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Good for iPods, but bad for patients

By John M. Maraganore | March 22, 2008

A "PERFECT storm" in Washington is currently building against biomedical patent protection. Pending decisions by the Supreme Court, the patent office, and Congress could fundamentally change the ground rules for patent protection within the life sciences industry to such a degree that in a decade we may not have an industry remaining.

This storm includes at least three components. First, recent Supreme Court rulings have significantly shifted the "goal line" for inventiveness standards in patents, making it much harder for patents to be awarded, and have destabilized patent licensing.

Second, the US Patent and Trademark Office is seeking to change its review process for patent applications by placing shorter limitations on the needed time it takes to invent biotechnological innovations. This action was halted temporarily by a recent US District Court ruling, but the ultimate outcome remains unclear.

And now, most recently the Patent Reform Act of 2007 was passed in the House and a bill is soon to come to the Senate floor. These measures introduce new ways to challenge issued patents after their issuance, resulting in prolonged periods of patent uncertainty. They also limit the scope of damages to those who violate patents, encouraging a lackadaisical attitude among infringers.

The stimulus for the proposed congressional changes comes from the information technology industry, which has spent millions in lobbying efforts. Its view, which is fundamentally at odds with biotechnology's, is that patents are little more than a nuisance, since the time it takes to introduce new products is measured in months and other people's patent claims can decrease profits due to costly litigation and needed royalty payments.

No one wants to have to pay more for (or lose) their BlackBerry or iPod, but the patent changes sought by information technology firms would be nothing short of disastrous for the millions of patients around the world that have benefited from biomedical breakthroughs in diagnosing, treating, and curing disease.

Indeed, in recent years we have witnessed incredible medical advances in cancer therapy, the treatment of heart disease, and autoimmune disorders like arthritis and multiple sclerosis.

Central to these discoveries is a delicate relationship between the scientists and clinicians in academic institutions, the entrepreneurs in the biopharmaceutical industry, and private and public company investors.

The simple economics of financial incentives for investors are fundamental to the success of these companies and relationships. The risks within this industry are truly unlike any other; companies spend about $750 million over a decade to generate a single drug.

Despite these daunting financial challenges, the industry has consistently delivered the world's most important new medicines. However, this is only possible because of the availability of substantial capital investments to fund breakthrough medicines, which are in turn only possible due to the financial incentives patents provide to investors. Patents are a fundamental part of a system where innovators are rewarded for the risks they take; patents allow companies to recover their significant R&D investment during the period of patent-protected sales.

Now this perfect storm of challenges to existing patent rules has the potential to wash away this fundamental landscape of intellectual property protection within the life sciences industry. They would make it much harder to get patent protection that, if obtained, would be both less certain and less valuable. Investors, without the

opportunity to recognize a needed and earned reward from the high costs and long time frames required for the advancement of medical innovations, will simply stop funding research. The result: the destruction of an entire industry that has relied on a strong patent system to discover, develop, and deliver breakthrough medicines to patients.

The Supreme Court rulings and patent office changes are not fully settled yet. There is still time for the Senate to reject or substantially alter the pending bill in light of its potentially devastating impact upon biomedical research. Before moving ahead with new legislation, the consequences of recent judicial rulings should first be evaluated over time, to understand their impact on intellectual property protection. For the sake of patients, this is a time where legislators need to take the Hippocratic Oath.

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