The Outer Limits of Non-Consensual Patent Use Regimes and their Implications for Competitive Follow-On Innovation in Pharmaceuticals: A Comparative Perspective on Europe and the United States

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Long Abstract

Patents in the pharmaceutical industry incentivize and enable innovation by increasing R&D appropriability, attracting venture capital, and facilitating upstream technology markets and division of labor between academia, biotech start-ups, and pharmaceutical incumbents. Pharmaceutical innovation, however, reveals a degree of cumulativeness. New medical uses of patented large or small molecules may be discovered, including through serendipitous events; new formulations of patented biopharmaceuticals may be developed (i.e. "biobetters" and biosimilars offering innovation in drug delivery); patented compounds may be integrated into fixed-dose combinations providing therapeutic advantages that each of the compounds cannot offer as a mono-product; patented research tools and platform technologies may be necessary to research and develop novel drugs, and the former may or may not be incorporated into these drugs.

Under its utilitarian function to drive technological change, the patent system must also account for the need to ensure optimal *follow-on* innovation, as it may offer substantial therapeutic value. One model to that end is illustrated by "prospect" patents that presuppose a process of industrial follow-on innovation centrally managed by the pioneer inventor. In the alternative, follow-on innovation may unfold as a competition-driven process in the form of parallel and independently managed R&D projects. The current model of promoting follow-on innovation in the US and Europe seems to represent a mixture of these two.

To delineate the limits on the freedom to operate of independent follow-on innovators, this work analyzes the current the scope of non-consensual patent use regimes in both jurisdictions. These regimes include Bolar and research exemptions from patent infringement; European compulsory licensing for patent dependency and public interest; governmental rights under the US Bayh-Dole Act and the governmental use exemption under 28 U.S.C. § 1498; the US reverse doctrine of equivalents and patent misuse doctrine; and the proportionality/balance-of-interests assessment of injunctive relief requests carried out by both European and US courts at the remedies stage of patent litigation.

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This work suggests that the US system of non-consensual patent use regimes generally offers greater freedom to operate of independent follow-on innovators. The main limitation of the European system seems to be its fragmented nature, creating a situation where a single unauthorized follow-on activity may be lawful in one jurisdiction but not in another. In both Europe and the US, research tool uses, early-stage R&D, and research aimed at introducing incremental innovation seem more vulnerable to blocking strategies, as compared to late-stage R&D, product commercialization efforts and R&D related to potentially breakthrough and disruptive innovations, provided the latter is not too incipient.