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MBBP Quarterly Life Science Newsletter Q2 - 2009

MBBP Continues to Expand Life Science and Intellectual Property Practices

We are pleased to announce that Stanley F. Chalvire, formerly Intellectual Property Counsel and Corporate Counsel at Oscient Pharmaceuticals Corp., has joined MBBP as a member of the firm's Intellectual Property and Life Science practices. Dr. Chalvire holds a Doctor of Pharmacy degree in addition to a law degree, and he is registered to practice before the U.S. Patent & Trademark Office. Dr. Chalvire's practice will focus on patent prosecution and counseling in the areas of pharmaceuticals and small molecule chemistry.

First Recipients of New Loan Program Announced

Two clients of MBBP, Pluromed and Spectra Analysis, were selected as initial recipients of a new state-funded loan program. The Massachusetts Life Sciences Center (MLSC), a quasi-public agency tasked with implementing Massachusetts' $1 billion Life Sciences Initiative, recently announced the awarding of $3.4 million in loans. MLSC's Accelerator Program provides loans of up to $500,000 to early stage companies in Massachusetts engaged in life sciences research and development, commercialization and manufacturing. Following the initial announcement of the program, eighty-eight companies applied to receive the loans. MLSC, with the help of volunteers from academia, venture capital investors, and industry narrowed the pool to seven awardees in a rigorous process that included a double-blind peer review and live presentations from the finalists.

The loans provided under the Accelerator Program to Pluromed, Spectra Analysis and the other initial recipients will match grants and investments from the federal government, foundations, non-profit agencies, institutional investors and other sources of capital. By leveraging other sources of capital, MLSC hopes to provide support to companies at the most critical stages of their development cycle. Support for the Accelerator Program is augmented by the Life Science Center's recently established Corporate Consortium Program, which provides matching funds for MLSC's investment activities. Corporate charter member Johnson & Johnson (NYSE: JNJ) will contribute $500,000 over two years to the Corporate Consortium, and MLSC intends to add additional members over time.

Pluromed, Inc. (Woburn) is pioneering the use of atraumatic vascular gel plugs to improve the safety, efficacy and economics of medical interventions. The company's products address a broad surgery and interventional market, and are based on its patented rapid reverse thermosensitive polymer technology; the plugs are liquid at low temperature and quickly transition to a high viscosity gel at body temperature.

Spectra Analysis, Inc. (Marlborough) is a leading supplier of molecular spectroscopy systems and applications for chromatography. Their current products focus on real-time connection of infrared spectroscopy to gas and liquid chromatography. Its DiscovIR systems make it possible to collect full infrared spectra for each component in a separation, either stand alone or in parallel with mass spectroscopy.

For more information about MLSC's Accelerator Program and other initiatives, contact Joe Martinez at jmartinez@mbbp.com.

Pending Tax Legislation Would Improve R&D Tax Credit Provision

On June 8th Senate Finance Committee Chairman Max Baucus (D-Mont.) and Senator Orrin Hatch (R-Utah) introduced legislation (S. 1203) that would replace the existing research and development tax credit with a permanent simplified version.

Under current law, the research credit generally is equal to 20% of the amount by which a taxpayer's qualified research expenses (such as labor and equipment costs) exceed a specific "base amount" unless the taxpayer elects the "Alternate Simplified Credit," now 14% for tax years after December 31, 2008.

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The proposed legislation would allow the traditional credit to expire in 2010 and increase the Alternate Simplified Credit to 20%of the qualifying expenses. In order to allow companies enough time to shift to the new credit program, companies would be given the option to claim the credit under current law in 2009 and in 2010.

The research tax credit was created as a temporary incentive in 1981. While it has been extended as needed in the past, there is always the chance that it could expire. The proposed legislation bill would make the credit a permanent part of the tax code and eliminate the need for regular extensions.

For more information, contact Robert M. Finkel at rfinkel@mbbp.com.

Immigrant Visa Availability: Options for Highly Accomplished Foreign Scientists to Avoid Visa Backlogs

Foreign workers and their U.S. employers are witnessing unprecedented backlogs in immigrant visa availability, making the path to U.S. Lawful Permanent Resident (LPR) status a virtual obstacle course. Each year 140,000 employment-based immigrant visas are allotted for applicants seeking LPR status, with percentages of those visas allocated by "preference categories." No one country is allowed more than 7% of the total number of visas allocated under a specific category. Backlogs for immigrant visas are now approaching a decade, depending on the employment-based visa preference category and the place of birth of the visa applicant. Two of the most heavily utilized employment-based visa preference categories are the employment-based 2nd Preference (EB-2), for jobs requiring an advanced degrees or for individuals who possess exceptional ability in the sciences, arts or business, and the employment-based 3rd Preference (EB-3), for jobs requiring a bachelor's degree or at least two years' experience. At present there are no visas available for EB-3 applicants, and when they once again become available, they will only be available to individuals for whom sponsorship was commenced some six to eight years ago. Individuals who were born in India and (mainland) China face the longest waits: visas under the EB-2 category are only available to India or China natives if a labor certification or immigrant visa petition was filed on their behalf before January 1, 2000.

> **Backlogs for immigrant visas are now approaching a decade...**

Most foreign nationals who seek an employment-based immigrant visa require sponsorship by a U.S. employer and must obtain "labor certification" from the U.S. Department of Labor before applying for an immigrant visa. In a labor certification, the sponsoring U.S. employer must certify that it has advertised and actively recruited in the local job market to find a qualified, willing, and available U.S. worker for the position but that it was unsuccessful. The process is very regimented and unforgiving, placing form over substance. One data entry mistake on a form or in an advertisement can lead to denial and result in a substantial waste of time and money. The application is also highly consuming both in administrative time and in the time it takes to secure approval (anywhere from 6 months to 2 years) – and that is just the first step.

Highly accomplished foreign scientists and engineers are among the lucky few that have the ability to potentially skirt these long immigrant visa backlogs. How? There are three separate ways: based on immigrant petition under employment-based 1st Preference (EB-1) for classification as (1) an "Alien with Extraordinary Ability"; (2) as an "Outstanding Researcher/Professor"; or (3) as "Alien with exceptional ability" for whom a waiver of the labor certification requirement is "in the National Interest." A petition for classification as an "Outstanding Researcher/Professor" requires sponsorship by a U.S. employer. The other two do not, which means that highly accomplished foreign scientists can self-petition. All three avoid the painful and time-consuming application for alien labor certification – a process which requires the applicant to have a sponsoring U.S. employer and involves the testing of the local job market to show that, despite the employer's good faith recruitment, no qualified, willing, and available U.S. worker applied for the position.

To qualify for "Extraordinary Ability" classification, the applicant must document that he or she is among the top percentile in his or her field and that he or she has sustained national or international acclaim and recognition in the field of expertise. To qualify for classification as an Outstanding Researcher or Professor, the applicant must have at least three years experience in research or teaching, be coming to a lab or university that has documented research accomplishments, and be recognized internationally as outstanding in the field. To qualify for a National Interest Waiver, the applicant must document that: he or she holds an advanced degree and/or is an individual with exceptional ability in the field; that his or her work is of 'substantial intrinsic merit' and national in scope; that he or she stands significantly above his peers with like qualification and training as based on his or her achievements/ accomplishments; and that the national interest would be adversely affected if a labor certification were required.

With the Department of State Visa

Office predicting increasing backlogs, foreign scientists and engineers who potentially qualify for classification under one or more of these categories should strongly consider pursuit of an immigrant visa under the most appropriate classification. Mainland China and Indian born applicants, in particular, will need to seek one of these EB-1 qualifications, if possible, as visas in the EB-2 and EB-3 categories will continue to experience backlogs of many years absent an immigration overhaul.

For more information, contact John J. Gallini at jgallini@mbbp.com.

Minimizing Personal Liability and Conflicts in Down Round Financings

The deteriorating US economy has worsened in the last six months as evidenced by the credit crises, real estate depreciation, and increased unemployment. Venture capital has not been immune, which has resulted in decreasing company valuations, causing companies to consummate down rounds of financing.

A "down round" is a venture capital financing in which new investors place less value on the company than prior investors, translating into a lower price and superior rights to existing investors. Most painful is dilution to existing investors as the company sells more shares than in previous rounds to generate equal capital, thereby eroding stockholders' equity. An alternative is to sell the company, but this may be premature and consummated at a deep discount to existing investors' expectations regarding the optimal exit value.
Significantly, most down rounds are interested director transactions, where certain directors (i.e., a VC director) have a material interest in the deal's outcome that isn't shared by the company, other directors, or shareholders. This

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conflict is exacerbated if they constitute a board majority or exercise material control over its actions.

Most board financing decisions are subject to the Business Judgment Rule (BJR), which assumes the board acted in the company's best interest. Courts uphold such decisions, if challenged, provided that they were made in good faith and with due care. However, because down rounds tend to be insider led, a board's decision regarding the transaction runs the risk of losing the BJR's presumptive protection and being subject to the Entire Fairness Test (EFT). The EFT states that a board's actions will be upheld if the entire transaction is fair as determined by the adequacy of the (i) purchase price, and (ii) process utilized to achieve the price and terms. A court's finding that a board didn't satisfy the EFT can result in personal liability to director(s) and raises questions about the transaction's proper authorization, which could void the deal.

The following independent steps can be taken to effectively negotiate a down round/interested director transaction:

- Create a committee of independent/disinterested directors to evaluate/approve the terms.

- Obtain majority approval from disinterested directors or stockholders after disclosure of all material facts, which may include an independent third party valuation from an investment banker or outside investor leading or participating in the round.

- Initiate a rights offering to existing stockholders to (i) maintain their respective equity percentages, or (ii) limit the down round's dilutive impact, which will be subject to pertinent federal and state securities laws.

Effectively negotiating acceptable terms and conditions in a down round is critical. The above recommendations should limit unanticipated/unnecessary legal issues.

If you would like to learn more about MBBP's venture capital practice or down round financings, please contact Shannon Zollo at szollo@mbbp.com.

Are Non-Compete Agreements at Risk In Massachusetts?

Life Sciences companies take varied steps to protect their substantial investment in proprietary information, trade secrets, and customer good will. Typically, one such step is to require key employees to sign agreements, at the beginning of their employment, to not compete with the company for a period of time following the termination of their employment. The legitimate purpose of such agreements is to protect the employer's interests in its customer good will and proprietary information by preventing former employees from using the access they were given to proprietary information or good will of the employer to unfairly benefit a competitor and

harm the former employer.

Less restrictive agreements, such as non-disclosure and customer non-solicitation agreements, are often viewed as insufficient protections in certain cases involving employees in possession of vital trade secrets or other highly sensitive confidential business information because the damage that can be done by the employee's use or disclosure of this information cannot be discovered until after it has occurred. Only by preventing an employee from working for a competitor, it is often argued by employers, will the former employer's business interests be adequately protected. Although Massachusetts courts have always "disfavored" non-compete agreements as restraints on trade that restrict an employee's ability to earn a living in his or her chosen profession, courts have been willing to enforce such agreements when they are necessary to protect an employer's legitimate business interest and to the extent such restrictions are reasonably drafted (e.g., limited in scope and time).

As drafted, the first bill would make non-competition -- and customer non-solicitation agreements -- unlawful in Massachusetts.

Two recently proposed laws in Massachusetts would abolish or curtail the enforcement of non-compete agreements for employees. This possible shift in the law is of great interest, and -- depending on one's perspective -- also great concern. One side of the debate views restrictive agreements as necessary to protect companies from unfair competition and views an outright ban on non-compete agreements as hostile to business. The other side counters that non-competition agreements stifle innovation and allow established companies to unfairly chill the movement of knowledge workers to smaller start-ups. After all, this side argues, there has been no demise of innovation in California, which has banned non-competition agreements for many years, and, moreover, businesses are already sufficiently protected by existing laws prohibiting the misappropriation of trade secrets.

As drafted, the first bill would make non-competition -- and customer non-solicitation agreements -- unlawful in Massachusetts. House Bill 1794 filed by Representative William N. Brownsberger provides in relevant part:

"Any written or oral contract or agreement arising out of an employment relationship that prohibits, impairs, restrains, restricts, or places any condition on, a person's ability to seek, engage in or accept any type of employment or independent contractor work, for any period of time after an employment relationship has ended, shall be void and unenforceable with respect to that restriction. Whoever violates the provisions of this section shall be liable for reasonable attorneys' fees and costs associated with litigation of an affected employee or individual."

A second bill, House Bill 1799, filed by Representative Lori Ehrlich would substantially curtail existing case law governing the enforcement of non-compete agreements by, among other things, limiting the enforcement of such agreements to employees having total annual compensation of over $100,000, and by further requiring a former employer to pay to a former employee 50% of the employee's compensation or $100,000 during the restricted period. The second bill would not alter existing law covenants governing non-solicitation of customers.

Should either bill become law, either as currently drafted or in modified form, Life Sciences companies will need to review and revise their key employment agreements, and also closely scrutinize internal company practices to ensure that proprietary business information will qualify for protection under laws prohibiting the misappropriation of trade secrets.

For more information, contact Scott J. Connolly at sconnolly@mbbp.com.

MA Biopharma Industry Shines in Dark Economy

The Beige Book is the Federal Reserve Bank's summary of current economic conditions for each Federal Reserve district and is published eight times a year. Each Federal Reserve Bank gathers anecdotal information on current economic conditions in its District through reports from Bank and Branch directors and interviews with key business contacts, economists, market experts, and other sources. The Beige Book summarizes this information by District and sector. An overall summary of the twelve district reports is prepared by a designated Federal Reserve Bank on a rotating basis.

According to the Fed's June "Beige Book": While most businesses in the Boston (First) District reported ongoing declines in sales or orders from a year earlier, a bright spot again this month was the biopharmaceutical industry. With other businesses continuing to struggle and almost all manufacturing and related services in the First District reporting that sales or orders have fallen significantly below year-ago levels, biopharmaceutical businesses reported that sales continue to increase strongly.

For more information, contact Jeff Steele at jsteele@mbbp.com.

"A Patent By Any Other Name" – A Lesson in Ambiguity

If you've seen one patent assignment, you've seen them all. Well, not quite. It's easy to let your mind – and pen - rest upon the drafting language of those who have come before you. After all, why reinvent the wheel? But, even seemingly straightforward IP transfers can cultivate ambiguity, if you look carefully enough. Take the lesson learned from the recent case of Euclid Chemical Co. v. Vector Corrosion Technologies, Inc., 90 USPQ2D 1220 (2009, now on remand).
This case deals with the assignment of a patent. Or patents. No one can really be sure which -and therein lies the problem.

The language of the patent assignment from the inventor to Vector purported to transfer all rights and interest in "my US, Canadian, and European applications for patents and issued US patent, namely" one issued US patent, 2 US applications, a European application, a Canadian application, and "any and all divisional applications, continuations, and continuations in part … and any and all Letters Patent which may issue or be reissued for said invention to the full end of the term for which each said Letters Patent may by granted…"

So, one may ask, how could a continuation-in-part (a "CIP") of this particular patent X conceivably be outside the language utilized above? The "any and all" terminology seems fairly straightforward. "Any" means "every" or "all." "All" means "any."

The issue hinges upon this: what if the CIP were to have issued before the assignment was executed? Now the potential ambiguities in the assignment start to surface. The CIP was no longer an application at the time the assignment was signed, it was an issued patent. Yet, the explicit language of the assignment refers only in the singular to the "issued US patent." Surely, if the drafter had meant to include the issued CIP, he or she would have used the plural "issued US patents" to include both patent X and this specific issued CIP, or referenced the patent number of the CIP. Furthermore, the later language in the assignment states "any and all divisional applications, continuations, and continuations in part thereof…" It is also worth noting that the claims of the CIP might be drawn to an invention distinct from "the invention" of the parent patent and not disclosed in the parent patent. Thus the CIP might have been intentionally excluded.

As such, the Court of Appeals for the Federal Circuit (CAFC) determined that the language could be interpreted to mean that the assignment encompasses only those divisionals, continuations, or CIPs which were applications at the time of execution, or might be later filed. Back to the district court for review of extrinsic evidence to resolve the ambiguity, the CAFC decreed.

With some additional attention to the details, this potential ambiguity in the assignment could have been avoided. For example, the inclusion of language such as "…and any and all divisional, continuation, and continuation-in-part applications of patent X and patents resulting from said applications, whether granted prior to or after the execution date of this assignment..." would have done the trick. Perhaps use of the word "including" rather than "namely" would have been helpful. Alternatively, the CIP could have been explicitly excluded from the grant of rights. A few small tweaks, and the scope and intent of the assignment become indisputably clear. Take the time to look at familiar drafting language with new eyes. It could save you from future episodes of semantic squabbling.

For more information, contact Ashley K. Long at along@mbbp.com.

CAFC Split on Product-by-Process Claims Finally Resolved

A product-by-process claim in a patent specifies a product with reference to the method by which the product is made (e.g., product X produced by, obtained by, made by, obtainable by, etc., process Y). Historically, the use of product-by-process claims was reserved for circumstances in which the product could not be defined or distinguished from the prior art except by reference to the process by which the product was made. Inherent in this format was the presumption that the process by which the product was made imparted distinctive characteristics to the product. However, today product-by-process claims are commonplace even where the process imparts no distinctive characteristics to the product in comparison with prior art products.

The U.S. Patent & Trademark Office (PTO) analyzes patentability of a product-by-process claim based on the product itself, without deference to its method of production. That is, if the product in the product-by-process claim is the same as or obvious from a prior art product, the claim is unpatentable even though the prior art product was made by a different process.

Interestingly, the law with regard to infringement of product-by-process claims has been less clear. Different panels of

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the Court of Appeals for the Federal Circuit have set out differing opinions on the question of whether process limitations of product-by-process claims are limiting. One panel held that product-by-process claims cover any product that is the same as the product produced by the recited process steps (i.e., that the claim is not limited by the recited process steps). This panel reasoned that product-by-process claims must be considered the same way for both validity (or patentability) and infringement; that is, the claims may not be construed one way in order to obtain their allowance and in a contrary way with regard to infringement. A different, subsequent panel held that product-by-process claims cover only those products that are, in fact, produced by the recited process steps.

Since 1992 this split at the Federal Circuit has made it difficult to determine the scope of product-by-process claims and to assess whether a product made by a different process infringed such claims. Happily, the Federal Circuit has finally reviewed this question *en banc* and brought clarity to the picture.

In Abbott Labs v. Sandoz (Fed. Cir. 2009), the Court of Appeals for the Federal Circuit, sitting *en banc*, chose to follow the line of cases holding that infringement of a product-by-process claim requires practicing the claimed process steps. Thus, one may produce the claimed product using a different method and avoid infringing a product-by-process claim.

This decision results in an interesting dichotomy: in order to be patentable in the eyes of the PTO, a product-by-process claim must define a novel and unobvious product without reference to the process by which it is made. However, such a claim will not be construed to cover all such products when the patent is enforced; rather the claim will only cover a product produced by the recited process. Accordingly, patent applicants are well advised to include claims to the novel and unobvious product *per se*, perhaps including unique properties conferred by the process of making it but without reference to the process itself, in order to preserve the broadest claim scope.

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Trademark Use in Clinical Trials: Use in Commerce?

U.S. trademark applicants must, as a condition of obtaining a U.S. registration, establish use of their mark by displaying the mark on their goods when transported or sold in interstate commerce in the ordinary course of business. That standard contemplates transporting or selling a reasonably high volume of goods to the consumer with a relatively high degree of both frequency and continuity, which seems to preclude limited use of a mark during pre-clinical and clinical trials. Or does it?

Clinical Trials Conducted Within the U.S.

In G.D. Searle & Co. v. Nutrapharm, Inc., 1999 WL 988533 (S.D.N.Y.), Searle relied on shipments made in the course of its clinical trials conducted in the U.S. to assert rights in its unregistered CELEBRA mark to allege infringement arising from Nutrapharm's use of the CEREBRA mark. In pressing its claim, Searle presented evidence that it had conducted FDA-approved clinical trials, during which it shipped celecoxib under the name CELEBRA to an independent laboratory in the U.S., and had used the CELEBRA mark in ongoing clinical trials. Searle also submitted a declaration alleging that it had commenced Phase III clinical trials for celecoxib, involving patients in a clinical setting approximating the environment in which the drug would be used. The declaration stated that Searle used the CELEBRA mark on labels affixed to cartons of celecoxib during an open label safety study as part of its Phase III clinical program. Searle further averred that it had shipped to selected clinical investigators and hospitals throughout the country approximately 1,400 cartons of celecoxib bearing the CELEBRA label, and continued to make shipments at an approximate rate of 300 cartons per month.

Nutrapharm moved to dismiss on the ground that Searle had not made a bona fide use of the CELEBRA mark in the ordinary course of trade because neither the shipments made for clinical testing nor the pre-sale advertising and promotional activity constituted a bona fide use of the mark in commerce. Nutrapharm argued that such shipments did not meet the requirement of bona fide use because the testing laboratories were not purchasing or otherwise acquiring the drug as consumers, and laboratory testing did not create any association between the mark and the product in a significant segment of the purchasing public.

The court first reviewed the standard for determining "use in commerce" as set forth in Section 43(a) of the Lan-

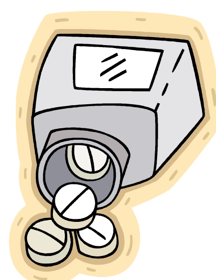
> While the purpose of the amendment was to preclude token use of a mark undertaken solely to claim use in commerce to facilitate registration, Congress understood that certain uses, although limited, were genuine.

ham Act, then turned to the legislative history of the Trademark Law Revision Act of 1988, which became effective in 1989:

In the legislative history discussing the 1989 Amendment to the Lanham Act, the Senate Judiciary Committee Report and the House Report cite as an example of sufficient use in commerce a pharmaceutical company's shipment to clinical investigators during the FDA approval process. S.Rep. No. 100-515, at 44-45 (1998) (other citations omitted) (emphasis added).

While the purpose of the amendment was to preclude token use of a mark undertaken solely to claim use in commerce to facilitate registration, Congress understood that certain uses, although limited, were genuine. Based on the statutory language and the legislative history, the Court concluded that Nutrapharm had not shown, beyond any triable issue of fact, that Searle's use of the mark in commerce was not genuine, and therefore denied Nutrapharm's motion to dismiss.

Pre-Clinical Trials Conducted Outside the U.S.



More recently, in Alfacell Corporation v. Anticancer, Inc., 2002 WL 31121389 (Trademark Tr. & App. Bd.), Alfacell petitioned to cancel Anticancer's ONCASE mark based in part on a claim that Anticancer's drugs were not the subject of any ongoing clinical trial in the U.S. Specifically, Alfacell argued that Anticancer's activities did not constitute "use in commerce," alleging that pre-clinical trials which take place in foreign countries do not constitute "use in commerce" inasmuch as Congress lacks authority to regulate clinical trials outside the U.S.

In response, Anticancer maintained that it had sold its pharmaceutical products in interstate and foreign commerce for use in connection with pre-clinical and clinical studies; that in connection with such sales, it had placed labels bearing the ONCASE mark on bottles containing the pharmaceutical products; and that shipments of pharmaceuticals for the purpose of clinical trials constitute "use in commerce" within the meaning of the Trademark Act.

The question before the Trademark Trial and Appeal Board (TTAB) was whether Anticancer's shipments of its pharmaceuticals for purposes of clinical trials within the U.S. and to foreign countries constituted "use in commerce."

Like the Court in G.D. Searle, the TTAB began its analysis with the text of the statute and then turned to the legislative history of the Trademark Law Revision Act of 1988:

While use made merely to reserve a right in a mark will not meet the standards, the [House Judiciary] Committee recognizes that the "ordinary course of trade" varies from industry to industry. Thus, for example, it might be in the ordinary course of trade for an industry that sells expensive or seasonal products to make infrequent sales. Similarly, a pharmaceutical company that markets a drug to treat a rare disease will make correspondingly few sales in the ordinary course of its trade; the company's shipment to clinical investigators during the Federal approval process will often be in its ordinary course of trade … (emphasis added). House Judiciary Committee Report on H.R. 5372, H.R. No. 100-1028, p. 15 (Oct. 3, 1988).

…

The [Senate Judiciary Committee] intends that the revised definition of "use in commerce" be interpreted to mean commercial use which is typical in a particular industry. Additionally, the definition should be interpreted with flexibility so as to encompass various genuine, but less traditional, trademark uses such as those made in test markets, infrequent sales of large or expensive items, or ongoing shipments of a new drug to clinical investigators by a company awaiting FDA approval …" (emphasis added). Senate Judiciary Committee Report on S. 1883, S. Rep. No. 100-515, p. 44-45 (Sept. 15, 1988) (other citations omitted).

The TTAB concluded that Congress intended that "use in commerce" encompass shipments of pharmaceuticals for pre-clinical studies as a reflection of common industry practice. Further, the TTAB rejected Alfacell's argument that shipments to foreign countries for clinical testing do not constitute "use in commerce:" "In such circumstances, the "use in commerce" that Congress can regulate is the actual shipment of the pharmaceuticals overseas, and it is not necessary that Congress be able to regulate the clinical testing."

Clearly, Congress understood that shipments to clinical investigators constitute "use in commerce" in the pharmaceutical industry because such shipments– although limited and not directed to consumers – are genuine trademark use. Pharmaceutical companies based in the U.S. having long drug development and approval cycles should leverage their trademark use during pre-clinical and clinical trials in both the U.S. and in foreign countries to establish and facilitate the registration of those rights.

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