nature biotechnology

Patent reform acts ugly

Controversial US patent system reforms and rule changes currently being proposed spell big trouble for biotech.

If legislators around the world want to know how to stop the biotech revolution in its tracks, they should look no further than the US Patent Reform Act of 2007 (H.R. 1908), which on September 9 passed the House of Representatives and is slated for passage through the Senate in the coming weeks.

The reform is long overdue—the last time US patent law was overhauled, Sputnik was circumnavigating the earth and computers used punch cards, not silicon chips. Today, the US Patent & Trademark Office (USPTO) is drowning under a backlog of 600,000 applications. And some argue that intellectual property (IP) is becoming fragmented and overlapping, with the potential to create an 'anti-commons' effect that hinders innovation. What's more, a lack of understanding of technology or, less charitably, a deliberately obfuscating approach adopted by patent agents, has increased the number of overly broad or poorly written patents. This has created profitable businesses for 'patent troll' companies (which quietly amass IP and then shop around for windfall settlements from infringers), with patent litigation costs nearly doubling through the 1990s.

The new Act contains some welcome proposals. For example, it would harmonize the US patent process internationally by switching to a first-to-file, rather than the first-to-invent, system. This would eliminate costly interference proceedings. But it will also require significant changes in mind-set for US researchers and make it more difficult for individual inventors to compete with deep-pocketed corporations that can file multiple applications.

Overall, there is a great deal more to dislike in this Act than to like.

Under the new law, patent filers must submit a search and patentability analysis with every application. That is a job currently done by USPTO examiners—their main job, one would imagine. So that should certainly lighten their workload, albeit in a way that will radically increase applicants' filing costs.

To help applicants do the patent examiners' job, the USPTO has already implemented some important administrative restrictions. From this month, it will limit to three the number of 'continuations' each invention is allowed (the current rules allow as many continuations as necessary to get the desired breadth of claims). This will clearly be a challenge for biotech companies, which use continuations to add to their early IP as preclinical and clinical development render additional claims to practice. What's more, USPTO now stipulates an arbitrary limit of 25 claims for each patent application, more than the 10 originally proposed in the draft rule, but probably still insufficient to cover groundbreaking biological inventions.

However burdensome these administrative alterations appear, they pale into insignificance compared with parts of the Act that threaten to diminish the value of biotech patenting altogether.

For instance, the Act, if implemented, would direct the courts to base damages for infringement on the economic value of the patent component that was infringed (subtracting all the 'prior art'), rather than on the market value of the entire product, as at present. Equating damages to the marginal value of the invention kills the incentive to defend patents for all but the most obstinate or well-heeled of inventors. Revenue-rich, market-dominant companies (that is, firms like Microsoft and Oracle, which are backing the Act) hardly need worry about patent infringement, whereas inventive, research-based biotech firms can expect little reward, even if their claims stand. And calculating the incremental value of a biotech patent is a feat that would require not only knowledge of the market value of the exploiting products (which is feasible) but also of the product's hypothetical value without the invention. Quite how this would work for biological advances where the inventive step might be a minor, but vital, sequence change or a nuanced but essential difference in a molecular structure is difficult to fathom.

Not only does the Act reduce the incentive to defend patents, it also makes it easier for others to attack them. It proposes 'post-grant reviews' under which third parties could challenge granted patents through procedures that cost a mere $100,000 rather than ~$1 million, on average, for conventional court proceedings. Under these post-grant reviews, the burden of proof of patent invalidity would be much lower than currently required in court, where patents are presumed valid. And patents could be challenged at *any time* during their life (compared with the system in Europe, for example, which allows post-grant review only in the first 12 months after issue). By increasing the frequency and ease of patent challenge, the Act would be a *coup de grâce* for patent value.

The question for legislators is how can a biotech firm, or any high-technology firm for that matter, persuade investors to part with money to support the development of new products when the value of IP is compromised on so many fronts? The Act would make patents narrower and more difficult to build from, facilitate challenges and virtually remove any incentive to defend them.

If the USPTO is understaffed and overwhelmed, the solution is to simply hire more patent examiners and reduce staff turnover—not to destroy the IP bedrock on which biotech is built. If some bad patents are getting through, let opponents weigh in earlier by publishing patent applications before grant of the patent, as is done elsewhere in the world. To have meaningful patent reform, what must change is the administration of the USPTO, not what happens *after* a patent is issued.

What is the point of Congress voting $30 billion to R&D at the US National Institutes of Health if the IP from universities, researchers and the companies that spring from them is stifled at birth? Why would investors put capital into biotech if IP is so radically devalued? And why should our best minds apply themselves to R&D, given a system that so clearly would ridicule their contribution?

Under no circumstances should the Patent Reform Act be passed. It should not be tweaked. The Senate must reject it.