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Covid-19 Vaccine Highlights the Need for Balanced Patent Policy

By David J. Kappos and Jonathan M. Barnett

A balanced approach in patent policy is critical at a time when vaccines are highlighting the importance of a strong patent system to global health and the global economy. Cravath partner David J. Kappos, former director of the USPTO, and Jonathan M. Barnett, professor at the University of Southern California Gould School of Law, suggest steps the Biden administration can take to maintain an equilibrium between deterring patent abuses and rewarding innovation.

For more than a decade, almost every branch of the federal government has taken steps to restrain what has been perceived to be an "explosion" of patent issuance and litigation. The results have been palpable.

A patent owner that brings suit against an infringer must now often fund multi-venue proceedings in federal district court, the Patent Trial and Appeals Board (PTAB) and, in some cases, the International Trade Commission. Expansive judicial understandings of the "abstract idea" and "law of nature" exclusions mean that patents covering software-enabled or medical diagnostic inventions operate under a cloud of potential invalidity.

Even if successful in defending validity and showing infringement, increasingly large percentages of patent owners are likely to fall into judicially created categories for which injunctive relief is practically unavailable.

This shift toward a weak-IP trajectory has rested on widespread views that:

- patent litigation is widely brought on nuisance grounds by "patent trolls",
- the U.S. Patent and Trademark Office (USPTO) regularly issues patents for trivial inventions, and
- the proliferation of patents generates litigation and transaction costs that often result in innovation roadblocks.

While these views were supportable to some extent a generation or more ago, they have since come to lack evidence and policymakers who continued acting to restrict patents failed to consider

the adverse effects on innovation and investment that have now emerged in patent-dependent technology markets.

A once axiomatic guiding light has been forgotten: The costs attributable to a robust patent system must always be balanced against the gains arising from the role that patents play in attracting investment in R&D and the commercialization efforts that convert R&D into new, innovative products and services.

Importance of Patents for Innovation

Skeptics argue that patents are somehow not necessary to support innovation. This line of argument has no credible support in the life sciences sector that most directly impacts human well-being. The gap between the R&D and testing costs of a new drug and the imitation costs borne by an entrant is simply too great for private capital to enter the market without the promise of legal exclusivity.

Additionally, patents enable smaller innovators to compete, including by monetizing their R&D through contractual structures that outsource the testing, production, and distribution functions that are necessary to bring a new drug to market. Consider the partnership between BioNTech and Pfizer to develop a Covid-19 vaccine: a patent-driven alliance between a smaller firm that specializes in innovation and a larger firm that has expertise in the "heavy lifting" required to bring an innovation to market.

Outside of the life sciences, skeptics may fairly point out that some IT companies do not rely on patents to support innovation. Yet that is often because larger platform-based firms can monetize innovations by integrating them into systems technologies that have an entrenched customer base and are difficult to replicate.

By implication, other firms seeking to develop components for established platforms, or breakthrough technologies to challenge those platforms, do rely on patents to earn a return on R&D through licensing and other contractual relationships that avoid the massive costs involved in constructing an end-to-end pathway to market. These relationships result in an innovation "win-win" by promoting technology dissemination among producers, which then promotes technology adoption by consumers.

Balanced Policy Emerged

Under the leadership of Makan Delrahim, the recent head of the Department of Justice's Antitrust Division, and Andrei Iancu, the recent director of the USPTO, a more balanced patent policy has emerged that takes seriously innovators' reliance in the life sciences and IT markets on robust IP rights.

At DOJ, Delrahim redesigned agency policy on standard-essential patents in a manner that recognizes the reliance of chip design firms on patents to monetize their R&D investments, including through licensing relationships with device makers.

At the USPTO, Iancu adopted sensible "due process" modifications to the inter partes review process that have provided patentees with more meaningful opportunities to defend patent validity when challenged by petitioners.

Maintaining Equilibrium

As the Biden administration settles in, it is worthwhile to consider what steps can be taken to maintain this balanced approach toward engineering an innovation ecosystem that deters abuses of patents in litigation while ensuring that legitimate inventors can rely on patents to earn a commensurate return on their high-risk investment.

It is also worth keeping in mind that the U.S. runs a uniquely large IP trade surplus with the rest of the world. The institutional devaluation of patents through judicial decisions, legislative enactments, and administrative actions is counterproductive and risks impeding the ability of U.S. innovators to earn a fair return for their valuable contributions to the global knowledge economy.

The three branches previously took aggressive action to deter abuse of the patent system. In the process, they devalued innovation incentives excessively. Restorative progress has been made, and the new administration needs to continue on that course to ensure that incentivizing innovation remains a prime objective.

As one of us has documented in a recent book, the U.S. has a long history of technological breakthroughs by inventor-entrepreneurs who have relied on the patent system to challenge incumbents that can outperform on every parameter except innovation. For too long, patent and innovation policy has been dominated by a single-minded narrative that has overlooked the constructive uses of patents in supporting innovation and facilitating the cooperative partnerships that ultimately deliver value for consumers.

Innovators, and the investors who back them, are unlikely to undertake the difficult task of disrupting technological paradigms without some meaningful expectation of exclusivity if that objective is achieved. A robust innovation ecosystem demands a commitment to a robust patent system.

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