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Impact of Patent Law Changes on Biomedical Investment and Innovation

Executive Summary

Life sciences research is extremely expensive, and attracting investment into companies developing the next generation of treatments, therapies, and technologies depends on a strong, reliable patent system. However, there have been several recent developments related to patent law that could have serious implications to the biomedical industry in California and nationwide. These changes are as follows: (1) the Supreme Court's apparent growing anti-patent stance; (2) patent reform legislation being considered by Congress; and (3) the heavy handed approach taken by the U.S. Patent and Trademark Office (USPTO) towards making and promulgating new patent rules.

- In the May 2006 *eBay, Inc. v. MercExchange, L.L.C.*, the U.S. Supreme Court reduced the availability of permanent injunctions, even if infringement has been found. This decision weakens the value of patent rights for patent owners who are not commercializing their inventions by making it more difficult for those parties to enjoin an infringer. In January 2007, the Supreme Court turned to patent license agreements. In *MedImmune, Inc. v. Genentech, Inc.*, the Court made it easier for a patent licensee to challenge the validity of the patent being licensed. In its most recent patent opinion, *KSR International Co. v. Teleflex, Inc.* the U.S. Supreme Court lowered the standards used to evaluate obviousness, making it harder for applicants to obtain a patent in the USPTO and easier for defendants to invalidate a patent in litigation.

- Many of the reforms proposed in the Patent Reform Act of 2007 reflect the fundamental difference in business models between industries. In general, life science inventions require years of development, extensive clinical testing and regulatory approval before they can be marketed. In contrast, the software, IT, and other high-tech industries operate on a far shorter innovation cycle. Such products are quickly developed and commercialized, with no regulatory delay. Once in the market, such products are soon superseded by improved products, whereas life science products are long-lived. The high-tech sector is currently procuring patents at a much higher rate than the life sciences sector. Accordingly, unlike life sciences products, hundreds, or thousands, of patents, often cover software, IT and other high-tech products. Therefore, the relative value per patent is much higher in the life sciences. Investors must be able to rely on such patents to justify the vast investments in time and money needed to bring a life science product to market. The Patent Reform Act of 2007 includes provisions, tailored to meet the needs of the software, IT, high-tech and financial services industries, that threaten to devastate life sciences investment and innovation. Specific concerns include provisions dealing with apportionment of damages, the post-grant review "second window," and expansive PTO rulemaking authority.

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- The PTO's proposed changes regarding the limitation of continuation claims would significantly change the way applicants file their applications and would decrease an applicant's ability to obtain full patent coverage for its inventions. As proposed, the rules would have a devastating effect on mid-sized and start-up life science companies. Additionally, because there is a critical window during which an applicant must demonstrate value to a prospective investor, an applicant may be motivated to accept narrower claims in return for prompt issuance of a patent. Limiting continuations would decrease an applicant's ability to file for the broader protection and would limit the opportunity to develop an adequate prosecution record for eventual appeal. While the PTO suggests that filing an appeal remains a possibility, the length of time required to complete the appeal process will likely extend beyond the time allotted for investment decisions. Consequently, the inventor may not obtain the critical funding needed.

Each of these changes creates special challenges for biomedical companies. Taken individually, they create changes that make the obtaining of patents more complicated and costly. In totality, these changes represent an extensive and dramatic shift that will make patents harder to obtain, easier to invalidate, and cheaper to infringe, thus creating incalculable problems for the life sciences community in procuring and maintaining the essential patent protections for their inventions. The net effect will reduce the value of patents and threatens a chilling effect on biomedical investment and innovation.

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The California Healthcare Institute (CHI) would like to bring attention to several recent changes in patent law that could have serious implications to the biomedical industry. These changes are as follows: (1) the Supreme Court's apparent growing anti-patent stance; (2) patent reform legislation being considered by Congress; and (3) the heavy handed approach taken by the U.S. Patent and Trademark Office (USPTO) towards making and promulgating new patent rules. Taken separately, each item provides significant challenges to continued biomedical research, investment and innovation in California; together they threaten the fundamental business model that has made the state the global leader in life sciences innovation.

Life sciences research is extremely expensive, and attracting investment into companies developing the next generation of treatments, therapies, and technologies depends on a strong, reliable patent system. The biomedical industry in California consists mainly of relatively small, entrepreneurial, and venture capital-backed firms that have yet to bring products to market. For these companies, intellectual property (IP) is typically their most valuable – sometimes only – asset. Thus, the ability to reliably obtain and enforce patents is a top priority for California's research universities and biomedical industry leaders, along with the state's small life sciences companies and inventors.

Supreme Court Activity

In several recent cases, the Supreme Court appears to have been taking an increasingly anti-patent stance. In its June 2005 *Merck v. Integra* decision, the Court weakened the ability of patent holders to enforce their rights against companies performing drug research. In the May 2006 *eBay, Inc. v. MercExchange, L.L.C.*, the Supreme Court reduced the availability of permanent injunctions after the patent has been determined to be valid and infringed. This decision weakens the value of patent rights for patent owners who are not commercializing their inventions by making it more difficult for those parties to prevent an infringer from continuing to infringe.

Diagnostics was the next area that the Court turned to in its June 2006 decision in *LabCorp v. Metabolite*. The key question in the case was whether a claim calling for performing an assay and correlating the result of the assay with a diagnosis was invalid because it sought to patent a law of nature. Although the Court dismissed the appeal on procedural grounds, three justices (Breyer, Stevens, and Souter) dissented, saying they would have found the claim invalid. The Court will likely address this issue again and there seems to be strong support for a ruling against diagnostic patent claims that include a generic assay step and a correlation step.

In January 2007, the Supreme Court turned to patent license agreements. In *MedImmune, Inc. v. Genentech, Inc.*, the Court changed the standards under which a patent licensee can challenge the validity of the patent being licensed. In its decision, the Court eliminated the longstanding requirement that a patent licensee must first terminate or otherwise breach a license agreement before it can ask a court to hold the underlying patent invalid, unenforceable or not infringed. Thus, licensees now have a mechanism for challenging the licensed patent while maintaining their license rights, i.e. without running significant business risks: A successful validity challenge will eliminate future royalty obligations, while an unsuccessful challenge will merely result in business as usual. The *MedImmune* decision significantly altered the dynamics of the relationship between patent licensors and licensees, changed the way patent owners approach potential licensees in negotiations, and opened up the possibility of more declaratory judgment challenges to patents by licensees, which undermines the certainty of patent licensing arrangements.[i]

To be patentable, an invention must be novel, useful, and non-obvious. In its most recent patent opinion, *KSR International Co. v. Teleflex, Inc.* the U.S. Supreme Court changed the standards used to evaluate obviousness. In a unanimous ruling, the Court rejected the "rigid" application of the teaching, suggestion, or motivation test (TSM test) by the Court of Appeals for the Federal Circuit (CAFC). The TSM test was perceived as

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requiring an explicit teaching, suggestion, or motivation in the prior art in order to combine prior art references and demonstrate obviousness. The Court stated an "expansive and flexible approach" was required as set forth in 35 U.S.C. §103 and in *Graham v. John Deere Co.,* the Court's leading interpretation of the statute.

The Court, by striking down the "rigid preventative rules" designed by the CAFC to thwart obviousness determinations based on hindsight bias, has made it easier for examiners and courts to find an invention obvious. Due to the modified standard and the uncertainty in how the ruling will be applied by the USPTO, patent applicants will have to spend more time and effort advocating for the patentability of their inventions. Once a patent has been issued, the patent holder will have to spend more money defending its patent against validity challenges. Specifically, the implications to the life science industry are likely to include increased patent prosecution time and costs, narrower patent claims, and a greater ability for adversaries to challenge patents in court. All of these implications will divert precious resources away from research and development. For start-up companies the change in the obviousness standard may be especially difficult because investors are hesitant to supply funding without strong patent protection of the start-up's technology.

Patent Reform Legislation

Congress has actively considered patent reform for several years. Various bills have been introduced and many hearings have been held, but nothing has been enacted thus far. The most recent patent reform bill is the Patent Reform Act of 2007, introduced identically in both the House (H.R. 1908) and the Senate (S. 1145). Due to the unique use, complexity, and valuation of biotechnology patents, we believe that some provisions of H.R.1908 threaten to devastate life sciences investment and innovation.

Many of the proposed reforms reflect the fundamental difference in business models between industries. In general, biomedical inventions require many years of development, extensive clinical testing and regulatory approval before they can be marketed. In contrast, software, IT and other high-tech inventions are quickly developed and commercialized, with no regulatory delay. Profits from biotechnology inventions are seldom realized until late in the life of a patent (after FDA approval), whereas profits from software, IT and other high-tech products are realized comparatively early in the product's life. In fact, many software, IT, and related products become obsolete long before their patents expire.

Below are some specific provisions of concern to the biomedical industry.

Apportionment of Damages (Sec. 5)

H.R. 1908 proposes several significant changes to the manner in which courts determine damages for infringement.

1. A reasonable royalty is applied only to that economic value properly attributed to the patent's "specific contribution over the prior art," with the exclusion of the economic value of the prior art.

2. A patentee would be required to show that the patent's contribution over the prior art is the "predominant basis for market demand" for damages to be based on the entire product.

Damages for patent infringement are one of the mechanisms that enable a patent owner to enforce a patent. Since the Supreme Court limited the availability of injunctions in *eBay* (see above), patent holders need strong and predictable damages law to deter potential infringers. Under current law, damages are either awarded based on lost profits or, at the patentee's option or when lost profits cannot be shown, a reasonable royalty. The determination of a reasonable royalty is highly fact-specific, and courts currently have discretion to look to many factors when determining the economic value of an invention in the complicated commercial context in which the infringement occurred. H.R. 1908 would radically change the concept and determination of a "reasonable royalty" by directing courts to apply it "only to that economic value properly attributable to the patent's specific contribution over the prior art," and to further exclude the economic value of prior art elements in the infringing product. In other words, the court would be required to first subtract from the patent claim all elements that independently existed before, regardless of whether they ever existed in the claimed configuration. Second, the court would subtract all such elements also from the infringing product. After these subtraction steps, the court would apply the remainder of the patent claim to the remainder of the infringing product.

The resulting residual royalties would be far below those required under current law, and in many cases inadequate to compensate the patentee for the harm caused by the infringement. While the concept of a component of a larger machine or system makes some sense for inventions in the IT/computer fields, it is not as germane to the inventions typical in the biotechnology or biomedical field. The determination of what constitutes the prior art and what the patented component has contributed to that prior art in order to apportion the damages to the contribution of the invention would be a complicated analysis, more prejudicial to the biotechnology/ biomedical industry because of the nature of the already complex inventions.

The section further shifts the burden from the infringer onto the patent holder by explicitly proscribing damages from being based upon the entire market value of the infringing product or process, unless the claimant "shows that the patent's specific contribution over the prior art is the predominant basis for market demand for an infringing product or process." The concept of "predominant basis" represents a higher bar for establishing the contribution of a patented component to the economic value of the entire infringing product.

The likely result is that an infringer could pay some sharply limited amount of damages, *and then continue the infringement*. This is tantamount to compulsory licensing, will substantially weaken the value of patents, and encourage infringement by making the practice considerably less risky and less expensive. In other words, patent infringement will become just another business decision. The net effect will be a damages calculation process that is more complex, expensive, and time-consuming than what is presently used. This will inevitably discourage venture capitalists and life sciences companies from investing in the high-risk research necessary to develop next-generation therapies, treatments and technologies.

Most recently, the U.S. Department of Commerce suggested in a letter addressing its views on H.R. 1908 that while "the appropriateness of damages awards in a number of patent cases may be subject to debate, [the Department] does not believe that a sufficient case has been made for a legislative provision to codify or emphasize any one or more factors that a court must apply when determining reasonable royalty rates." Chief Judge Paul Michel of the U.S. Court of Appeals for the Federal Circuit also recently wrote that the legislation's apportionment provision would require "a massive undertaking for which the courts are ill-equipped [because] … generalist judges lack experience and expertise in making such extensive, complex economic valuations," inundate courts "with massive amounts of data, requiring extra weeks of trial in nearly every case," and invite "an unseemly battle of 'hired-gun' experts opining on the basis of indigestible quantities of economic data."

Post-Grant Review "Second Window" and Evidentiary Standards (Sec. 6)

H. R. 1908 proposes post-grant review of issued patents in four situations:

1. The petition is filed no later than 12 months after the grant of the patent, with a time extension of up to six months for extraordinary circumstances,
2. At any time, if the petitioner establishes a substantial reason that the patent causes or is likely to cause him significant economic harm,
3. The petitioner has received notice of alleged infringement, or
4. The patent owner consents in writing to the proceeding.

Confidence in the validity of patents issued by the USPTO is essential to attracting the capital needed for commercial biomedical research and development. Under current law, a patent, once granted, is presumed valid unless a challenger proves in court by "clear and convincing evidence" that the patent fails to meet one or more statutory requirements for patentability. For the biomedical industry, this presumption of certainty at the issuance of the patent is essential. Without it, entrepreneurs would be sharply hindered in their ability to raise the capital investment necessary for years of further research, development, and commercialization.

While a limited post-grant review procedure within the USPTO may have value, the post-grant procedures proposed in H.R. 1908 would undermine patent certainty by providing for the unlimited administrative challenges of a patent not only within 12 months of a patent's (re)issuance, but *at any time* throughout the patent's life. This is contrary to the practice in other patent systems, such as the European Patent Office (EPO), which only provides a single post-grant review that must be filed within nine months of grant.

The resulting uncertainty about patent validity, worsened by reducing the "clear and convincing"

evidentiary standard to a lower "preponderance of the evidence" standard, would sharply reduce the value of patents to investors. This is of great significance to the biomedical industry, in which commercialization can take more than a dozen years and over $1 billion.

A limited single window provides adequate opportunity, particularly in combination with the existing other options available, to identify and address any perceived deficiencies in an issued patent. Patent applications are made public 18 months after they are filed, typically a year or more before they mature into patents. This is done precisely so that potential competitors can see what is "coming down the pike." At that time, potential challengers can submit published materials that raise patentability issues to the patent examiner. They can also file so-called "protest" proceedings. After the patent issues, challengers could use the new one-year limited opposition proceeding. Thus, under a limited single window opposition system, patent challengers would have at least two years and multiple opportunities to "do something" about a potentially problematic patent. Having been given ample notice and opportunity, a challenger should not be able to "lie in wait" while the patent holder, who has benefited the public by bringing a new product to market, is denied any certainty.

Rulemaking Authority (Sec. 11)

H. R. 1908 would also give the Director of the USPTO the authority to promulgate such rules, regulations and orders that are deemed necessary to govern the operation and organization of the Office. Such expansive rulemaking authority raises many concerns, particularly in light of the controversial rule changes recently proposed by the USPTO. The proposals by the PTO to administratively enact restrictions on continuation applications and the number of claims in patent applications are especially damaging to the biotechnology industry.

In the life sciences industry, "strong patent protection" often means the ability to obtain multiple patents that protect the many innovations and improvements that arise over the course of the lengthy R&D process. The FDA approval process, currently twelve to fifteen years on average for new drugs, and the attendant clinical trials that occur in the course of that process, also significantly contribute to the development of further innovations and improvements on an initial discovery. Therefore, it is extremely important for the life sciences industry that the patent application process is flexible and provides mechanisms for innovators to disclose and protect the new knowledge, discoveries and innovations gleaned through the lengthy R&D and FDA approval processes. To date, this critical flexibility has been supplied, in part, through the existing continuation practice.

The bringing to market of ground breaking life sciences technologies involves long time lines and substantial capital investment. Without the flexibility that the current continuation practice provides, life sciences companies would be forced to enter capital markets relying on claims drafted many years before. This will make the already difficult task of securing funding even more difficult. The end result will be to hamper innovation and deprive patients of all of the promise the biomedical industry has to offer.

The PTO's proposed restrictions to continuations practice and the number of claims have received a record number of negative public comments. The comments filed by stakeholders opposed the substance of the proposed rules and argued that the PTO does not have the authority under its current rulemaking powers to promulgate rules that substantively affect patent holders' rights. In light of the controversy that surrounds PTO's interpretation and use of its current rulemaking authority, granting PTO even greater rulemaking power should not be included in patent reform legislation.

Proposed Rule Changes by the USPTO

As briefly described above, the USPTO has proposed extensive changes to the rules governing patent applications. On January 3, 2006, the PTO published a rules package proposing changes to the permissible number of claims and continuation applications. These proposed rules would significantly change the way applicants file their applications and would decrease an applicant's ability to obtain full patent coverage for its inventions. As proposed, the rules would have a devastating effect on mid-sized and start-up biotechnology, pharmaceutical, and medical technology companies.

Additionally, because there is a critical window during which an applicant must demonstrate value to a prospective investor, an applicant may be motivated to accept narrower claims in return for prompt issuance of a patent. The applicant files a continuation application to pursue the broader protection to which he feels entitled. Limiting continuations would decrease an

applicant's ability to file for the broader protection and would limit the opportunity to develop an adequate prosecution record for eventual appeal. While the USPTO suggests that filing an appeal remains a possibility, the length of time required to complete the appeal process will likely extend beyond the time allotted for investment decisions. Consequently, the inventor may not obtain the critical funding needed.

There is a higher percentage of continuation applications filed by biomedical applicants and, as such, the proposed limitations disproportionately affect the biomedical industry. There are many legitimate business reasons for the life sciences industry's reliance on continuing applications. Restricting applicants' options would negatively impact the industry and thereby reduce the development of companies and new products and jeopardize the position of the United States as the global leader in biomedical innovation.

In some engineering fields, it is possible to develop an invention, run prototypes, identify issues, and pick the best solution before filing a patent application. Biotechnology is different. Inexplicable and unpredictable results often occur as a product advances through the cellular, animal and human studies required for the regulatory approval process. At the time the patent application is filed, the inventor has identified several or a family of compounds which impart desirable biological effects for a particular purpose, but the ultimate product is many years and many formulations, tests, trials, and approvals away. It is almost impossible to select the correct 10 claims right out of the box, given the additional evaluations that must occur before bringing the product to market. Coverage of the many different aspects of the invention, including compounds, compositions, methods of treatment and methods of production, takes a number of applications and generally more claims than would be permitted by the rules being proposed by the USPTO.

Recently, the rules package was submitted to the Office of Management and Budget (OMB) for review. It is rumored that the rules submitted to OMB were different than the rules as originally proposed due to the unprecedented opposition from the public, but the text of the rules as submitted has not been made public. While any easing of the rules as proposed would be beneficial, any restrictions on claims and continuations are disproportionately damaging to the biotechnology and biomedical industries.

The USPTO has also proposed rules related to the filing of Information Disclosure Statements (IDSs). An IDS is the mechanism by which an applicant submits relevant prior art. The proposal would require an applicant who submits more than twenty prior art references to provide explanations of each reference and its relevance. Because there is significant activity in the biotechnology and biomedical fields, there often are numerous references to be cited. Additionally, any comments made during the prosecution of the application, such as those that would be required under the proposed IDS rule, can later be used against a patentee to support an infringer's defense of inequitable conduct during litigation. The proposals of the USPTO also run counter to the case law, which increasingly requires applicants to submit prior art. Although CHI supports the disclosure of pertinent prior art to assist the USPTO in granting high quality patents, the promulgation of these rules without the reform of the inequitable conduct standards would be particularly problematic for the biomedical and biotechnology industries.

Another change being considered by the USPTO relates to alternatives or Markush groups recited in claims. A Markush claim allows an applicant to cover a group of similar components in a single claim, which is particularly important for biopharmaceutical inventions. Because of the nature of the subject matter, biotechnology applications very frequently utilize Markush claims to cover the scope of the inventions. Any changes to the manner in which Markush claims are counted or examined would have a detrimental and unfair effect on biotechnology and chemical applications since, unlike other types of inventions, there are no generic terms that can be utilized to cover the groups being claimed. As a result of limitations being considered or proposed, applicants would be forced to file numerous applications in order to adequately cover the different components of the invention. Without current Markush claiming practice, an applicant would be forced to limit its claims, making it easier for a competitor to design around the claims and forcing the applicant to file a larger number of applications or separate claims to adequately cover its invention.

Many of the USPTO proposals would apply the changes retroactively, which would unduly punish applicants for past behavior when they were not on notice that such actions were going to be subject to future limitations.

Because of the limitations of the proposed rule changes as described above, more applications will be filed to cover the scope of the invention, which will increase the costs for the applicant and the PTO.

Conclusion

Each of these changes creates special challenges for biomedical companies. Taken individually, they create changes that make the obtaining of patents more complicated and costly. In totality, these changes represent an extensive and dramatic shift that will make patents harder to obtain, easier to invalidate, and cheaper to infringe, thus creating incalculable problems for the life sciences community in procuring and maintaining the essential patent protection for their inventions. The net effect will reduce the value of patents and threatens a chilling effect on biomedical investment and innovation.

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[i] The impact of the *MedImmune* case extends beyond the context of patent license agreements. Specifically, in footnote 11, the Supreme Court rejected the Federal Circuit's "reasonable apprehension of suit" test for establishing an Article III case or controversy in the context of declaratory judgment actions in general. The effect of that change in the law was evidenced in *Sandisk v. STMicroelectronics*, (Fed. Cir. March 26, 2007), where the Federal Circuit interpreted the *MedImmune* decision as meaning that:

> "where a patentee asserts rights under a patent based on certain identified ongoing or *planned* activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights" (emphasis added).

As acknowledged by Judge Bryson in his concurring opinion, "the rule adopted by the court in this case will effect a sweeping change in our law regarding declaratory judgment jurisdiction."