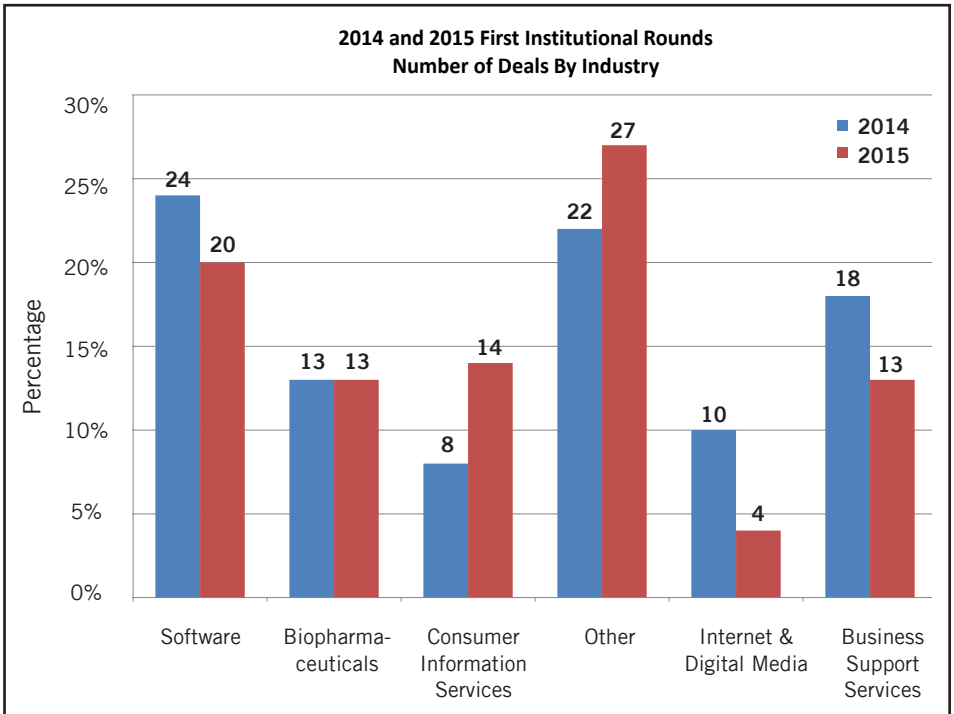
Weatherly Ralph Emans, Corporate Senior Attorney - As a member of the firm's PIFA team in the corporate group, Weatherly focuses her practice primarily on private investment funds, including private equity funds, venture funds, hedge funds and funds of funds. Weatherly's practice also includes venture capital transactions and providing general corporate advice to early stage companies.

Amanda R. Phillips, Litigation Associate - As a member of the firm's litigation practice, Amanda focuses her practice on commercial civil disputes and securities litigation, and has broad experience working with clients under investigation by federal and state government agencies.

2016 Life Sciences Panel Series

At the second of our Life Sciences panel Series: "Laying the Foundation for Growth: Entity & Equity", experts discussed whether a corporation or a limited liability company is the "Right Stuff" for building an emerging company, and how to structure and optimize the equity compensation of the team.

MBBP's John Hession moderated the panel, which included Marc Cote of Accellient and Jeff Solomon of Katz Nannis + Solomon. Stay tuned for details on Panel 3 in the fall.



Software companies had the largest number of financings in 2015 as they have in previous years. Companies focused on consumer information services had an uptick over the prior year with a corresponding decline in the number of deals for business support services companies. Internet and digital media companies also had a downturn in the number of transactions in 2015.

Wait a Minute Mr. Postman...

Sooner or later many companies with a successful product or service will receive an overture from a patent holder. Some are almost friendly, proposing a potential mutually beneficial business relationship involving the patent. Others are decidedly less so, leveling claims of patent infringement and seeking immediate termination of the activity or product sales and/or significant financial compensation. This entire range of written communications is commonly referred to as "demand letters."

So - what's the next step if your company receives a demand letter?

First, take a moment to appreciate your company's success - generally a patent holder will contact only companies which have, or are poised to have, a commercially successful product or service. Then, begin thinking strategically; there are both offensive and defensive tactics which can be brought to bear depending on the situation.

- ***Obtain as much background information about the patent and patent holder as possible.*** Does the patent holder have a competing service or product, or are they a non-practicing entity? Has the patent been involved in prior litigation or patent office proceedings (inter partes review, reissue, etc.)? Are there other patents or applications in the patent family? Is there information available about similar notifications to other companies?

- ***Compare your products and services to the claims of the patent.*** If the demand letter identifies a particular product or service, begin there. Generally a careful review of the claims of an issued patent should be undertaken by a patent professional, because the construction of claim terms must be determined after review of the application and the prosecution history. However you, as most knowledgeable about your company's products and service, can provide invaluable information and perspective on the properties of your company's product or service.

- ***Consider the wording of the letter.*** Interestingly, demand letters which are too strongly worded and/or provide too much information can put the recipient in a position to take immediate action in court if desired, asking the court to hold that the patent is invalid, unenforceable, and/or not infringed. On the other hand, demand letters which are too vague and uninformative may not provide enough information for you to make any kind of strategic decision. It still may be prudent to respond to even a vague letter, however.

- ***Review your company's own IP portfolio to identify potentially useful properties.*** Particularly in technology fields with complex patent landscapes, your company may already have rights in patents or patent applications relevant to the products or activities of the party that has contacted you. These may be especially valuable to prevent litigation and instead focus the parties on licensing or cross-licensing possibilities. In extreme cases, you might consider having your company acquire rights in key intellectual property for the express purpose of asserting it against the party that contacted you.

- ***Determine whether to respond.*** Patent holders can have different motivations for demand letters. Some may be interested in opening a dialog, for example, to better understand whether there is actual infringement occurring, to pave the way for a licensing (or cross-licensing) discussion, etc. Others may care only about putting your company on notice that their patent exists, as certain of the patent holder's legal rights may begin only when the potential infringer becomes aware of the patent. Still others send out many such demand letters in the hope that some or all of the recipient companies will enter into quick financial deals rather than risk potential legal action.

- ***Make sure that the letter is "just" a demand letter.*** If the letter encloses a complaint, summons, subpoena, or any other legal document you should notify your company's attorney immediately. Court rules provide for strict deadlines for responding to such documents. In the worst case, failure to respond within the allotted time

period can lead to entry of a default judgment against your company. Even if the letter simply states that the sender will start a lawsuit if a response is not received by a certain date, you should contact your company's counsel to determine the appropriate response, which may be for your company to initiate a proceeding before the sender can act. In such instances time is of the essence.

Your company's initial response, if any, can set the tone for future interactions and may also establish or forfeit certain of your company's legal rights; thus the approach should be carefully considered both from the business and legal perspectives. For more information, contact Lisa Warren at *lwarren@mbbp.com*, or John Tumilty at *jtumilty@mbbp.com*.

Supreme Court Denies Sequenom's Petition to Clarify Scope of *Mayo* in *Sequenom v. Ariosa*

On June 27, 2016, the United States Supreme Court denied a Petition for Writ of Certiorari filed by Sequenom, Inc. requesting the Supreme Court to clarify the scope of its *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012) decision, as applied to Sequenom's claimed inventions. The *Mayo* decision, which held that a method correlating a drug dosage regimen and levels of the drug in the blood was an unpatentable law of nature, has had the profound effect of narrowing the scope of patent-eligible subject matter in the United States and has cast doubt on the validity and enforceability of previously-issued United States patents.

Sequenom's discovery related to the discovery of cell-free fetal DNA circulating in maternal plasma, which was used to invent a groundbreaking test for detecting fetal genetic conditions in early pregnancy, and thereby avoid subjecting the mother to dangerous, invasive techniques such as amniocentesis. The Federal Circuit agreed that Sequenom's invention combined and utilized man-made tools of biotechnology in a new way that revolutionized prenatal care; however, in view of *Mayo*, such inventions were deemed patent-ineligible as a matter of law, since their new combination involved only a "natural phenomenon" and techniques that were "routine" or "conventional" on their own.

> The Supreme Court's denial of certiorari preserves the Mayo decision and confirms the Federal Circuit's holding that Sequenom's groundbreaking prenatal test was not patent-eligible.

Despite the Federal Circuit's reluctant holding that Sequenom's claimed inventions were patent-ineligible, multiple judges wrote separately to explain that while this result was probably not intended by *Mayo*, that decision controlled and only the Supreme Court could clarify *Mayo's* reach to prevent a "crisis of patent law and medical innovation." Sequenom's petition asked the Supreme Court to clarify the scope of its *Mayo* decision in view of Sequenom's claimed inventions, and to determine whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery.

Since Sequenom's filing of their petition, twenty two amicus briefs have also been filed urging the Supreme Court to grant certiorari. The Supreme Court's denial of certiorari preserves the *Mayo* decision and confirms the Federal Circuit's holding that Sequenom's groundbreaking prenatal test was not patent-eligible.

For more information, contact Stanley Chalvire at *schalvire@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.

iSPECIMEN®

Overview
iSpecimen is a trusted, one-stop source of customized human biospecimen collections. Compliantly sourced from our diverse partner network of hospitals, labs, biobanks, blood centers, and other healthcare organizations, our solid tissues, biofluids, and cells are delivered directly into the hands of biomedical researchers using our unique, turnkey technology. Scientists gain access to a ready supply of the high-quality, richly-annotated specimens they need from the patients they want. Supply partners gain an opportunity to further contribute to biomedical discovery as well as their bottom line.

The Technology
Our technology consolidates the specimen procurement process by watching patient and specimen flow in real time across our vast network of supply partner sites. When a match to a research request is made, lab personnel are instructed to pick, pack, and ship the specimens to our customers. Our technology interfaces seamlessly with existing IT infrastructure at partner sites, where we implement free of charge, and is fully compliant with all relevant regulations, including HIPAA.

The Biospecimens
The specimens we source may be remnant, banked, or collected for research use specifically. Our offerings include solid tissues, biofluids, and cells paired with de-identified patient and laboratory data. Some of the many sample types we source include whole blood, plasma, serum, urine, stool, cancer blocks and slides, fresh or frozen tissue, bone marrow, stem cells, and more. Because our technology taps into electronic medical record data where available, researchers can request specimens based upon specific criteria such as lab tests and results, demographics, diagnoses, medications, and procedures.

Value for Partners and Customers
The iSpecimen solution creates value for our supply partners and researchers alike. Traditional specimen procurement methods are highly fragmented and inefficient, requiring researchers to approach dozens of labs or biorepositories to obtain the specimens they need, often with little compliance oversight. Specimen quality and quantity remain problematic and accompanying medical data may be limited. The iSpecimen solution solves these problems for researchers, gives supply partners the opportunity to contribute compliantly to medical research and earn revenue, and systematizes what has long been an ad-hoc process. When specimen matches are made, our supply partners not only gain new revenue, but also play an instrumental role in contributing to important medical research.

Support from Patients
Patients are largely supportive of contributing their specimens to research. A collection of studies amassed by *Public Responsibility & Medicine in Research* showed that 53-90% of patients were willing to allow such use. A study from *Biopreservation & Biobanking* found that 90% of tissue donors felt they were "contributing" and supporting a "good cause," and that it "feels good to help."

For more information about iSpecimen, please visit www.ispecimen.com. If you're interested in procuring specimens, please email *sales@ispecimen.com*. If you have specimens to contribute to our network, please email *partners@ispecimen.com*.

MORSE BARNES-BROWN PENDLETON PC