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Special Guest Editors

Patent Reform: Effects On Medical Innovation Businesses

This special issue of Medical Innovation & Business is devoted to evaluating the potential consequences of the Patent Reform Act of 2010, currently pending in the Senate as S.515 and in the House of Representatives as H.R.1260, with emphasis on university researchers, university spin-offs, emerging start-ups and small life sciences companies, especially those in the medical sciences.

We, as the editors of this special issue, are deeply concerned that the Patent Reform Act will severely harm medical and small company innovation. As an academic researcher who invented a blockbuster drug, Restasis®, a patent lawyer who has helped small companies and their investors, and an inventor/entrepreneur who founded and raised investment capital for two start-up companies based on patentable inventions, we have seen how the robust American patent system enables new, innovative companies to secure investment funding and to negotiate with strategic partners. We have seen how patents enable entrepreneurs and researchers to turn raw ideas into useful products. A strong patent system benefits patients and helps the economy grow by giving companies the competitive position and incentives they need to get new pharmaceuticals, medical devices and procedures into the technology pipeline. Innovators can invest in R&D, testing and FDA approval because patents allow investors to recoup their investments in these staggeringly expensive activities. We are very concerned that the Patent Reform Act undercuts the entire idea-to-product pipeline by weakening the investment value of patents in several ways that selectively impact the most innovative companies. If Congress gets Patent Reform wrong, products characterized by high development costs and low production costs, typical in medical innovation, will die in the lab. The capital investment necessary to get ideas to market will simply dry up, and be diverted to companies that don't need patents to attenuate risk.

In this special issue we have assembled a panel of experts, some to give a "state of the patent system" overview, some to evaluate specific effects of the Patent Reform Act. Many of the articles address Patent Reform issues that are important to classes of companies that have not been heard from, either because they don't exist yet, or because they are too small and decentralized to sponsor a major lobbying campaign: today's small companies, tomorrow's start-ups, tomorrow's university spin-offs, with a focus on medical companies.

As Patent Reform was originally framed among industry groups in the early 2000's (before anything was introduced in Congress), the goals were two fold: (a) to react to public outcry against "bad" patents, and (b) to simplify a few parts of the patent system. Patrick Doody discusses the problem of defining "bad" patents in his article *What is a Bad Patent?* and Dr. Ron Katznelson describes the adverse effects that the one-sided "patent quality" outcry campaigns have had on Patent Office operations in his article *Patent Reforms Must Focus on the U.S. Patent Office.*

As introduced in 2005, the Patent Reform Act reflected the concerns of two large lobbying coalitions, the Coalition for 21st Century Patent Reform headed by several large pharmaceutical and manufacturing companies, and the Coalition for Patent Fairness headed by the large information technology companies. PhRMA and BIO (the trade associations for the large pharmaceutical companies and biotechnology companies) joined the fray to oppose some of the more heavy-handed

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anti-patent proposals. In spring of 2007, the Innovation Alliance, a group of non-manufacturing R&D companies, staked out the most pro-patent positions of the major lobbying coalitions and began to lobby for stronger patents and better examination.

Small businesses and start-ups weren't effective in their messaging until year end 2009. Though independent inventors tried to make their voices heard earlier, in several hearings before the Senate Judiciary Committee, not a single representative for start-up companies or for individual inventors was called to testify and the House Judiciary Committee did only slightly better. It was not until late 2009 that groups such as the National Small Business Association and the newly-formed Small Business Coalition on Patent Legislation assembled enough voices to be heard on issues important to small companies, start-ups, individual inventors and university faculty.

In March 2010, a compromise was announced among several senators, the Patent Office and the large companies that had lobbied the bill for years. The compromise withdrew or softened most of the anti-patent provisions. For example, a provision that would, in many cases, have reduced litigation damages below the value of a voluntarily-negotiated license was replaced by a provision that requires judges to control damages presentations and evidence at trial to restrict runaway jury discretion, as explained by Philip S. Johnson in his article *The Gatekeeper Patent Damages Compromise of S. 515*.

The March 2010 Senate compromise scales back provisions for Patent Office re-review of issued patents' validity, but nonetheless leaves a patentee with less certainty and less access to the capital markets than under current law. Meanwhile, the most anti-patent version of post-grant review remains pending in the House of Representatives. The business aspects of post-grant review are discussed by John Neis in *Post-Grant Review—Our Next Nightmare? VC Perspective* and the legal aspects are discussed by Dr. Kevin Noonan in *Post-Grant Review of U.S. Patents: Will Past Be Prologue?* Dr. Charles E. Miller and Daniel P. Archibald discuss a related provision that at first glance appears to be technicalia only for patent attorneys, but on closer scrutiny reveals major erosion of current judicial protections that would have substantial effects on inventors, in *Attenuated Judicial Review of Patent and Trademark Office Decisions: "Technical Amendment" or Stacking the Deck Against Inventors?*

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Another provision, long pushed by a group of large pharmaceutical and industrial companies, remains in both versions of the bill: it would redefine the one year deadline for filing a patent application and would significantly impair the ability of American companies to develop their products before seeking patent protection. The nominal purpose was to reduce the costs of patent litigation, but the provision overlooks the costs that will arise as companies adjust their behavior to the new law. Also, the provision selectively favors large international companies to the disadvantage of American-based start-ups and small companies. David Boundy and Matthew Marquardt discuss this provision in *Patent Reform's Weakened Grace Period: Its Effects on Startups, Small Companies, University Spin-offs, and Medical Innovators*. This provision moves "derivation" (that is, where a person either reuses or republishes something learned from the patentee/inventor) from a peripheral role under current law to a center-stage player under Patent Reform. Charles Gholz, in his article, *Would Derivation Proceedings be the Same as Derivation Interferences?* points out a number of open questions and differences between current law and the proposed statute.

Not surprisingly, as of late May 2010, the bill reflects the interests of the large market incumbents that have extensively lobbied the bill and is, we fear, skewed against start-ups, small companies, individual inventors, university faculty inventors, university spin-offs and similar small entities. These

adverse effects arise, we believe, simply because the most important questions haven't been asked. In this issue, we hope to get many of these concerns on the table, so that informed public debate can occur. The relationship of venture capital, small businesses and the patent system are discussed by Gary Lauder in *Venture Capital—The Buck Stops Where?* (Boundy and Marquardt also discuss the differences between small companies' and large companies' use of the patent system.)

Finally, lawmakers seem not to have considered transition costs. Business and investment under the present Patent Act are predictable because most issues have been settled by a century of court decisions, developed at great expense and after excruciating delay. Each revision to the Patent Act introduces new ambiguities that will require expensive litigation to reach a new judicial interpretation. Sweeping changes will inevitably introduce many unintended consequences that will be exploited by litigators. Industries will be forced to readjust to a whole new set of rules and will be adrift in a new zone of uncertainty for years, in some cases for decades, until the provision is judicially resolved. Lawmakers have not attempted to quantify these transition costs or evaluate the effects of discouraging private capital investment in innovation while these ambiguities and business risks are resolved. Mr. Gholz's article raises a number of these issues.

Strikingly, there is one feature of the patent system that *everyone* agrees needs major reform: the Patent Office. The Office is underfunded and woefully backlogged. For the last decade, examiners' incentives have been misaligned with the public policy goals of the patent system. Examiner morale has been low and examiners have been leaving the Patent Office in droves. Because the Patent Office has been unable to maintain a cadre of experienced examiners, productivity and perceived patent quality have fallen, and backlogs have nearly tripled in a few short years. Nearly all stakeholders agree that the major factor is "fee diversion," where Congress sets the Patent Office's fees at cost-recovery level, but then appropriates a smaller budget to the Patent Office. Effectively, Congress raids the Office and inventors in order to fund general government. Yet, on this core issue where everyone (except the Appropriations Committee) is in complete agreement—Congress must guarantee that the Office can keep its fees—the bill is eerily silent. It even neglects to fund the extra work that the bill asks the Patent Office to do. Nicholas Godici, the former Commissioner of Patents and Acting Director of the Patent and Trademark Office, discusses funding for the Patent Office in *Adequately Funding the USPTO: A Critical Problem That Must Be Solved*. Dr. Katznelson, an acknowledged authority on statistical trends of world patent systems and the U.S. Patent Office in particular, discusses in his article several other problems that stem from the chronic under-investment in the U.S. Patent Office.

Many of the issues that originally prompted calls for Patent Reform have been addressed by the courts. For example, the Supreme Court raised the bar for the amount of difference over the prior art required for patentability and made it more difficult for patentees to win an injunction to shut down infringement. The Federal Circuit, the federal appeals court that hears appeals in patent infringement litigation from throughout the country, raised the bar for trebling of damages, by requiring a higher showing of willfulness. The role of the courts in patent reform is discussed by the retiring and incoming Chief Judges of the Federal Circuit, Paul Michel and Randall Rader, in an interview with Matthew Dowd, *Conversations with Two Chief Judges.* Also, Ed Reines and Nathan Greenblatt comment on a provision that was in earlier versions of both bills and has now been removed only from the Senate bill, in their article *The Proposed Interlocutory Appeals Provision of Patent Reform—Is It Dead Yet?*

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We believe these issues are as important to the long-term future of the U.S. economy as anything pending before Congress. We hope that the insightful views of our authors are instructive for you. ■