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Freedom to Operate: Patent Landscapes

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Background

In a recent speech at Stanford, Alan Greenspan acknowledged publicly what has been known for over 20 years. He observed that the global economy had grown increasingly dependent on, and subject to volatility in, intangible properties but had no adequate means of understanding the management of these changing dynamics.[1] Echoing a sentiment hotly debated by the U.S. Senate Banking Committee, the OECD, the World Bank, and accounting standards bodies, his observations highlight the growing challenge of adapting industrial-age financial practice to the knowledge economy. What are intangible properties? What risks and opportunities do they uniquely present? How can market forces be managed in the face of growing opacity in global recognition and enforcement of these important value accretive interests?

Throughout the early and mid-1980s considerable concern grew out of the realization that internationally, the legacy innovators of the U.S. and Europe were being overtaken by, and in some instances, surpassed by innovations from emerging research and development powerhouses, notably in Asia. Thus informed and affronted, the U.S. and Europe significantly modified intellectual property laws to expand the perceived gross innovative product of their respective national interests. Patent filings grew in number and complexity. The subject matter allowable for patenting expanded. Copyright terms and legislation were revised. International harmonization efforts were undertaken to agree on a common understanding

[1] Speech by Alan Greenspan, Chairman, U.S. Federal Reserve, Stanford Institute for Economic Policy Research Economic Summit, Stanford, California, February 27, 2004.

"It is, thus, no surprise that, as a result of the increasing conceptualization of our GDP over the decades, the protection of intellectual property has become an important element in the ongoing deliberations of both economists and jurists."

"If our objective is to maximize economic growth, are we striking the right balance in our protection of intellectual property rights? Are the protections sufficiently broad to encourage innovation but not so broad as to shut down follow-on innovation? Are such protections so vague that they produce uncertainties that raise risk premiums and the cost of capital? How appropriate is our current system--developed for a world in which physical assets predominated--for an economy in which value increasingly is embodied in ideas rather than tangible capital? The importance of such questions is perhaps most readily appreciated here in Silicon Valley. Rationalizing the differences between intellectual property rights as defined and enforced in the United States and those of our trading partners has emerged as a seminal issue in our trade negotiations."

of intangible property interests through a variety of treaties and the harmonization of the Uniform Commercial Code and its sovereign equivalents. The Knowledge Economy Cold War battle lines were drawn with the Trilateral forces dictating the rules of engagement (and defining the enemy).

While great public policy and public resource went into the creation of properties for the knowledge economy, conspicuously little was done to adapt financial markets to deal with the changing actuarial dynamics. Regrettably, standards for invention and patentability were lowered to usher in the era of "defensive patenting" – a concept that overtly breaches the social contract of patents in which society is the chief beneficiary of the disclosure of something new by an inventor who, in exchange, receives a limited temporal commercial advantage.

This social contract is embodied within the 35 U.S.C. §101 and its international equivalents, stating 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 therefore, subject to the conditions and requirements of this title." It is helpful to clarify that the term "Invention," core to the establishment of the patent system has been co-opted by courts, policymakers, academia, and industry to also include "Innovation" and "Incrementalism." For the purposes of clarification, the following definitions may be helpful.

- *Invention* connotes a creation or discovery – something that is derived *ex nihilo*.
- *Innovation* describes the novel advancement of a thing from one state to the next via improvement or modernization.
- *Incrementalism* is the subtle optimization of a thing for specific use and refers to change in definable steps.

The public interest created generational monopoly interests as a reward for invention. For a number of reasons, public policy has drifted to embrace innovation and incrementalism in the same construct, a lexical error with profound adverse market consequences. When one considers that, in the global economy this same drift now plagues patent authorities in over 100 countries in countless languages, confidently establishing that any idea is new on the face of the earth is a task for which no one is fully prepared.[2] Add to this insurmountable information deficit the fact that patent applicants have no duty to disclose any proof that they have exhaustively established title to their inventions and place that burden on patent office examiners who, on average, have less than 25 hours to review "all relevant information"

[2] *Pools, and Standard-Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam Jaffe et al. eds., 2001). " Quote from: *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy.* A Report by the Federal Trade Commission October 2003. Page 8.

pertaining to the patentability of an invention and one can easily appreciate the default to issuing unsubstantiated monopolies.

Thomas Jefferson, resigned to the notion of limited monopoly rights in a nascent economy, called the constitutionally authorized Patent system, "a public embarrassment."[3] His sentiment described quite aptly a macroeconomic compromise – to enjoy the benefit of the entrepreneurial vision of a new Republic, society must establish inducements to favor those who will be its benefactors.[4] In exchange for the social gain from the promotion of "Science and the Useful Arts," limited monopoly rights would be granted. Thus the social contract of the Knowledge Economy was reincarnated American style.

The social contract rests on three fundamental assumptions. First, intrinsic to the contract is the assumption that the beneficiaries of monopolies must first grant to society something that advances the public base of knowledge. The advancement is precedent to the award of the right. Therefore, under a functioning system, only those inventions, innovations or creations that are novel, non-obvious, and reducible to practice, ***and*** advance the public knowledge should be afforded status. Second, the patent system serves the public at the public's pleasure via judicial, sovereign state and treaty oversight. Finally, no provision is made for a patent paradigm that endorses the notion of defensive patenting – a relatively modern notion of creating vast quantities of patent claims such that no reasonable effort can discern the substance from the noise.[5]

While the global knowledge economies saw the birth of private and public equity markets to fill gaps created by the credit market's inability to understand or rate intangible risks and rewards, the associated cost of capital created vast imbalances and barriers to equal entry. The euphoria created by these imbalances was seen in speculation around licenses in energy and telecommunications in the 1970s and 1980s. Speculative behavior in the private equity and small caps markets grew through the 1990s during which time anything that was technology focused commanded unsustainable multiples. As with all

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[3] "Considering the exclusive right to invention as given not of natural right, but for the benefit of society, I know well the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not." From Thomas Jefferson's August 13, 1813 letter to Isaac McPherson in his explanation for denying a patent for a elevator and conveyor systems sighting, as prior art, work by Archimedes and reference work from the 16th century.

[4] http://earlyamerica.com/review/winter2000/jefferson.html

[5] "In some industries, such as computer hardware and software, firms can require access to dozens, hundreds, or even thousands of patents to produce just one commercial product. One industry representative from a computer hardware firm reported that more than "90,000 patents generally related to microprocessors are held by more than 10,000 parties." [internal reference to: Statement to FTC by Detkin 2/28 at 667-68.] Many of these patents overlap, with each patent blocking several others. This tends to create a "patent thicket" – that is, a "dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology."[internal reference to: Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam Jaffe et al. eds., 2001). " Quote from: *To Promote Innovation:The Proper Balance of Competition and Patent Law and Policy.* A Report by the Federal Trade Commission October 2003.

speculation – information control – not empirical merit allowed a few to benefit greatly, some to benefit modestly, and many to loose considerably. Each of these speculation frenzies created rapid corporate successes followed by highly visible collapses. Through it all, two critical oversights plagued the business, financial, and legislative communities.

First, little effort was taken in holding the public sector (the entity responsible for granting proprietary property or license interests) accountable for their distribution of property or license rights. Second, no accountability and disclosure requirements were promulgated and enforced to insure that the capital markets (both public and private financing interests) understood the risks and opportunities attendant to the changing landscape. As a result, two decades of chaos has created greater uncertainty than at any point in the global economy. As we examine the notion of "Freedom to Operate" and patent landscape analyses, we assiduously avoid the temptation to interchange "property" or "right" with the term "asset" – an egregious over-simplification which has paralyzed the policy-making, academic, accounting, and business professions for over a century. As will be evident, these properties and rights share a common challenge in that their existence, enforceability, and revocability by exogenous forces assault the very definition of an asset – namely, the ability to control and reliably expect future benefit.

The International Accounting Standard 38 defines an intangible asset as an identifiable non-monetary asset without physical substance that is ***controlled by an enterprise*** due to creation or acquisition and from which future ***benefit can be reliably expected***. As we will discern, in the instance of patents, neither control nor future benefit can be certain and, as such, attributing asset status is tenuous at best. Therefore, in our consideration that follows, we will seek to explore how, against this backdrop we can understand what Freedom to Operate actually means and how one might go about establishing policy that informs this critical risk management concept.

Freedom to Operate

Freedom to Operate (FTO) implies a state in which one is free to research, develop and commercialize a product, concept, or service having identified and managed all impairments that may arise from 3rd parties asserting claims to enablements, processes or end-products. Once the domain of legal opinion letters and litigation prone? design-around practices, increasingly FTO strategies have included licensing of 3rd party rights (in-licensing, cross-licensing, or participating in patent pools) as a means of affording some nominal protection against unintended business interruption. Not surprisingly, these strategies have done little to provide freedom in any sense of the word and a more careful approach needs to be considered. It is in that light that we will examine the concept of FTO from the perspective of the

economic development (both governmental and NGO), academic, emerging enterprise, and established enterprise levels.

During its EU Presidency, the government of Denmark attempted to shine a bright light on the growing challenge facing innovation holders arising from the increasing number of patents and patent thickets which were alleged to be stifling small and medium sized enterprise (SME) growth. While correctly identifying the need to alter imbalances in the existing paradigm, their clarion call fell largely unheard amidst the clamoring of many interests who benefit from the present chaos. They suggested, among other things, an alternative approach to FTO strategies which would involve the creation of a patent insurance scheme in which enforcement of intellectual property rights (IPR) could be supported through a purchased risk transfer product[6]. Since their suggestion in 2002, interest has ebbed and flowed with a recent resurgence of interest in the United Kingdom, Germany and a few other member states. The recognition that most economic development happens in the SME sector of established economies, FTO is both critical but largely impractical. This is due to a number of reasons.

First, no country has been willing to formally challenge the patent granting process that produces numerous rights which contain considerable overlap or outright redundancy. Asking for the private sector insurance industry to insure the job performance of any patent office is an actuarial risk that cannot be measured and therefore, a policy cannot be fairly priced. Who bears financial responsibility for allowance errors? Second, given the known deficiencies in patent quality both at the applicant and allowance level, enforcement typically involves establishing the legitimacy of the property itself through costly discovery. Underwriters have no ability to adequately assess this risk internally and, as a result rely on expensive, ill-equipped external contractors to quantify exposures. Finally, assertion requires some form of check-and-balance to avoid frivolous assertion. Given that considerable infringement arises from breaches of confidentiality agreements, material transfer agreements and other contracts, determining the appropriate claim and venue can be highly subjective.

Economic development FTO needs to reconsider fundamental principles. First, it should acknowledge that patent enforcement is critical for indigenous enterprises (regardless of their size). In that light, as the GDP contribution from innovation accrues to the sovereign (in the form of employment, taxes, trade advantages, etc.), the sovereign should only recognize those property interests that it is prepared to defend. In short, a patent grant should be legal tender backed by the state in which it is granted. When the economic consequence of a grant is part of the allowance calculus, the patent thicket forest will clear. Second, full exploitation value should be extracted from the excesses of the patent system. Through the

[6] Ironically, the United States Patent & Trademark Office had granted a patent for several elements of the patent insurance scheme in January 2000 in U.S. Patent 6,018,714.

1980s and 1990s the mad rush to patent resulted in the issuance of vast patent estates. Many of these estates were of little value – outside their alleged defensive use – and have been abandoned to the commons. Economic development interests should formalize and document Innovation Literacy Commons (ILC) constructed of unused and unmaintained patents which have no statutory enforcement value. These may be unenforceable due to lapsed maintenance fees, failure to protect in certain jurisdictions, or expired. By documenting the property in the commons, one quickly appreciates how little is protected. For example, if one looks at the anti-retroviral treatment for HIV-AIDS, while U.S. and European health institutes, universities and companies have received over 500 patents on base technology, due to abandonment alone the public domain is the single largest "assignee" having about 11% of the issued patents (now abandoned prior to their expiration). Ironically, the largest commercial interest has less than 7%. Rather than fighting the patents, creativity would exploit the commons.

Academic researchers have increasingly described the "chilling effect" of patents on the conduct of basic and applied research. Together with the emerging enterprise, few have the resources to conduct detailed legal reviews and few have the financial capacity or sophistication to know the right questions to ask should such a review be undertaken. While the siren song of technology transfer fortunes have lulled many a researcher into the rocks of injunction and infringement, no formal mechanism exists to conduct ***dependency*** (the degree to which practicing an intention requires platforms owned by others) and ***interdependency*** (the degree to which commercial exploitation requires enablements or utilities owned by others) analyses. Rather than focusing on patent claims, the academic FTO needs also to carefully consider the intended uses set forth in patent specifications. Many specifications encompass highly imaginative applications of technology that, while not reduced to practice, can anticipate future research or preclude future patenting activity. Few technologies are better examples of this phenomenon than the biochip industry in which the platform technology temporally preceded most utility "inventions" by over a decade. For example, Affymetrix received a patent for an array to detect cystic fibrosis in 2000 from an application that has priority to 1993[7]. On April 17, 2003, Thermo Electron Corporation and Quest Diagnostics announced the launch of the "First Commercial Gene-Based" biochip for screening cystic fibrosis gene mutations. Did the companies know of the Affymetrix patent and ignore it or did they simply simultaneously develop a technology that presented a commercial alternative in innocent isolation? In either instance, the outcome has considerable commercial and investment opacity. While numerous parties have referenced the Affymetrix patent in subsequent patent filings, neither Thermo Electron nor Quest is identified as assignee of record on those references. Monsanto has maintained patent application prosecution on foundational gene transfer and expression technologies with some applications pending since 1983 and still unissued. If these applications are allowed, one can reasonably infer that

[7] U.S. Patent 6,027,880.

none of the biotechnology plant industry or academic research efforts on plant genetics will be immune from the reach of Monsanto's frequently amended claims.

In short, academic and SME FTO analyses must include a thorough review of dependencies and interdependencies, examining both issued claims and imagined uses described in specifications. In addition, these same interests must actively monitor pending applications and, when necessary, inform patent offices prior to the issuance of inappropriate patents.

Emerging and established enterprises need to begin their FTO analysis by examining their own patenting activity. It is remarkably easy to identify the injustice in 3rd party activities while engaging in immoral and/or unethical behavior intramurally. (See the Appendix "Letter of Marque" op-ed piece.) If owned patents have been procured based on true, documented invention, assessment of interdependency should be conducted and identified impairments should be disclosed or remedied. If patenting activity has been devoid of comprehensive pre-filing due diligence, dependency analyses should be performed. In addition, enterprises should carefully consider the scope of enforcement given that frequently, international protection is weak or non-existent. While this fact can be simultaneously exploited, failure to measure the implications of this common oversight can expose an enterprise to great liabilities both in terms of commercial activity as well as misrepresentations in financing.

Increasingly, the financial markets are appreciating that the volatility caused by rapid erosion of an alleged proprietary position is both quantifiable and predictable. Pfizer's recent experiences with patents for Viagra™ and Lipitor™ highlight the market discomfort with administrative jurisdiction and re-examination actions emanating from China and the Public Patent Foundation, respectively. While hedge funds have found this volatility highly lucrative, the small or established enterprise finds its cost of capital greatly increased due to this risk.

Landscape Analysis and Risk Management

When one seeks to understand the freedom of operating in a particular field, great care must be taken. Given the dependency such an exercise has on the intentions of the query generator and the constituents that populate the analyte, active strategies to deal with known delimitations must be undertaken. Allow one example to illustrate this point. A commercial patent information tool exists that displays patent sets in a topographic viewer rendering the data as mountains, valleys, or blank landscapes[8]. Ironically, over 500 patents and copyrights exist for rendering digital data in 3-D representations based on intrinsic data associations. A patent analysis service (used by numerous public and private sector professionals) relies

[8] www.cartia.com/static.advanced.htm

on technology that is owned – at least in part – by numerous 3rd parties. This example highlights a considerable challenge to any FTO review.

First, we see an analyte challenge. How does the inquirer know what data to query to find the patents and copyrighted code? Given that patent offices are constantly challenged with this problem for patent examination, how much more will be the challenge to the uniformed public? Second, there is the thesaurus challenge. While we may easily identify keywords for Boolean searching (landscape, 3-D rendering, etc.) we may not think of other terms like "Euclidean coordinates" with "interpoint distances" for "visualizing the non-visual." In short, our query will be only as good as our thesaurus imagination.

This example is helpful for a number of reasons. While it serves to exemplify the fact that even the patent information processes undertaken by patent offices and commercial data suppliers may themselves be exposed to potential infringement[9], more importantly, it highlights the need for new paradigms where dependency and interdependency are acknowledged, assessed, and then handled under risk management strategies.

In conclusion, the fundamental principles of FTO analyses should include:

1. Confirmation of the uniqueness of title to the property right. While the presumption of validity is reassuring in the context of litigation, it is implicitly undermined by acknowledgements such as those from the USPTO's annual report in which they acknowledge that their own patent examination procedures were followed 86% of the time without reporting what happened in the 14% of cases where they were not followed[10]. Under the insightful leadership of Under Secretaries of Commerce Rogan and Dudas, Director Re-examinations have taken on more consequential cases which, while of great importance, further highlight the breadth of industries where wrongfully issued patents have held sway. Ironically, both the re-exam records and the second-set-of-eyes examination pilots – actual measures of patent quality – are not reported in the ***accountability*** report. In the EPO, at least 2/3 of the patents that are opposed are either amended or rejected. On January 1, 2005 the JPO deleted the patent opposition system[11].

2. Commercial Impairment Assessment is essential to understand the dependency and interdependency dynamics of any granted intellectual property right. This process includes a complete

[9] To date, we are aware of no patent office that has established externally available standards that insure that their information technology systems have been reviewed for patent or copyright infringements. If the patent offices don't employ their own FTO reviews in an open and transparent manner, what message is being sent to an industry that is encouraged to respect IP.

[10] Performance and Accountability Report Fiscal Year 2005 – USPTO

[11] Trilateral Statistical Report 2004

review of all processes involved in the specification in which reduction to practice is defined. Each process to practice or exploit the innovation should be documented and verified for its FTO. The combined resultant good, service, or commercial deliverable should then be considered in light of the degree to which others might infer claims based on overly broad authorized claim language. It is important to note that, by charter, no patent office has the resources or the competency to assess the commercial impact of their granting decisions and so any imputation of commercial value or validity based solely on the existence of a patent is hypothetical at best.

3. Risk management strategies must be deployed to act upon the information derived from steps one and two. While no current risk transfer product can be purchased for the patent quality defect problem attendant to inappropriate grants made by patent offices, both licensing and acquisition activities as well as insurance options may provide some support for commercial activities impaired by dependencies or interdependencies. Most importantly, the wealth of patents that have been granted but now exist in the public domain should be catalogued to provide enterprise or industry specific Innovation Literacy Commons so as to fully exploit the full value of the social contract that led to their creation.

APPEDIX I – Op-Ed Article January 15 2005

The Letter of Marque – An Intellectual Property Paradox

Dr. David E. Martin
January 15, 2005

In the dawn of the 19th century, considerable international commerce fueled the expanding markets of Europe and the newly independent United States of America. Caravans followed centuries old paths overland to bring goods from the East to markets in Europe. However, with growing populations eager for the exotic and with the need to more rapidly move goods from manufacture to market, the seas became the corridors for trade. Ships plying the trade routes were frequently exposed to piracy – a splendid business in which others bothered to retrieve goods which, with relative swiftness and aided by cannon, musket and sword, could be repatriated for the benefit of the opportunistic and strong. Napoleonic fervor fueled the court of Britain to create a class of civilized piracy to undermine the economy of France and its allies creating a designation of ships with the "Letter of Marque". Thusly empowered, these ships could "take prizes" (a terribly civilized term for piracy) with impunity surprising their quarry under false colors and in disguise. In other words, piracy was what others did – defense of economic interest was what Letter of Marque ships did.

This Wednesday, outgoing Secretary of Commerce, Don Evans, excoriated the Chinese for their failure to reign in intellectual property piracy. Suggesting that the Chinese should imprison those guilty of violating patent, copyright, and trademark laws, Secretary Evans' issued a clarion call for the defense of U.S. sovereign intellectual property rights. By suggesting imprisonment as a remedy for what in the U.S. calls for financial sanctions only when infringed parties have sufficient liquidity to seek remedy in the courts, his suggestions seem ironic in light of a historical position on human rights and due process criticisms of China. Was Secretary Evans representing a U.S. position which holds all intellectual property rights (IPR) as requiring united national defense or was he, like others, representing a minority of vocal business interests who defend a policy of the Letter of Marque? Namely, when others do it, it's piracy, when the U.S. does it, its called innovation.

Presaged at the World Trade Organization gatherings in Doha and Cancun, the duplicitous U.S. policy on IPR may be unraveling. We don't want our creative works annexed by others but we fail to address two fundamental inconsistencies. First, we deny the well-established reality that our IPR granting systems are ineffectual in ensuring that only legitimate rights are granted. The same Commerce Department, which oversees the United States Patent & Trademark Office, fails to defend international interests against U.S., European, and Japanese commercial entities who engage in the expatriation of the one

resource that emerging economies have in excess – namely, biodiversity and traditional knowledge regarding its beneficial uses.

Attributing to malevolence that which is ignorance is unjustified. In meetings with senior Commerce Department officials, we are aware that many of them are unaware of the depth of dysfunction in the IPR granting institutions whose products they wish to defend. Therefore, one can argue that Secretary Evans is merely guilty of an industry-advocated farsightedness in which the real IPR violations of others can be seen more clearly than the same activity at home. It is ironic that a number of European states are beginning to realize the need for national defense of IPR held by small and large business interests within their borders while in the U.S., enforcement is only available to those with liquidity to access the courts.

Where was Secretary Evans call for jail time when Columbia University sought to double-patent its co-transformation technology licensed to Amgen, Genetech, Abbott, and others? Who is serving time for applying for, granting, or enforcing patents on indigenous cultivars of China, Brazil, and India?

IPR theft is wrong in any context. Secretary Evans' passion is admirable. However, under the rule of law, precedent serves as a cruel master. Should the U.S. seek global respect for its commercial deployment of IPR, it should insure that it grants only that which is statutorily valid serving the Constitutional social benefit incumbent thereon and, once granted, advocate for equal enforcement regardless of venue. A Letter of Marque IPR policy is unsustainable and one day may be used against us.