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INTELLECTUAL PROPERTY ISSUES FOR HIGH TECHNOLOGY COMPANIES

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A well-developed intellectual property portfolio is a defining characteristic of successful high technology companies. In general, high technology companies have a comparatively modest fixed asset base, with offices, laboratories and equipment either leased or heavily mortgaged. Many high technology companies have low capital equipment requirements. For instance, software, bioinfomatics, and other information driven companies require high-end computers, but not much else. Biomedical and biotechnology companies often function as "virtual" companies, contracting out manufacturing and other tasks, thus requiring comparatively small laboratories.

While fixed or capital assets for high technology companies may be modest, the intellectual property assets must be significant. This presentation focuses on defining and developing the intellectual property base for a high technology company.

With any high technology client, the first step is to define and characterize the intellectual property base. The following factors should be explored at an early stage of representation, and preferably at an early stage of development of the company.

Facts Relevant to Development of an Intellectual Property Strategy and Portfolio

- Does the company have a defined commercial objective? Too many companies are based on a technological innovation, with insufficient attention paid to the commercial objective. Will the company sell products? Will it license products?

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Has the customer base been identified? Has any market research been conducted? Will it sell services? Will it license technology, such as manufacturing processes? These questions play a key role in defining the appropriate strategy to protect intellectual property. If a company plans to provide only services, it may be possible to protect critical intellectual property through use of trade secrets. If a product will be sold, then patent protection for that product may be key.

- Does the company have marketing or distribution capability? If not, does the company have realistic plans for either partnering to obtain this capability, or the ability and resources to develop this capacity?
- For companies that may market products or services, have appropriate steps been taken to protect critical trademarks and service marks? Has a search been conducted to determine whether federal or international trademark registration is feasible?
- For companies developing software or information-based products or services, have relevant routes of intellectual property protection been explored? For software, the actual program and code may be protected by copyright registration, which provides protection from actual copying such as software piracy. In general, a copyright of a software program protects the actual program, but not the ideas or concepts underlying the program. There is no prohibition against "reverse engineering" software, and incorporating someone else's concepts or ideas into a new program. However, a patent may provide protection for methods of obtaining results using specific algorithms or for other features of a software program. Has the use of appropriate licenses been explored, and is a realistic and enforceable software license in place? Particularly for high-priced programs or databases, a detailed license or use agreement may be appropriate, as opposed to the "shrink wrap" or "click" license applicable to lower-priced or consumer oriented programs.
- Does the company have current and in-depth information about potential markets, potential customers, competitors and available products or services addressing the market? This information is a critical component to developing a realistic intellectual property strategy. The appropriate steps to take differ widely if the company is developing a "me too" product with relatively modest improvements over existing technologies or services, as compared to a company developing a radically new technology or service with the potential to transform the market. For a company developing products of the same general types as are available which will compete in an existing market, potential patent infringement is a significant issue. Are there any dominant patents that must be licensed or "invented around" in order to operate? For companies developing a radically new technology or service, the scope of the innovation and the best way to describe the innovation may be difficult to easily define and claim. Ideally, the company will develop an internal database of "prior art"– information about competing products, services and technologies that can be used in developing an intellectual property strategy. This database should include

patent information, scientific or technical literature, publicly available information from competitors and the like.

- Does the company have an ongoing program and appropriate processes to identify and capture key intellectual property? Are appropriate agreements relating to intellectual property in place with all employees, collaborators and consultants? Are there appropriate non-disclosure or confidentiality agreements in place with critical contractors, suppliers, potential customers or licensees and the like? Is there a formal process for documenting inventions and discoveries, such as permanent laboratory notebooks and written invention disclosures? Depending on the nature of the business, grant applications and contract proposals may be the best-documented source of information on intellectual property. Is this information appropriately protected through non-disclosure agreements and patent filings?
- Has there been a thorough audit of the intellectual property of the company? This includes a review of all of the factors described above, including identifying key employees and consultants, employment and consulting agreements, technology and invention disclosures, public disclosures of the technology, and grant and contract proposals.
- Does the company have the resources to develop and protect its intellectual property? Depending on the specific industry, protection of intellectual property will be a significant ongoing cost component, and may total between 5% and 20% of the operating budget. For example, obtaining patent protection for a single invention in major industrial countries of the world can easily exceed $100,000 in three to six-year period.
- For intellectual property licensed in, particularly university-owned intellectual property, have licensing issues be fully explored? This includes review of ownership and inventorship issues, patent prosecution status, royalty rates, performance criteria, and termination provisions.
- Has sufficient due diligence been completed on the patents? A “patentability opinion” examines whether a patent will likely be obtained on an invention. An “infringement opinion” looks at whether a company product infringes a specific and identified third-party patent. A “validity opinion” determines the validity of an issued patent, considering issues such as prior art, “on sale” bars (sale, offer to sell or publication more than one year prior to patent priority date), disclosure obligations and prosecution formalities. A “freedom to operate” opinion is generally the most expensive, and examines whether any third party patents exist which would likely be infringed by an actual or proposed product.

These and related factors must be considered and analyzed before the scope of available patent protection can be determined.

A. Scope of Available Patent Protection

1. What can be Patented? 35 U.S.C. § 101 provides that:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

This is just as broad as it sounds; the Supreme Court has stated that this definition is intended to "include anything under the sun that is made by man." *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). There are, however, certain specific exceptions to what is patentable, and the Supreme Court has identified three such categories: "laws of nature, natural phenomena, and abstract ideas." *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

2. The Role Served by Patents. Patents are essentially offensive weapons. A patent provides the patent owner with the right to exclude others from making, using or selling the invention, as claimed in the patent, within the territory of the patent. A patent does not give the patent owner the right to make the product – there may be patents owned by others that would be infringed.

Patent protection is limited to the territory. Thus a patent issued in the United States does not affect the right of someone to make, use or sell a product covered by a claim of the patent in another country. However, under 35 U.S.C. § 271 (f), making components in the United States for use outside the United States "in such manner as to actively induce the combination of such components outside of the United States in a manner which would infringe the patent if such combination occurred with the United States" may be infringement. Similarly, under 35 U.S.C. § 271 (g) importing a product into the United States that is made by a process patented in the United States may constitute infringement.

Patents have significant infringement remedies, including damages that are "in no event less than a reasonable royalty" under 35 U.S.C. § 271, with treble damages and attorney fees possible for willful infringement and "exceptional" cases. In addition, injunctive relief to stop ongoing infringement is a possible remedy.

Finally, patents serve a very real role in establishing legitimacy and credibility. For any high technology company, a strong, or potentially strong, intellectual property portfolio is a requirement. A strong intellectual property portfolio also provides "playing chips," particularly for a company entering an existing market. Litigation is often avoided by entering into cross-licensing agreements – this is possible only where the company has a strong patent base.

3. Patenting a Process. A process or method is patentable under 35 U.S.C. § 101. A process consists of one or more steps performed upon specified subject matter to produce a physical result. A process may be a method of making a product, such as a new way to make a particular chemical compound. This method may be

patentable even though the actual chemical compound was previously known, and hence is not patentable. A process may also be a method of using a product, such as a new use for a particular chemical compound. Patentability of process claims depends on *novelty* and *obviousness*. For a method of making a product, the actual process steps must be nonobvious. For a method of using a product, the use must be nonobvious.

For process claims directed to making a product, patentability depends on either the nonobviousness of the actual steps or on the order or sequence in which the component steps are performed. This analysis is conducted against what is called the "prior art" – the existing knowledge, whether in patents, technical references or other publications, relating to the specific process. Thus a process for making a product may be obvious if it is a trivial modification of a known process for making a related product. Mere novelty – no one ever did this precise process before – may not be sufficient where the process would be obvious to someone of "ordinary skill" in the relevant technical arena.

For process claims directed to uses for a product, patentability depends on the state of knowledge with respect to the product and related products. For example, a new use for an old product may be patentable. Again, patentability depends on the state of knowledge in the relevant field. If it is known that a particular product can be used for a specified purpose, then it may be obvious that a related product can be similarly used.

Process claims can be applied to a wide variety of areas of endeavor. For example, methods of conducting a surgical procedure or technique may be patentable. Similarly, software programs and "methods of doing business" may be patentable. For process claims on software and the like, the program algorithm must be applied to some specific physical element or process step ultimately producing a physical result.

A type of patent referred to as the "business method" patent has engendered significant controversy in recent years. A patent owned by Amazon.com for "one-click" purchasing on an Internet based shopping system (U.S. Pat. No. 5,960,411) is emblematic of both the potential value of this type of patent as well as the potential problems. A method of performing a business-related transaction may be patentable, depending again on tests of novelty and nonobviousness. However, there is comparatively less documentation on the state of the art for many of these types of inventions, and thus determining nonobviousness is more difficult. However, it is clear that claims drawn to a method of doing business that produce a "useful, concrete and tangible result" are patentable like any other process claim. *State Street Bank & Trust Co. v. Signature Financial Group, Inc*. 149 F.3d 1368, 47 USPQ2d 1596 (Fed. Cir. 1998).

4. Patenting a Product. A physical entity, such as a chemical composition, a machine or anything "manufactured" may be patentable, again depending on tests of novelty and nonobviousness. For very practical reasons, a product patent is frequently preferable to a process patent. It is much easier to establish patent infringement by product sales than it is to determine infringement of a patented process. For example, surgical techniques are patentable. Yet, the practical difficulty of

documenting the use of a patented surgical technique is obvious. Thus a patented process may have limited commercial value because of the problem of policing infringement. However, a process claim can be valuable in some situations; for instance, when a method is applicable only in an industrial or manufacturing setting, or when the method or process would have a limited number of users.

The scope of the claims obtainable for a product depends largely on the state of the prior art. A minor improvement to a known device will typically have very narrow claims. However, discovery of a new class of compounds, or an entirely new device, may be entitled to correspondingly broad coverage.

There are particular problems in some technology areas. In the biotechnology arena informal rules and policies have developed regarding the scope of patent coverage that can be obtained. For example, demonstrating that a particular recombinant DNA technology works in mice may not entitle the inventor to an analogous technology claim in humans.

B. New Mexico Entities Leading the Way

Many high technology companies in New Mexico are based on work initially done at a university or national laboratory. These include the following areas:

- Bioinfomatics, the application of computational sciences to biological processes, is a growing field, particularly in the Los Alamos/Santa Fe area. Much of this work has resulted from human genome and related research at Los Alamos National Laboratory.
- Computational modeling is another growth field in New Mexico. Frequently models developed for specific government purposes can be adapted to commercial use. In this field, Los Alamos National Laboratory, the Santa Fe Institute and the University of New Mexico constitute an extremely high concentration of expertise in systems analysis and modeling.
- Optics is an emerging area, including application of optical technology to the semiconductor industry.
- Biotechnology and biomedical fields, in part growing out of research at the University of New Mexico and New Mexico State University, are small but growing sectors in New Mexico.

Sandia National Laboratories, Lovelace affiliated entities and other research and development entities contribute to the intellectual property base in New Mexico.

C. Licensing and Startup Company Issues

It is axiomatic that most startup high technology companies are undercapitalized and face what seem like insurmountable problems. One issue with a startup is ownership of the core or initial technology. Often the technology is the impetus for forming the company. When the technology exists before the company is legally organized, the question becomes how the company is to obtain the rights to that core or initial technology. If a founder is the inventor, and if no other entity has any rights to the invention, then the founder can either license or assign the invention and patents to the company. However, often a university, national laboratory or other employer employed the inventor when the invention was made, and the employer is thus the owner of the invention and any patents. In this situation, a license to the company may be the only way for the company to obtain rights to the technology. A license should cover at least the following points:

- The license must be exclusive to have significant commercial value. In one scenario, an exclusive field-of-use license can be obtained. In the case of for-profit owners, it may be possible to obtain an exclusive license for all uses other than the specific use of the owner, coupled with options or other rights to allow the owner to have access to the technology.
- The license should not have unrealistic performance criteria. Some performance criteria may be appropriate, but frequently new companies are unduly optimistic about what can be accomplished.
- The license fees paid by the company can include equity or the right to obtain equity (warrants or stock options) in the company. This preserves the cash of the company while providing a significant up-side potential for the owner.
- The royalty rate must be structured so that the license is a win-win situation for both the company and the owner.
- The company should have the right to grant sublicenses, and the royalty and other proceeds payable to the owner in this situation must be clear and unambiguous.

As a new company develops, it may be in a position to license its intellectual property to other companies. The following considerations are relevant to outlicensing intellectual property:

- Any significant disclosure should take place only in the context of as broad and comprehensive a confidentiality agreement as can be negotiated.
- Any license should be exclusive only for a narrowly and precisely defined field-of-use. Defining the field should be a high priority in the negotiation.
- One approach to performance criteria is to have escalating minimum annual royalties, so that after an appropriate period of time the minimum royalty approximates the

royalty on sales that the licensee should have by that time. This requires a realistic and comprehensive marketing analysis.

- Audit rights should be standard, with the licensee bearing the cost of the audit if there is significant underpayment.
- The company should obtain rights, such as by cross-license, to any improvements made by the licensee.

There are a wide variety of other issues relating to startup companies and intellectual property that should be considered. These include the following:

- To the extent possible, avoid U.C.C. financing statements and liens that include rights to intellectual property.
- While difficult, it is possible to "collateralize" intellectual property, and essentially borrow money against patents.
- Venture capitalists and astute investors will expect a comprehensive intellectual property strategy that includes at least pending patent applications. The investors are making their investment decision based largely on two factors: the strength of the intellectual property portfolio and confidence in the management team.
- The inventors, who frequently are founders of the company, have to realize that at some point they will no longer control the patents and intellectual property. Particularly for businesses with high initial capital requirements, loss of control comes early in the process. While risks can be minimized, they cannot be eliminated.
- Control of stock in high technology companies is frequently inadequate. Stock options and stock grants should be clearly documented and reviewed by a corporate attorney with expertise in securities law. In the event of an acquisition, major venture capital investment or public offering all stock transactions will be closely scrutinized.
- Incentive-based compensation to employees can be creative. For example, a royalty to inventors of new technology (even if capped at an annual or total dollar amount) can provide a more realistic and concrete incentive than stock options.

LITIGATION OF INTELLECTUAL PROPERTY CLAIMS

A. Initial Considerations Regarding Patent Infringement Claims

Patent infringement litigation is costly and involves a specialized body of law. The following points are helpful in preliminary evaluation of a potential patent infringement claim.

- If there is any possibility of being sued for patent infringement, a thorough review and infringement opinion by a patent attorney is critical. Besides providing comfort to the client, an opinion provides a good faith basis for the client's actions (assuming that the opinion concludes that the client's product or process does not infringe), thereby limiting exposure for treble damages for willful infringement under 35 U.S.C. § 284.
- Jurisdiction of patent infringement claims is exclusively in federal courts to 28 U.S.C. §§ 1331 and 1338(a). Supplemental jurisdiction theories, such as pendent or ancillary jurisdiction, may be asserted with respect to state law counts, such as breach of contract or misappropriation of trade secret claims. 28 U.S.C. § 1367. In addition, depending on the facts diversity jurisdiction can be pled. Personal jurisdiction is the same as in any federal question litigation, generally involving a minimum contacts due process analysis, together with analysis of the applicable "long-arm" statute. An appeal from a federal district court on a matter involving "Patent Laws" is not to a regional circuit, but is rather to the Court of Appeals for the Federal Circuit.
- Patent infringement litigation involves a complex, evolving and arcane body of knowledge. With the advent of the Federal Circuit Court of Appeals, there is one appellate court deciding virtually all patent law issues, and the judges of that court are experts in this field.
- Patent infringement litigation typically involves two central issues: does the accused device or method infringe the patent, and is the subject patent valid. Within each of those issues are a myriad of sub-issues, most turning on points unique to patent law.
- Determination of infringement typically involves "claim construction" – determining what the scope and meaning of the words employed in the claims of the patent. In this process the prosecution history of the patent before the Patent and Trademark Office is frequently key. Were admissions made that limit the claims or meaning of words in the claims? Prosecution history estoppel frequently limits or clarifies the meaning and scope of the claims.
- Literal infringement requires that every element of the patented claim be found in the infringing device. According, it is possible to avoid literal infringement by making changes in the device so that it does not have the exact elements disclosed in the patented claim. *Southwall Technologies Inc. v. Cardinal IF Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995).

- The Supreme Court established the "doctrine of equivalents," which essentially holds that small or insubstantial changes in a device do not negate infringement if the elements of the accused device are "insubstantially" different from those disclosed in the patent claim. *Warner-Jenkinson Co. v. Hilton-Davis Chemical Co.*, 520 U.S. 17, 24-25 (1997) (citing *Graver Tank Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 609 (1950)).
- In this context, the recent Supreme Court decision in *Festo Corp v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), has made it clear that most amendments that narrow the scope of patent claims, or change the patent application for reasons relating to patentability, create prosecution history estoppel. More important, any such amendment to a specific claim element may result in a determination that "no range of equivalents is available for the amended claim element" under a doctrine of equivalents infringement analysis.
- Determination of infringement typically involves extensive use of expert witnesses. Such witnesses may also testify as to the state of the art at the time the invention was made.
- Invalidity of the patent involves arguments relating to whether the patent was novel and nonobvious as required under 35 U.S.C. §§ 102 and 103, whether the patent application contained the disclosures and was within the scope required by 35 U.S.C. § 112, and other issues relating to the patenting process. A patent is presumed valid under 35 U.S.C. § 282.
- A patent can also be invalid under the public use and on-sale defenses under 35 U.S.C. § 102, if the product or method was in public use or on sale more than one year prior to the date of the application of the patent.

B. Initial Considerations Regarding Trademark Infringement Claims

- Federal courts have exclusive jurisdiction of trademark infringement claims based on federal statutes, just as in patent infringement cases. An appeal is to the appropriate regional circuit, not the Federal Circuit Court of Appeals. There are state law causes of action for trademark infringement, and these are not preempted by federal law.
- Under the Trademark Act of 1946, frequently called the Lanham Act, an action can be brought whether or not the trademark owner has obtained federal registration of the mark. If the mark is federally registered, an action for federal trademark infringement may lie under 15 U.S.C. § 1114 (1). A cause of action requires proof of validity and protectability of the mark, ownership of the mark, and a likelihood of confusion.
- A cause of action may also be based on 15 U.S.C. § 1125 (a) (frequently referred to as § 43 (a) of the Lanham Act). This requires proof of a protectable trademark and a likelihood of confusion.

- Trade dress infringement actions can also be brought based on either product design or product packaging trade dress. However, at least as to product design trade dress, the rules have gotten much more difficult. As the Supreme Court recently held, "product design is intended not to identify the source, but to render the product itself more useful or more appealing." *Wal-Mart Stores, Inc. v. Samara Brothers, Inc.*, 120 S.Ct. 1339 (2000). Thus in a trade dress infringement action "secondary meaning" must be shown, generally through consumer surveys and other methods that show that the relevant consumer group actually associates the trade dress with the owner of the mark – a difficult task.
- Absent a federal registration, "distinctiveness" of the mark must be proven. This can be done in two ways – proof that the mark is inherently distinctive (an arbitrary, fanciful or suggestive name), or proof of acquired distinctiveness through secondary meaning (such as by a consumer survey).
- Potential defenses in trademark actions are broad, including fair use, fraudulent procurement, laches or estoppel, implied license, First Amendment grounds, unclean hands and the like. Of course, proof that the mark is not entitled to protection, such as proof that the mark is merely descriptive, can also be pursued.

C. Investigation of Insurance Coverage

- Insurance coverage for intellectual property claims – copyright infringement, trademark infringement and patent infringement – should always be investigated.
- Commercial General Liability Policies generally provide "advertising injury" coverage. The form of coverage varies, and must be closely examined. In general, coverage is provided for actions that seek damages, and not actions that solely seek injunctive relief.
- Advertising injury coverage is frequently limited to claims arising out of the named insured's "advertisement."
- In general, advertising injury coverage provides protection for copyright or trademark infringement claims, but not for patent infringement claims.
- Coverage for patent infringement claims is available, and should be explored by clients making and selling products.

D. Preliminary Relief

- Injunctive relief is typically sought in a trademark infringement case. In many cases, the preliminary injunction hearing is dispositive, and is frequently consolidated with trial on the merits under Rule 65, Fed.R.Civ.P. Thus trademark litigation is frequently very fast paced.
- Preliminary injunctions are comparatively more rare in patent cases.

- Standards for a preliminary injunction in both trademark and patent infringement are the same: 1) the likelihood of success on the merits, 2) the potential for irreparable harm, 3) balance of hardships and 4) the public interest.

E. Understanding Damages and Other Available Relief

- For patent infringement, the remedies available include prospective injunctive relief and money damages for past infringement. There are two recognized theories for recovery of money damages – lost profits and a reasonable royalty. A lost profits analysis requires proof that "but for" the infringement the product sales would have been made. This requires proof of manufacturing and marketing capability. A reasonable royalty does not have any such limitations, and damages on this theory can be obtained by a patent owner who never made or sold the product.
- Up to three times actual damages can be imposed for "willful" patent infringement. Where a potential infringer has actual notice of another's patent rights, the potential infringer has an affirmative duty to exercise due care to determine whether or not there is infringement. Competent legal advice may serve as a defense to willful infringement. *Minnesota Mining & Mfg. Co. v Johnson & Johnson Orthopaedics, Inc.*, 976 F. 1559 (Fed. Cir. 1992).
- Attorneys' fees for patent cases are authorized by statute in "exceptional" cases. 35 U.S.C. § 285. As a practical matter, attorneys' fees are awarded only for those cases involving bad faith litigation, fraud or inequitable conduct by the patentee in procuring the patent, or egregious willful infringement. Even if a factual predicate exists, an award of attorneys' fees is still discretionary with the court.
- Injunctive relief in patent infringement cases is almost always a remedy against future infringement.