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Review of Developments in Intellectual Property Law

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Inside this issue:

Maintaining Confidentiality in Technology Transactions: New Problems with an Old Concept

Confidential Disclosure Agreements (CDAs) have been around forever, which leads to one of the primary problems associated with their use: complacency in their drafting and implementation. This is especially true in today's biotechnology-oriented healthcare industry, considering the endless pursuit of discussions with potential partners, information sharing, and ongoing collaborations and alliance partnerships.

Reusing old forms can be dangerous, and today's transactions make it even more imperative that the exchange of information and materials be carefully negotiated, controlled, and monitored. Unwanted consequences can result when CDAs are not carefully considered, when unanticipated circumstances arise, or when the terms are not fully understood by those charged with their implementation. These risks are leading many companies to simply refuse to sign CDAs, forcing (in most cases) smaller entities seeking a buyer or partner to either abbreviate their most compelling story or avoid negotiating with their most fruitful prospects.

The following discussion focuses on a few of the many potential pitfalls, business problems, and litigation risks associated with negotiating, drafting, and implementing CDAs. With careful consideration, drafting, and implementation, these risks can be effectively managed and minimized.

continued on p. 2

Patent Valuation: How to Reduce Vulnerability and Increase Value

Patent valuation can be a useful tool in a variety of business circumstances, including financial and tax reporting. Numerous approaches have been developed for valuing patents, and they include multiple factors and assumptions. There has been much debate on how practical patent valuation is in determining the true value of a patent, particularly since patent valuation can be affected by so many different factors, including the marketplace for the invention and the economy. While there is tremendous uncertainty associated with assessing the value of patents, there are a number of basic factors within a patent owner's control that may affect patent vulnerability and thus the value of the patent. This article briefly outlines the three main patent-valuation approaches, and then discusses several factors that patent holders should consider to reduce a patent's potential vulnerability, thereby increasing its value.

What is Patent Valuation?

Patent valuation is a complex process for determining the value of a patent, and accounts for economic, technological, and judicial factors.[1] There are numerous valuation approaches, some of which are considered overly complex and unreliable. While there is no standard valuation approach, the three most popular are the cost approach, the market approach, and the income approach. Within each of these, there are numerous specific methods.

The cost approach is premised on the idea of replacement.[2] That is, the value of the patent would be the cost to replace the protection right (*i.e.*, the right to exclude others from making, using, or selling the claimed invention), including costs for the development of the invention. One problem

continued on p. 5

Maintaining Confidentiality in Technology Transactions: New Problems with an Old Concept

continued from p. 1

Identifying Confidential Information

It is notable how often the most important aspect of a CDA – the identification of the confidential information itself – is not accurately presented in the document. Disputes readily arise when it is unclear whether information that is exchanged during a confidential relationship is intended to be confidential. Consider the following exemplary language:

> Disclosing Party shall disclose to Receiving Party nonpublic information that Disclosing Party designates as confidential or which, **under circumstances surrounding disclosure, ought to be deemed as confidential.** Confidential information includes, without limitation, any information that relates to the business operation, proprietary technology, trade secrets, studies, discoveries, intellectual property, policies and procedures, **and any and all conversations whether or not they are recorded and documented** (hereinafter referred to as "Confidential Information").

This language is fraught with ambiguity. What are the "circumstances surrounding disclosure" such that one would understand that information "ought to be deemed as confidential"? This phrase conjures up images of the dark parking lot where Deep Throat told Bob Woodward all of President Nixon's Watergate secrets. Even if information is exchanged without such clandestine circumstances, when, exactly, would the referenced circumstances arise?

The point is that this receiving party risks breaching the agreement by disclosing received information that has an uncertain status. Likewise, this disclosing party risks losing the confidential status of its information by disclosing it without unambiguous indicia of confidentiality.

In addition, this language states that the confidential information may be documents and/or verbal communications, without describing how any such information would be marked. As a general matter, all confidential information should be documented to avoid dispute. And agreements contemplating verbal communications should require that any confidential content be confirmed in writing shortly after disclosure.

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Consider a second example in which everything is simply marked as confidential:

> Confidential Information for the purpose of this Agreement shall mean any and all information, **whether proprietary in nature to a Party or not,** that is exchanged between the Parties, and shall include, but not be limited to, physical and chemical characteristics of compounds…

Here, the receiving party agrees that all information it receives is confidential. While most agreements have a number of exceptions to the definition of confidential information – *e.g.,* information that (i) is already in or comes into the public domain through no fault of the recipient, (ii) is lawfully obtained or available from a third party who is lawfully in possession of the information and free to disclose it, or (iii) was already known to the recipient at the time of disclosure by the disclosing party — the identification of all information as confidential burdens the receiving party with the task of determining whether all of the information falls within any enumerated exceptions.

These two examples highlight the importance of clearly defining the confidential information to which an agreement pertains. The drafter should also require that all information be clearly marked and documented to avoid dispute.

Identifying Recipients

The identity of specific persons at the receiving party who are allowed access to confidential information is often ignored in CDAs. While the receiving party generally would rather avoid naming specific people, as it is just one more restriction that can create a headache, the disclosing party should at least insist that access to the shared information be limited to a finite number of recipients.

So how could the following language be improved?

> The Receiving Party shall prevent unauthorized disclosure, use or reproduction of the Confidential Information, including by limiting access to Confidential Information only to those **employees or directors** of such Party or of its respective **Affiliates** who **perform or facilitate the purposes of the Agreement**.

While this clause allows access by any number of "employees or directors," it at least limits disclosure to persons charged with

continued on p. 3

Maintaining Confidentiality in Technology Transactions: New Problems with an Old Concept

continued from p. 2

"perform[ing] or facilitat[ing] the purposes of the Agreement." That is helpful as long as the agreement states a specific purpose other than simply to control the exchange of confidential information. Indeed, an agreement should identify a project or collaboration to which the information is related. The agreement can then limit disclosure to only those persons working on the project or collaboration.

What about the "Affiliates" in the above example? This term often appears in the description of the parties to various agreements, but it may be dangerous when it appears in a CDA because it can have a very broad meaning.

The above language can be improved by limiting the persons associated with the project to those "who have a need to know," or by limiting the recipients of confidential information to only a limited group of people described specifically by title or name. This should help avoid distribution to a wide group of recipients.

Specifying Term

When do obligations of confidentiality end? It seems that many agreements use five years as the standard for the non-disclosure period, but that is probably more out of habit than for any other reason, especially when both parties have the same habit. While a definite period for keeping information confidential should be included to avoid any ambiguity, the period should be commensurate with the importance and "shelf life" of the information. As one important consideration, the confidentiality period may take into account the rate at which technology changes in the industry. A recipient of confidential information may not be willing to agree to a long confidentiality period if the information will be obsolete in a much shorter period of time.

Consider the following example:

> Either party may terminate the discussions with a written notice, for any reason, at any time, and without liability or restriction, other than the obligation of confidentiality and non-use and the obligation to return the disclosed Confidential Information. The Receiving Party's confidentiality obligation shall continue for five years following disclosure of the Confidential Information.

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This clause is helpful to the extent that it explicitly states how termination is effected. And it is useful in that it requires the return of confidential information to the disclosing party. But when does the "five years" begin and end? If the parties are working together for several months or years, and confidential information is exchanged on several occasions, this clause places the termination of the confidentiality obligations at multiple times, depending upon when the information was originally disclosed. The drafter should ensure that there is a time certain for the termination of confidentiality obligations, either by a specific date, or by reference to the execution or termination of the agreement.

Additionally, if a trade secret is being disclosed as part of the confidential information covered by the agreement, the confidentiality period should be significantly long or indefinite in order to protect the information's status as a trade secret. A drafter may consider avoiding using a blanket CDA for trade secrets altogether when those secrets are mixed with other confidential information. Instead, it may be prudent to use a separate contract related to specific trade secrets that a party does not ever intend to make public.

Considering Choice of Law

Some drafters purposely avoid using choice-of-law provisions in agreements, the basis being that, unless there is a clear reason to use the law of one forum over that of another, choice of law can lead to more confusion and expense in litigation than it is worth.

Consider the following:

> This Agreement shall be governed as to validity, construction and in all other respects by the laws of the State of Illinois applicable to contracts made in that State.

This language seems to clearly cover contract interpretation issues, but trade-secret litigation frequently involves common law tort claims (unfair competition, misappropriation of trade secrets, etc.) in addition to traditional breach-of-contract claims. Therefore, even if the agreement is controlled by the laws of a certain forum with respect to contract issues, the law that controls the tort claims may be subject to dispute.

Things can get even muddier if a foreign jurisdiction is involved. While U.S. courts will follow the law of foreign jurisdictions when an

continued on p. 4

Maintaining Confidentiality in Technology Transactions: New Problems with an Old Concept

continued from p. 3

agreement so requires, U.S. courts will need to be educated in foreign laws, which can be different both substantively and conceptually from U.S. law. In some cases, a court may allow the parties to retain experts to explain the applicable foreign law to the U.S. court. This, however, can add significantly to the expense and complexity of litigation.

To avoid some of the ambiguity often associated with a choice-of-law provision, it can be effective to include language that makes it clear that all disputes are covered by the law of a particular forum: "All disputes arising out of this Agreement and any breach thereof…are controlled by the laws of the State of Illinois." Note that a choice-of-venue provision should also be considered.

Conclusion

Like most contracts, the vast majority of CDAs are executed and implemented without issue. Despite the high-risk/high-reward nature of many of today's technology transactions, the prospect of landing in court as a party to a dispute regarding a CDA is a real deterrent to vigorous exchange of information. Careful drafting of agreements can, however, avoid many of the risks associated with confidential disclosures, and make both parties confident that they can engage in protected and productive discussions and collaborations.

The authors thank Jim McCarthy of EGEN, Inc., W. Ray Guffey of Nestlé Purina PetCare Global Resources, Inc., and Adrian Dawkes of PharmaVentures, Ltd. for their helpful discussions on the content of this article, which were not conducted under a CDA. The authors and contributors will be offering a workshop with further analysis of some of these issues at the LES Annual Meeting, in San Francisco on October 18-22, 2009. For more information, please visit http://www.lesusacanada.org.

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Patent Valuation: How to Reduce Vulnerability and Increase Value

continued from p. 1

with the cost approach is that it does not consider the relationship between costs and real market value, and therefore could lead to an implausible valuation result. Since the cost approach is based on historical cost-based factors, this approach has been criticized as not being particularly useful in making business decisions.

The market approach is based on the assumption that transactions involving comparable patents have occurred, and the values of these transactions are known.[3] That is, the value of a patent is the present value of a comparable patent in the marketplace. However, the market approach fails to consider that such information is generally not public, that comparable patents may be difficult to identify, and that the comparable transaction may have been over- or undervalued.

Finally, the more popular income approach involves forecasting the future economic benefit of the protection right, and discounting it with a risk-adapted interest rate to its actual cash value.[4] That is, the value of a patent is equivalent to the value of the net anticipated economic benefit of the patent. However, this approach has been criticized as being based only on predicted values.

Because patent valuation requires knowledge of market conditions, familiarity with relevant inventions, and a careful selection of economic factors, as well as other factors such as the timing of the transaction and the negotiation skills of the parties, patent valuation is somewhat of a black art. In summary, it is difficult to predict the true value of a patent with certainty.

Actions to Enhance Patent Value

As discussed above, there is much uncertainty associated with assessing the value of patents, particularly because certain relevant factors, such as economic conditions, are usually beyond a patent holder's control. However, the patent holder can exercise control over other relevant factors in order to reduce a patent's vulnerability to an invalidity or unenforceability attack, thereby enhancing the value of the patent. Some of these factors are discussed below.

Determining Inventorship

A patent holder should always make sure that the inventors listed on the face of a patent are properly named as inventors. Patents with incorrect inventorship may be deemed invalid.[5] Avoid excluding inventors simply because they are not employees, or including non-inventors, such as department managers, that had no role in the conception of the invention. Inventorship determinations should be made at certain key points during patent prosecution, preferably prior to filing the application, and can be updated at anytime during prosecution, particularly if claims are amended or cancelled. However, if incorrect inventors are listed on the face of the issued patent, inventorship can and should be corrected, either with a reissue application[6] or a certificate of correction.[7] Because inventorship is a legal determination, any questions should be resolved by a patent attorney.

Securing All Rights to the Invention

A patent holder should make sure that the inventors have assigned their rights to the invention to the patent holder as early as possible, and that the assignments are recorded as quickly as possible. A patent issues in the name of the inventors and, in the absence of an assignment, the inventors own the invention disclosed and claimed in the patent.[8] Whether an employee-inventor has an existing obligation to assign his or her invention depends on the scope of the inventor's employment agreement. But what if there is no employment agreement in place? Generally, the employer owns the invention if it is related to the employee-inventor's employment and was developed during the course of employment, on company time, and using company resources.[9]

Furthermore, it is better to secure the assignment as early as possible, as it may be difficult to secure an assignment once an employee-inventor leaves the company. If outside contractors have been hired by the company, the business owner should make sure that the contractual agreement requires that rights to any invention developed during the scope of the agreement will be assigned to the company.

Failure to secure the rights of all of the inventors with an assignment may raise issues later on, particularly if a lawsuit is filed to enforce a patent, or during negotiations for licensing or sale of the patent.[10] Under U.S. law, inventors having rights in the invention can license or assign their rights to third parties without accounting to other inventors or assignees of the patent.[11] Furthermore, failure to timely record an assignment may create problems in the case of subsequent assignees of the patent.[12]

Complying with the Duty of Disclosure

Applicants are obligated to disclose to the Patent Office all information that may be material to the patentability of the invention(s) disclosed and claimed in the patent application.[13] Failure to disclose known relevant information, including prior art, to the Patent Office can result in invalidation of the patent claims as well as charges of inequitable conduct.[14] Prior art can include not only prior patents or literature, including marketing materials, but also information relating to prior public use of the invention, prior sales, or prior offers to sell a product or process covered by the patent claims.

continued on p. 6

Patent Valuation: How to Reduce Vulnerability and Increase Value

continued from p. 5

The patent holder should ensure that all prior art of which the patent holder and the inventors are aware is cited to the Patent Office as early as possible during prosecution of the application.[15] While there is no obligation to conduct a prior art search, the results of such a search may be helpful in identifying the prior art and determining the proper scope of claims for the invention. If relevant prior art is discovered after a patent has issued, the patent holder may want to have the patent reexamined in order to have the new prior art references considered.[16] During reexamination, claims can be narrowed or cancelled outright in order to preserve the validity of the remaining claims.[17] To determine whether certain information qualifies as prior art or whether a reexamination should be initiated, the patent holder should consult with a patent attorney.

Meeting Statutory Requirements

In order to obtain a patent, there are several statutory requirements, including providing a written description of the invention, and enabling the claims.[18] A good invention disclosure goes a long way in helping an attorney or agent draft an application that satisfies these requirements. And in addition to meeting the written description and enablement requirements, the application must satisfy the best mode requirement.[19] That is, the application must disclose the best way of practicing the invention. While it is tempting for business owners to keep the best mode as a trade secret in order to gain an advantage over their competitors, the results can be devastating to the value of a patent.[20] Failure to disclose the best mode is a basis for invalidating a patent.[21] Thus, if the business owner is reluctant to disclose the company's best mode for practicing a particular invention, then the business owner should consider keeping that invention as a trade secret rather than attempting to secure a patent.

Identifying Potential Blocking Patents

A patent claim does not give the patent holder an exclusive right to make, use, or sell the claimed invention, only the right to prevent others from doing so.[22] Thus, a competitor with a patent that has broader claims may be able to prevent another patent owner from practicing her invention in the absence of a license to the broader patent. It is therefore worthwhile to consider having a freedom-to-operate search performed as early as possible, perhaps even before the patent application is filed, to identify any third-party patents having claims that could be infringed. Those third-party patents may reduce the potential value of the business owner's patent. The patent holder can work with a patent attorney to investigate any potentially problematic patent claims and to determine whether such claims could be infringed.

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Considering Accelerated Examination

Some industries undergo such frequent and rapid innovation that some inventions are obsolete by the time they are patented. Indeed, in some fields, particularly semiconductors and electronics, the backlog of applications at the Patent Office is such that the pendency period[23] of these applications has increased to three or four years.[24] Even if technology obsolescence is not an issue, long delays in the patent examining process can shorten the amount of remaining effective patent term.[25] If a business owner wants to secure a patent fairly quickly on a particular innovation and/or wants to maximize patent term, then the business owner should consider taking advantage of the Accelerated Patent Examination procedure offered by the Patent Office, which attempts to reduce patent pendency to no more than 12 months.[26] On average, the entire process from filing the application to conclusion of examination takes approximately six months, with about 63% of applicants being able to secure a Notice of Allowance.[27]

Conclusion

Patent valuation is a complex analysis involving some factors, such as economic conditions, that are beyond the control of patent holders. However, there are a number of actions, including those detailed above, that patent holders can and should take to positively affect the value of their patents.

Endnotes

1. *See generally* Ted Hagelin, *A New Method to Value Intellectual Property*, 30 AIPLA Q.J. 353 (2002) (describing methods for valuing assets generally and intellectual property assets specifically).
2. Mohammad S. Rahman, *Patent Valuation: Impacts on Damages*, 6 U. Balt. Intell. Prop. L.J. 145, 150–51 (1998).
3. *Id.* at 153–54.
4. Hagelin, *supra* note 1, at 363–64, 369.
5. *E.g.*, *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1350–51 (Fed. Cir. 1998) ("[I]f the patentee does not claim relief under [35 U.S.C. § 256] and a party asserting invalidity proves incorrect inventorship, the court should hold the patent invalid for failure to comply with section 102(f).").
6. U.S. Patent & Trademark Office, Manual of Patent Examining Procedure (MPEP) § 1412.04 (8th ed. rev. 7 2008).

continued on p. 7

Patent Valuation: How to Reduce Vulnerability and Increase Value

continued from p. 6

7. 35 U.S.C. § 256 (2006).
8. MPEP, *supra* note 6, § 301 ("The ownership of the patent (or the application for the patent) initially vests in the named inventors of the invention of the patent. The patent (or patent application) is then assignable by an instrument in writing, and the assignment of the patent, or patent application, transfers to the assignee(s) an alienable (transferable) ownership interest in the patent or application.").
9. *E.g.*, *Standard Parts Co. v. Peck*, 264 U.S. 52, 59–60 (1924). After *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938), state law rather than federal law governs whether an employee is under a duty to transfer inventions to his or her employer. *Am. Tel. & Tel. Co. v. Integrated Network Corp.*, 972 F.2d 1321, 1324 (Fed. Cir. 1992). However, state courts tend to rely upon *Peck* and other leading Supreme Court decisions regarding this question. 8 Donald S. Chisum, Chisum on Patents § 22.03[4] (2005).
10. For example, all co-owners of a patent must generally join as plaintiffs in an infringement suit, and an inventor who has not assigned his or her interest could refuse to join the suit. *Int'l Nutrition Co. v. Horphag Research Ltd.*, 257 F.3d 1324, 1331 (Fed. Cir. 2001), or the inventor could assign his or her interest to a party adverse to the inventor's employer, *e.g.*, *Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys.*, No. 2008-1509, 2009 U.S. App. LEXIS 21465 (Fed. Cir. Sept. 30, 2009).
11. 35 U.S.C. § 262.
12. *E.g.*, *FilmTec Corp. v. Allied-Signal Inc.*, 939 F.2d 1568, 1573 (Fed. Cir. 1991) (noting that a "bona fide purchaser [of a patent] for value [without notice of a prior assignment] cuts off the rights of a prior assignee who has failed to record the prior assignment in the Patent and Trademark Office by the dates specified in the statute"); *see also Leland Stanford Junior Univ.*, 2009 U.S. App. LEXIS 21465, at *19–23.
13. 37 C.F.R. § 1.56 (2008).
14. *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1354 (Fed. Cir. 2004) (holding patent "invalid and unenforceable by reason of prior use and sale under 102(b)"), *rev'd on other grounds*, 546 U.S. 394 (2006).
15. *See* MPEP, *supra* note 6, § 2001.04 (noting that "each individual associated with the filing and prosecution of a patent application has a duty to disclose all information known to that individual to be material to patentability").
16. *See* 35 U.S.C. §§ 301–302. Presently, the Patent Office will consider only prior art patents and printed publications during a reexamination proceeding, and will not consider evidence of public use or offers to sell. 35 U.S.C. § 301; MPEP, *supra* note 6, § 2247.
17. 35 U.S.C. §§ 304–305; *see also* MPEP, *supra* note 6, § 2250.
18. 35 U.S.C. § 112, ¶ 1.
19. *Id.*
20. *Gargoyles, Inc. v. United States*, 113 F.3d 1572, 1582 (Fed. Cir. 1997) (noting that "fact the ingredient was trade secret did not excuse failure to disclose") (citing *U.S. Gypsum Co. v. Nat'l Gypsum Co.*, 74 F.3d 1209, 1214 (Fed. Cir. 1996)).
21. *Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306, 1319 (Fed. Cir. 2002).
22. *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 879 (Fed. Cir. 1991) ("It is elementary that a patent grants only the right to exclude others and confers no right on its holder to make, use, or sell.").
23. The time it takes for a patent to issue once an application has been filed.
24. Peggy Focarino, Deputy Commissioner for Patent Operations, U.S. Patent & Trademark Office, 2004 Report from the USPTO on Patent Operations, Patent Policy, and E-Government (Jan. 27, 2005), http://www.aipla.org/ (search "2004 Report from the USPTO on Patent Operations, Patent Policy, and E-Government").
25. The term of a utility patent filed on or after June 8, 1995, is 20 years from its earliest effective filing date. 35 U.S.C. § 154. The term of any patent in force or pending on June 7, 1995 is the longer of 17 years from the date of issue or 20 years from the filing date. *Id.*
26. MPEP, *supra* note 6, § 708.02(a) ("The objective of the accelerated examination program is to complete the examination of an application within twelve months from the filing date of the application.").
27. U.S. Patent & Trademark Office, Accelerated Examination Statistics (Feb. 5, 2009), http://www.uspto.gov/web/patents/accelerated/ae_stat_charts.pdf. Among a total of 977 final dispositions, 611 applications were allowed. The average time to complete prosecution is 197 days.

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Revisiting the Patent Eligibility of Genes[1]

Gene patenting, accepted in the U.S. and less generously in other industrialized countries, has increasingly come under attack by an assortment of patients' rights groups, academicians, civil liberties organizations, and individuals in favor of restricting patent rights in general. While there has never been a direct judicial determination in the U.S. that genes are patentable, the U.S. Supreme Court provided a broad standard for patentable subject matter ("everything under the sun made by man") in *Diamond v. Chakrabarty*[2] and the U.S. biotech industry has since patented approximately twenty percent (20%) of the 25,000 or so known human genes. Less than one percent (1%) of these patents have been litigated (31 patents) over the last two decades.[3]

The subject matter of most gene patents falls into two categories: (1) genes identified as the result of a directed search for a nucleic acid encoding a protein known in the art (typically with variable knowledge of its amino acid sequence) or (2) more recently, genes identified from gene sequence databases produced as the result of genomic sequencing efforts (for humans, the Human Genome Project[4]), where an open translational reading frame is detected typically with little prior knowledge of the existence of the gene or the function of the encoded protein. For each, patentable gene inventions must be supported by disclosure of (1) the nucleic acid sequence (which must be novel, *i.e.*, it cannot be disclosed in the art even under conditions where its identity was not known); (2) the amino acid sequence of the protein encoded thereby, and (3) the function of the encoded protein (*i.e.*, by describing a specific, substantial, and credible albeit non-exclusive utility for the protein product).

In addition, of course, the specification must enable one skilled in the field to make and use the sequence for its stated purpose.[5] Even under the current regime, where genes comprise patent-eligible subject matter, applications for gene patents must also satisfy the requirements of non-obviousness and be supported by an adequate written description. In view of the renewed questioning of whether genes are or should be patentable, this article discusses some of the debate surrounding the current efforts to protect gene technology.

An issue that is the least developed but the most emotionally-charged in the gene patenting debate is whether genes should be patent-eligible subject matter at all. The expansive scope of 35 U.S.C. § 101 regarding patent eligibility under the Supreme Court's *Chakrabarty* decision has rendered genes patent-eligible for more than 25 years, but the Court has never specifically ruled that genes, particularly human genes, fall within the scope of § 101. Recently, with assistance from the American Civil Liberties Union, a coalition of individual patients and patient groups, individual doctors, and medical professionals organizations, and the Public Patent Foundation sued the USPTO, a genetic diagnostics company (Myriad Genetics), and a number of other defendants, over Myriad's patented genetic diagnostic test for breast cancer based on BRCA gene polymorphisms.[6] The plaintiffs' expressed aim is to bring the case to the Supreme Court, and their hope is to have the Court invalidate claims to genes based on the First Amendment to the U.S. Constitution and on established patent law.

The most plausible (on its face but not on careful consideration) of the arguments put forth by plaintiffs is that a gene is a "natural phenomenon" that should not be eligible for patenting. This argument against patenting genes proves too much, however, because precluding patent protection for a gene would by this rationale preclude patent protection for many other natural products. The contrary argument, of course, is that a gene "is but a chemical compound, albeit a complex one,"[7] and as such is as eligible for patenting as any other natural product.

It has long been the case that useful natural products made by microorganisms, plants, and animals are patentable provided they are isolated from their native state and purified to a useful form. Such products include anticancer drugs like Taxol®, made from yew tree bark, and various antibiotics, made by microorganisms such as bacteria, fungi, and molds. These natural products have been patentable for a simple reason: they are generally beyond the scope of synthetic organic chemistry to reproduce when they are discovered, and granting patent protection is the only way to provide incentives to develop these products as drugs and to disclose their existence and provenance.

Indeed, for natural products made by microorganisms, most countries require a deposit of the microorganism under the terms of the Budapest Convention, requiring that the depositor replenish the deposit at any time for 30 years after it is made, *i.e.*, longer than the term of any patent protecting the natural product. In addition, patent claims to natural products are limited to "isolated" or "isolated and purified" embodiments thereof, thus excluding from their scope the natural product in its native form (for example, the use of a naturally occurring source organism by indigenous peoples[8]). These boundaries on the scope of natural product patent claims properly restrict patent rights to what has evidenced "the hand of man."[9]

Gene patent claims are subject to the same strictures, and require that any claimed gene be "isolated" from its natural residence in an organism's chromosome. Moreover, the

continued on p. 9

Revisiting the Patent Eligibility of Genes

continued from p. 8

vast and overwhelming number of patented genes have been modified in a much more fundamental sense than other types of natural products must be in order to be patentable. This has to do with the realities of gene structure in higher organisms like man, which do not contain genes in a simple, linear order. Rather, the portions of the genes that encode for protein (the exons) are separated by non-coding portions of varying lengths (the introns) that must be spliced out before a useful version of the gene can be obtained. Claims to genes embodied as cDNA (DNA lacking non-coding regions) are thus not the same as claims to genes from naturally-occurring chromosomal DNA; although the human body can (under conditions of retroviral infection) have the ability to process mRNA back to DNA, it does not have the internal capacity to amplify and manipulate the DNA for genetic sequencing and, inevitably, patent protection.

While these technical requirements have become easier to perform over the past 30 years, they still provide a physical and chemical distinction between the native gene and the subject matter claimed in gene patents that is at least as great as (and in many instances greater than) the differences between other natural products and claims to patented embodiments thereof. Thus, if genes are not to be patent-eligible because they are natural phenomena, then many other natural products must be patent-ineligible as well. (This provides a clear problem for drug development, since upwards of 90% of all undiscovered pharmaceutical species are believed to be natural products produced by plants in regions like the Amazon basin.[10]) Should the argument precluding patentability for genes prevail based on their status as natural products, doctrinal purity and legal consistency will require mankind to forego patent incentives for developing these other kinds of natural product drugs.

Moreover, isolated genes provide the only way to make a variety of biologic drugs efficiently and safely, human blood clotting Factor VIII being a prime example. Prior to isolating the gene and being able to produce it recombinantly, the only source was from donated blood. Many hemophiliacs were infected by the human immunodeficiency virus from Factor VIII obtained from blood, a risk that is non-existent with the recombinant form. Other biologic drugs, including human growth hormone, erythropoietin, insulin, and tissue plasminogen activator, are all commercially available because the genes encoding them could be protected by patents.

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Granting patent protection is the only way to provide incentives to develop natural products as drugs and to disclose their existence and provenance.

The one area where gene patenting has the potential to be contrary to continued innovation is in the diagnostic arena, where the existence of a mutation – like a single nucleotide polymorphism, an amino acid change at a particular position, or a duplication of a repetitive sequence – can form the basis for a claim to identify such mutations in individuals. Such assays have been patented, and patent-related restrictions on these assays have caused much of the present consternation regarding gene patenting. Basic research, using databases or archival tissue samples, used not for profit making or current diagnosis but for genetic research – to determine mutation frequency in a population, for example, or to demonstrate genetic linkage between different markers for disease – will not run afoul of most diagnostic method patents based on genetic information. But unauthorized expropriation of patented diagnostic tests will likely incur patent infringement liability, if not for the practitioners themselves (who may be exempt from liability, for example, by statute in the U.S.), then for the diagnostics companies providing the reagents and instructions for such infringing tests.

These issues are to be presented in the Southern District of New York[11] and possibly in other patent cases in the near future. Surely they will continue to grow in significance as the age of personalized medicine begins, based in large part on the elucidation of genetic polymorphisms in individuals as they relate to disease susceptibility, drug resistance, and other medically-relevant characteristics. As patient populations age, improved methods for identifying appropriate drugs and treatment regimes will be needed and can be expected to be based on the genetic constitution of individual patients. This future can only exist if the use of genetic information can be protected by patenting to encourage the necessary investment to bring diagnostic tests from the lab bench to the market and the clinic.

At present, there are no best practices for protecting these types of claims, since the U.S. Supreme Court will write on a blank slate if they decide to hear any appeal eventually filed as the result of the ACLU lawsuit. For gene patenting claims involving production of recombinant proteins, it is conventional (and indeed wise) to include a claim to a recombinant cell, since such claims do fall squarely within the Supreme Court's *Chakrabarty* precedent and are the

continued on p. 10

Revisiting the Patent Eligibility of Genes

continued from p. 9

least likely to be declared patent-ineligible. Moreover, these are the embodiments used commercially and thus are most appropriate for patent protection. Claims to methods of producing a recombinant protein using such cells are also prudently included, since importation of the recombinant protein may fall within the scope of infringement defined by 35 U.S.C. § 271(g). For diagnostic method claims (which could support a separate discussion), at present it is advisable to include an active assay step, such as the one recited in the claims-in-suit in *Prometheus Labs. v. Mayo Clinic*[12], that will fall within the Federal Circuit's "machine or transformation" test enunciated in its *In re Bilski*[13] decision. However, it is likely that this test will be modified, if not overturned, upon pending Supreme Court review, making further recommendations premature.

Endnotes

1. This article has been submitted to *Financier Worldwide* for publication.
2. 447 U.S. 303 (1980).
3. Holman, Chris. Trends in Human Gene Patent Litigation. *Science*, 2008 Oct 10; 322(5899):198-9.
4. Human Genome Project Information. http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml.
5. 35 U.S.C. § 112; *see also* Human Genome Project Information. http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml#2.
6. *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, Case No. 1:2009-cv-04515-RWS, (S.D.N.Y, filed May 12, 2009).
7. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991).
8. *In re POD-ners*, No. 2008-1492, 2009 WL 2029976 (Fed. Cir., July 10, 2009) (affirming the unpatentability of Mexican "yellow beans" based on traditional use).
9. *Chakrabarty*, 447 U.S. at 310 ("Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.").
10. Laurie Goering, *Rain Forest May Offer New Miracle Drugs*, Chi. Trib., September 12, 1995, at 1, available at 1995 WLNR 4590290.
11. *Assn. for Molecular Pathology*, No. 1:2009-cv-04515-RWS.
12. *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 2008-1403, 2009 WL 2950232 (Fed. Cir. Sept. 16, 2009).
13. 545 F.3d 943, 956 (Fed. Cir. 2008), *en banc*, *cert. granted*, 127 S.Ct. 2735 (June 1, 2009).

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