Technical Proposal
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Incremental Innovation and Patent Policy in the Pharmaceutical and Medical Device Industries

In Response to the NBER Innovation Policy Working Group 2012-2013 Call for Research Grant Proposals

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Introduction: Are patent policies that differentiate between pioneer and incremental inventions feasible in the US, and might they offer a more socially cost-effective approach to incentivizing innovation than the current uniform patent system? This proposal outlines a three-part research agenda to study the extent and implications of incremental innovation in the US pharmaceutical and medical device industries. The completed research will form the main results in a manuscript suitable for submission to a peer reviewed journal. It will also establish the foundation for a more complete modeling exercise and additional empirical work in this area by the applicant.

Motivation: Patent protection is one solution to a well-recognized market failure, namely that if innovators are unable to appropriate the social value of their inventions they may invest too little in innovation from a social perspective (Arrow, 1962; Nordhaus, 1967). Patents are, however, at best a "second best" solution due to the welfare loss introduced by granting innovators monopoly power. Under current policy it is hoped that a uniform patent award incentivizes near-optimal investment in innovation in the aggregate. [1] Incentives for individual investment decisions may be misaligned under a uniform patent system especially when innovators use private information to distinguish between types of inventions or innovative activity. Much of the economic literature proceeds under the assumption that uniform patents are the only feasible policy alternative due to incomplete information on research and development processes and characteristics of individual inventions.[2]

The premise underlying this proposal is that a uniform patent policy is an increasingly tenuous match with the realities of innovative activity and output, especially in the pharmaceutical and medical device industries where incremental innovation is common (Mulcahy 2011; Berndt et al. 2006). Individual drugs and devices are often simultaneously protected by multiple patents (a "patent portfolio"). A typical portfolio includes one or more patents claiming a novel, important pioneer invention and other patents claiming related incremental inventions. Current uniform patent requirements and term do not reflect this obvious heterogeneity in inventions. As a result, innovators may have too little incentive to invest in in pioneer-type inventions and too great an incentive to invest in incremental-type innovation from the social perspective. Alternatives to a uniform patent policy are found in various settings. After patents are issued, the US judicial system has long embraced the differentiation of "pioneer" and "incremental" inventions in infringement litigation where courts have leeway to set broader boundaries for pioneer patents (Steinhauer 1992).[3] Outside the US, two-tier patent systems are common (e.g., in Germany and Australia), often featuring "petty" patents with less rigorous requirements and shorter-term protection for incremental inventions (Janis 1999; Lichtman and Lemley 2008).

Context: The pharmaceutical and medical device industries offer several advantages to a study of incremental innovation. First, both industries are characterized by sequential investments in innovation which are relatively easily categorized as either pioneer or incremental in nature. Second, anecdotal evidence suggests the role of incremental innovation and patents differs across these industries, with patents having more value to pharmaceutical innovators than to device innovators. Third, a database of pharmaceutical patent portfolios has already been compiled by the applicant (Mulcahy 2011). Finally, there is increasing overlap between these industries as drug-device combinations (e.g., drug eluting stents) benefiting from both drug and device patents become more common. While the specific study of these hybrid products is outside the scope of the current proposal, the research outlined herein provides the foundation for future work in this area which will be of interest to industry and regulators.

Approach: This proposal outlines three main tasks. The first is the development of a narrative conceptual framework which builds on a rich literature on sequential or cumulative innovation (see Scotchmer 1991). The key additions in the framework developed here include: 1) The inclusion of two types of inventions, pioneer and incremental, and two distinct R&D processes, one more likely to generate pioneer inventions and the other incremental inventions; 2) Incorporating the process by which innovators chose investments to maximize returns over a product's complete lifecycle; 3) Accounting for the benefit accruing to innovators from portfolios of claims[4] rather than individual patents; and 4) Conceptualizing a potentially nonlinear relationship between number of patents and benefit to innovator (due to the patent "thicket" concept (Shapiro 2001), or leverage in licensing negotiations (Cohen et al.

2000)). An additional assumption appropriate for the pharmaceutical and device industries is that incremental innovation is mainly internal, i.e., competitors do not introduce incremental improvements of an incumbent's product. Innovators choose investments in the two R&D processes given an initially uniform patent policy which will then be modified to match the policy alternatives described below.

The second, empirical component of the proposal is primarily descriptive and requires the construction and analysis of a claim-level[4] database on inventions relevant to specific pharmaceutical and device products. The specific products considered for this analysis will selected to correspond with the time and effort available for data collection with the aim of including products from at least three drug and device classes. Researchers will collect citation (self and other) and foreign approval data from the USPTO and the Derwent Innovations Index, invention type from an abstract scan and the FDA's Orange Book, related regulatory approvals from the Drugs@FDA database, and information on the perceived importance of the invention from SEC 10-Ks, manufacturer annual reports and releases, and other sources. The end product is a characterization of the contents of patent portfolios in terms of novelty and importance. Indices ranking patents on relative novelty and importance constructed from the quantitative and qualitative data noted above are one mechanism to report results and would allow portfolios to be rated and compared on these dimensions. While some patent-level data is already collected for pharmaceuticals (Mulcahy 2011), additional claim-level data will be collected for these drugs. Device data will be collected from scratch.

The third component is an analysis of alternatives to the current uniform patent policy drawing on the framework and characterization of patent portfolios outlined above. The goal is to describe how alternate policy regimes might affect investments in pioneer-type and incremental-type innovation and costs to society in the drug and device classes selected for empirical analysis. This is intended as a back of the envelope exercise to assess the relative "social cost-effectiveness" of one policy versus another at incentivizing innovation (Gilbert & Shapiro 1990). One key input in this exercise is information on the relative novelty and importance of patents and portfolios described above. Additional data and assumptions (e.g., product revenue and costs, characteristics of potential substitutes, investment decision timing) will be clearly introduced. One alternative policy is an *ex ante* multi-tier patent system where innovators sort inventions into multiple patent types.[5] Under this option, USPTO would reallocate resources to increase scrutiny of applications in the "first" tier while applications in the "petty" tier face less severe patentability requirements.[6] A second option is to abandon patents in favor of a regulatory exclusivity system, i.e., relying on FDA approval as a proxy for the traditional patentability requirements. Regulatory exclusivity already exists in the pharmaceutical and device context, e.g.., new drugs receive a five year "data exclusivity" period during which generic competitors cannot receive FDA approval, regardless of patents, and similar exclusivity will extend to future biosimilar regulation.

A third option is an *ex post* multi-tier payment system where the parameters of patent protection are determined in part by the social value demonstrated by a new invention. While this approach has long been viewed as impractical, it warrants reconsideration in the drug and device context where payers and regulators increasingly assemble evidence on value to inform reimbursement decisions and levels. Pressure from payers may result in a *de facto* two-tier intellectual property system for drugs and devices even as the USPTO continues to grant patents for (unreimbursed) incremental innovations.

Use of award: The $20,000 award will be used to provide coverage for Dr. Mulcahy to perform the tasks outlined above and one graduate student to assemble and clean patent and litigation data. Dr. Mulcahy's past work in pharmaceutical economics and intellectual property (including undergraduate research on biotechnology patents with F. M. Scherer and dissertation research on patent litigation in pharmaceuticals under Patricia Danzon at Wharton) demonstrates his expertise in the proposal subject area. Dr. Mulcahy will benefit from facilities, infrastructure, and interdisciplinary collaboration of The RAND Corporation.

Anticipated output: The research outlined above represents the main findings of at least one manuscript suitable for submission to, e.g., the Journal of Law and Economics or the Journal of Health Economics. Findings from this research will provide the foundation for future inquiry in this area by the applicant.

Notes

[1] There is, e.g., a single set of patent requirements (novelty, nonobviousness, and utility), a single patent term (20 years for recently filed patents), and a single process for resolving allegations of infringement.

[2] The literature does consider various permutations of length and breadth for uniform patents (Gilbert & Shapiro 1990).

[3] According to the US Supreme Court, the term "pioneer" is, "although used somewhat loosely, […] commonly understood to denote a patent covering a function never before performed, a wholly novel device, or one of such novelty and importance as to mark a distinct step in the progress of the art, as distinguished from a mere improvement or perfection of what has gone before" (170 U.S. 537(1898)).

[4] Patents often include multiple individual claims which collectively set out the scope of the patent.

[5] This is related to the patent renewal "menu" concept introduced by Scotchmer (1999) and Cornelli and Schankerman (1999) but also considers differing patent requirement or infringement provisions.

[6] Note the fee-based expedited review provisions of the 2011 America Invents Act shorten time to issue but do not modify patentability requirements or patent term.

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