

# Intellectual Property - Freedom to Innovation and Freedom to Operate

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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. This challenge arises from the increasing number of patents and patent thickets 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.

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. Recognizing that most economic development happens in the SME sector of established economies, FTO is critical but also largely impractical. This is due to a number of reasons.

First, no country has been willing to formally challenge the patent granting process which produces numerous rights that 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. 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 prin-

ciples. First, it should acknowledge that patent enforcement is critical for domestic enterprises (regardless of their size). In that light, as the GDP contribution from innovation accrues to a country's government (in the form of employment, taxes, trade advantages, etc.), the government 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 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 un-maintained patents having 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, look 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," possessing 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 academic researchers 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.

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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. 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 ambiguity.

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 still unissued and pending since 1983. If these applications are allowed, one can reasonably infer that 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 internally. 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.

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*continued on page 16*

# Intellectual Property

*continued from page 9*

international protection is weak or non-existent, enterprises should carefully consider the scope of enforcement. 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. For example: A commercial patent information tool exists that displays patent sets in a topographic viewer rendering the data as mountains, valleys, or blank landscapes. 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 on technology that is owned - at least in part - by numerous 3rd par-

ties. 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 unformed 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. 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. And, more importantly, it highlights the need for new paradigms where dependency and interdependency are acknowledged, assessed, and then handled under risk management strategies.