

Vector

MBBP Life Sciences Newsletter

Spring 2017

MBBP Firm Highlights

David Czarnecki and Stanley Chalvire Elevated Within the Firm

We are pleased to announce that David Czarnecki and Stanley Chalvire have been elevated to Member.



Dave is exceptionally proficient in guiding both buyers and sellers through a wide range of corporate transactions. His

practice includes a special emphasis on advising emerging growth companies on a wide range of legal matters, including formation, capitalization, equity incentive plans, employment issues, corporate governance, securities issuances, and taxation.



Stan is a Registered Patent Attorney, specializing in the licensing of intellectual property and related counseling. Stan

advises clients in developing and implementing strategies to protect their intellectual property and advises clients with respect to a variety of related strategic collaborations, with a particular focus on clients in the life sciences industry.

Amanda Phillips Named 2017 Up & Coming Lawyer



Litigation associate Amanda Phillips has been named a 2017 Up & Coming Lawyer by *Massachusetts Lawyers Weekly*. The

recognition is awarded to a select number of attorneys who have been practicing for fewer than 10 years but whose professional achievements are noteworthy and whose service to the community is also significant.

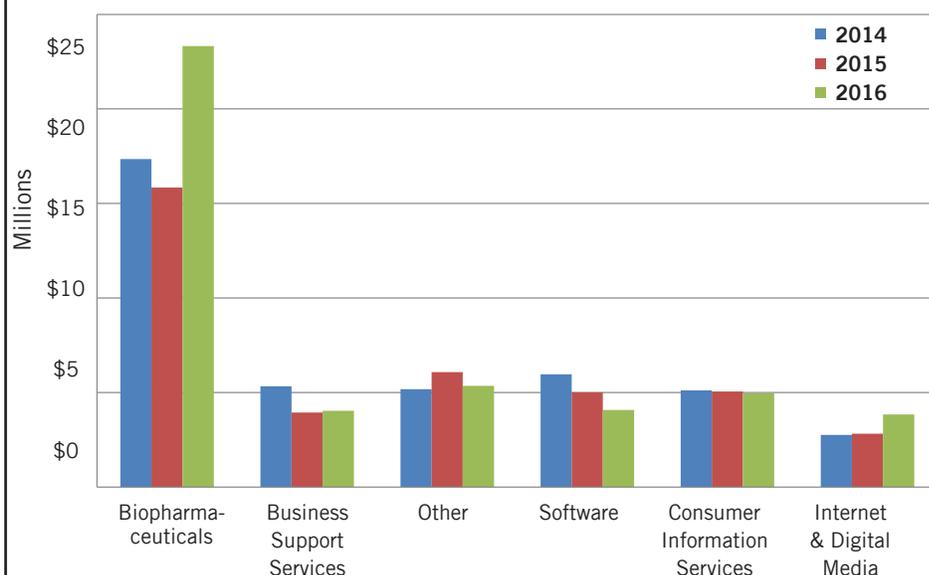
Corporate Attorney Michael Jabbawy Joins Firm as Partner



Michael's practice is focused primarily in the areas of emerging and growth technology companies, venture capital, M&A transactions, and corporate governance.

As a member of the Corporate Department, Michael advises technology and other emerging companies through each stage of growth. Prior to joining MBBP, Michael was a member of the Technology Companies group at Goodwin Procter LLP.

2014-2016 First Institutional Rounds Average Investment*



* By default, the average investment amount assumes that all authorized shares of preferred stock have been issued, but the final data also takes into account information gathered from companies.

Recent Life Sciences Transactions

John Hession and Erik Thompson helped structure and consummate a convertible debt investment in **iSpecimen**, a biorepository company connecting Pharma and research organizations with hospitals and academic medical centers and other suppliers of tissue and fluid samples.

John Hession and Erik Thompson helped structure and consummate an investment in **Orionis Biosciences**, an early-stage drug discovery company in the oncology space.

John Hession and Erik Thompson helped structure and consummate an equity investment in **First Light Biosciences**, a diagnostics company involved in hospital-acquired infections and pathogens.

John Hession and Ryan Perry helped structure and consummate an equity investment in **Manus Biosynthesis**, a company involved in the bio-engineering and bio-manufacturing of flavors and fragrances.

Freedom to Operate: Prevention is the Best Medicine

Launching a new product or service can be fraught with uncertainty and involve large expenditures of limited resources. An FTO opinion can reduce uncertainty and provide some insurance against loss from an unfavorable finding of infringement of another's patent.

An FTO opinion makes a determination whether a product or service infringes issued patents. In other words, the opinion indicates whether or not there is "freedom

to operate" the product or service within the patent landscape. Often, FTO opinions also identify patent applications that, if later issued as patents, may be problematic.

I already have a patent and/or a patentability opinion; do I need an FTO opinion as well?!

A patent gives the holder the power to stop others from making or using the product or service but does not give the holder the right to practice the invention. There are many instances where practicing the patented product or service would infringe another patent. For instance, Patent A may claim a method of making a drug by steps 1, 2 and 3. Another patent claims only steps 1 and 2. The inclusion of step 3 allowed the method of Patent A to be patented but performing the patented method may still infringe the other patent. Alternatively, Patent A may claim a new drug. However, the method of producing the new drug may infringe another patent. Thus, possessing Patent A or a favorable patentability opinion regarding Patent A does not necessarily show that the invention of Patent A can be practiced without infringement.

Ok, I see the value in an FTO opinion. How much do they generally cost?

The cost of a formal FTO opinion is often in the \$10,000 to \$30,000 range. There are often a lot of initial patents to examine and construing the meaning of potentially conflicting claims can be time intensive. However, an FTO

opinion may help prevent substantial losses from having to withdraw or reconfigure a product or service after market entry. Further, the findings of an FTO opinion may initiate negotiations with a potential licensor before market entry, obviously a far better time point than after market entry. Possessing an FTO opinion can also help prevent the award of triple damages in an infringement suit as evidence that the infringement was not willful.

When should I obtain an FTO?

Ideally, an FTO opinion should be prepared as soon as most of the specifics of the product or service are set. Having a clear picture of the product or service will improve the efficiency of the patent search and the applicability of the FTO opinion. The earlier the FTO opinion is prepared, the less time and money will be wasted if the product or service needs to be modified or shelved due to infringement concerns.

The launch of a new product or service can involve a tremendous amount of time and money. If a competitor can show that the new product or service infringes their patent, these resources may be wasted. A Freedom to Operate (FTO) opinion can reduce the possibility of this scenario, conforming to the old maxim that "Prevention is the Best Medicine."

For more information, contact Bill Schmidt at wtschmidt@mbbp.com.

The Patent Process: Get on the Fast Track

One of the biggest frustrations for patent applicants is the incredibly slow pace at which an application proceeds from filing to receipt of a substantive examination report to allowance. On average it takes 15.7 months for a patent application to receive even a first substantive examination report, though there is significant variability across technology areas. The Patent Office has recognized this problem and implemented several initiatives which attempt to address the problem from different angles. Two programs in particular have gained traction: the Patent Prosecution Highway (PPH) and Track One Prioritized Examination.

The PPH, for which there is no fee, leverages the positive results of examination in one participating jurisdiction to jump start examination of corresponding claims in another participating jurisdiction. Upon receiving an indication of allowability of at least one claim in a first country (for example, Canada, perhaps under their expedited examination program), an applicant may request fast track examination of corresponding claim(s) in a corresponding patent application pending in a second country (e.g., the US). Notably an applicant can capitalize on an indication that a claim meets the requirements for novelty and inventive step even at the PCT stage as the requisite “first country” as long as the examining authority is one of the participating countries. Due to the popularity of this program, there has been a recent backlog in the US

in determining that an application qualifies for participation in the program, though the PTO has devoted resources to this problem in an effort to reduce the time to decision to 2-3 months. Once an application has been accepted into the PPH program, a first substantive examination report is typically issued in about half the time it would normally take (7.5 months in PPH applications vs. 15.7 months for non-PPH applications), and that first report is an allowance about 20% of the time (compared with 14% in non-PPH cases). Overall PPH applications have a higher allowance rate than non-PPH cases (84% vs. 68%), owing to the fact that the claims presented have a greater likelihood of novelty and inventive step due to the prior examination in the first country. For those seeking a cost-effective approach and who are willing to conform their claims to the allowed claims of another jurisdiction, the PPH may be a viable option.

The Track One program, on the other hand, requires no connection to another application and does not place limitations on the claims which can be presented (aside from limiting each application to 4 independent claims and 30 total claims). Under the Track One program the goal is to move an application from grant of a petition requesting entry into the program to final disposition within twelve months. The fee for the Track One program is substantial (\$4000 for a large entity, \$2000 for a small) and is required in addition to all the regular filing and examination fees. Upon grant of a petition to enter the Track One program, which for a new application must be made

before the first substantive examination report is issued, the average time to first substantive examination report is 2.1 months. Moreover, the average pendency of the application from entry into the program to final disposition is 6.5 months. One trap for the unwary, however, is that final disposition includes not only Notice of Allowance, but also Notice of Abandonment and Final Rejection. Thus the primary value for the Track One program is in obtaining a first examination report quickly and subsequently achieving a fast response to the arguments and amendments an applicant may submit in response. Thereafter the benefits end, and the application reverts to the normal timeline. This head start can often be considerable, however, particularly in technology areas in which the time to first substantive examination is measured in years. The Track One program presents a faster, albeit more expensive, option for expediting examination.

To learn more about which program is best suited to get your patent application on the fast track, contact Lisa Warren at lwarren@mbbp.com.

Ownership of Arising Inventions in Joint Development Agreements

Collaboration remains a valuable means of fostering innovation and advancing scientific, clinical and commercial objectives. Towards that end, two or more parties contemplating a collaboration often consider entering into a Joint Development Agreement, where they define, among other things, their respective contributions and responsibilities

towards their common objectives. These types of collaborations require a careful and thorough consideration of the disposition of intellectual property rights that may arise as a result of each party's performance of its responsibilities under such collaborations.

Under U.S. Patent Laws, each inventor is the owner of his or her patented inventions, absent a written agreement to the contrary. Similarly, when there are multiple owners of a patented invention, each co-owner has the right to make, use, and sell the patented invention in the U.S. without the consent of and without accounting to the other owners, again, absent a written agreement to the contrary.¹

These "default" ownership provisions are typically inconsistent with the objectives of the parties to a Joint Development Agreement. As a result, a key term of these Joint Development Agreements concerns defining each party's interests in any inventions arising as a result of their efforts thereunder. This frequently involves the parties pre-negotiating their respective rights in any such arising inventions, often leading to disagreements between the parties as to who will own and control the rights to such arising inventions. Seeking a fair, equitable solution to a stalemate regarding the ownership of any arising inventions, the parties may consider jointly owning these arising inventions, which is an outcome that the parties should

fully appreciate, since each joint owner will have the right to make, use, and sell the patented invention in the U.S. without the consent of and without accounting to the other owners. This outcome may also lead to problems, for example, stemming from the parties' potentially divergent plans for the subject inventions. These problems may be further compounded by the fact that, in order to enforce a jointly owned U.S. patent against third party infringers, each of the joint owners must agree to participate in the third party infringement suit. Further complications may arise outside the U.S., where the laws of some jurisdictions vary significantly and, for example, may prevent the parties from licensing or enforcing their respective interests in the arising inventions without the consent of the other owner, absent their agreement to the contrary.

Parties to a Joint Development Agreement should carefully consider how the ownership of arising inventions will be addressed and, if they elect to jointly own those inventions, they should do so with a clear understanding of the implications associated with this structure, both in the U.S. and abroad.

Alternative structures that can be considered in lieu of joint ownership may include, for example, allowing one party to own all rights to the arising inventions, coupled with granting the other party a license to such inventions or an option to negotiate such a license in the future. Another alternative may be for all joint owners to form a separate corporate entity for the purposes of holding, licensing, commercializing and/or enforcing the arising inventions, the new corporate entity to be owned and controlled by the parties.

If the parties nonetheless agree to jointly own any arising inventions, the Joint Development Agreement should clearly define each owner's respective rights in the arising inventions. For example, the parties can agree that neither one can exploit, out-license or enforce such arising inventions without the other party, effectively forcing them to act in concert. Alternatively, the parties can agree to divide the interest to any arising inventions into discrete fields of use (e.g., therapeutic uses vs. diagnostic uses), and each party would retain rights within its pre-defined field, allowing each party to maintain some exclusivity to these inventions, albeit narrower than the full rights. The parties can also agree in advance to share in any proceeds or royalties that they each receive as a result of their exploitation of such jointly owned arising inventions, and/or define their respective rights to enforce such inventions against third parties.

Parties to a Joint Development Agreement should carefully consider how the ownership of arising inven-

¹ Note that technically patents do not confer a right to make, sell or use, but instead confer the right to exclude others from making, selling, or using the claimed inventions.

tions will be addressed and, if they elect to jointly own those inventions, they should do so with a clear understanding of the implications associated with this structure, both in the U.S. and abroad. Since the applicable domestic and foreign laws governing the rights of joint owners will often conflict with the parties' intentions, the parties should clearly pre-define their rights and expectations in writing and give careful consideration to whether alternative ownership structures may be used to satisfy each party's objectives.

For more information or to discuss the implications of joint ownership of arising inventions or patent licensing, contact Stan Chalvire at schalvire@mbbp.com.

GUEST COLUMN

For Skilled Immigration to the U.S., The Times, They May Be Changing

The last year of the Obama Administration saw an increased activism by President Obama in the area of skilled immigration. Through Executive Orders and regulations, the President made a number of important changes including providing Employment Authorization for spouses on H-4 visas, increasing the period of post-graduate employment authorization for foreign students in STEM fields (Science, Technology, Engineering and Mathematics), increasing the number of academic fields included in STEM and formalizing a grace period for foreign nationals on H-1B visas that find themselves between jobs. These changes were met with praise from

technology and life science companies that rely heavily on skilled immigration and that have pushed Congress for years to enact new laws that would streamline and enhance the skilled immigration process. President Obama signaled to that community that he intended to ease the processes by which U.S. companies recruit, hire and retain skilled foreign professionals.

In contrast, President Trump, on the campaign trail and in the first few months of his Administration has signaled general hostility towards skilled immigration. The Trump Administration's only concrete efforts in the immigration arena to date, two Executive Orders banning Syrian refugees and the citizens of 7 (now 6) predominantly Muslim countries, have been stifled by the Federal courts. What is left, however, is a fairly consistent public record by the President as well one leaked Executive Order on the topic of skilled immigration. Whether these will turn into policy, regulations or law is not certain at this point, but they do provide some insight into the current Administration's view of skilled immigration.

The following are several possible trends in the area of skilled immigration that we believe are likely to occur either in response to, or as a result of, the current Administration:

- New Cap-Subject H-1B Visa Will Likely Be Harder to Get – Last year, approximately 240,000 people applied for the 78,200 new H-1B visas in the first week of April. As a result, and as in years past, USCIS stopped ac-

cepting new H-1B petitions and determined who would get the limited visas available through a lottery system. The odds of being selected in the H-1B lottery process if a person had a U.S. Master's degree were about 45% and the odds of being selected if a person did not have a U.S. Master's degree were about 30%.

With the new H-1B cap season about to begin on April 3, 2017, it is very likely that many more people will try to get out of what they consider to be a vulnerable visa status (F-1 students in STEM fields and TN status holders) and into H-1B status. As a result, we project that the number of applicants in the 2018 H-1B cap process are likely to increase significantly, making it that much more difficult to obtain an H-1B visa this year.

- The Potential for Significant Delays in the Visa Application Process at U.S. Consulates Abroad – President Trump's first Executive Order (now tied up in Federal court) terminated the "visa interview waiver program", which was used primarily by foreign nationals applying to renew certain employment-based visas who had previously gone through a security check process. In addition, in the third week of March, the State Department instructed all Consular Officers (responsible for issuing visas to foreign nationals abroad), to increase the level of review of each applicant for a visa. These measures are likely to increase the processing time for visa applications at high-volume posts.

The delays could be significant, trapping skilled foreign nationals abroad when they file for their visas.

- Increased Backlogs in the Employment-Based Immigrant Visa Process – The current backlogs in the availability of employment-based Immigrant Visas (also called “Green Cards”) are based on the number of people applying and the annual quotas on available Green Cards. As anxiety over the anticipated actions of the Trump Administration grows, we have seen more and more foreign national employees push their employers to begin Green Card cases for them. This trend will only increase the backlogs in this already very slow process.
- Uncertainty About the TN Program – President Trump has made clear his intent to renegotiate and possibly simply terminate NAFTA, the Treaty that created the TN visa/status program for Mexican and Canadian nationals with U.S. offers in a range of professional occupations. In that process, there is clearly a possibility that the TN program will either be ended or curtailed.

One important piece of evidence of what an activist Trump Administration could do in the field of skilled immigration, is contained in a leaked draft of a new Executive Order specifically on skilled immigration. The President has threatened on

several occasions to issue the Order but so far he has not – and of course we can't be sure whether the provisions contained in the leaked Order will make their way into a final Executive Order. But the language of the leaked Order is startling in the extent to which the Trump Administration could try to roll back rules on skilled immigration. The following are just a few examples of that language from an otherwise lengthy Order – these are instructions to the Secretary of the Department of Homeland Security:

- Within 90 days, review all regulations that allow foreign nationals to work in the U.S. to determine which of them violate immigration laws or are otherwise not in the national interest and should be rescinded, and then propose a regulation to rescind or modify such regulations.
- Propose a rule to restore the integrity of the employment-based nonimmigrant worker programs and better protect U.S. and foreign workers affected by those programs.
- Within 180 days, begin performing site visits at places of employment for all L-1 nonimmigrant workers and to develop a plan to expand the site visit program within 2 years to cover all employment-based visa programs.
- Propose a rule that will reform practical training programs for foreign students to prevent dis-

advantaging U.S. students in the workforce.

Time will tell how aggressive President Trump intends to be in restricting skilled immigration to the United States. What we know at this point, however, is that the business-friendly skilled immigration policies of the prior Administration may not survive and certainly will not be the hallmark of the current Administration.

Donald Parker is an immigration attorney with the firm Parker Gallini LLP. For more information, contact Don at dparker@parkergallini.com.

PARKER GALLINI

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 mabbp@mabbp.com.



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