# *Patent Validity Across the Executive Branch: The Case of the Life Sciences*

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Within the executive branch, agencies and offices other than the Patent and Trademark Office ("PTO") implement -- and sometimes even formulate – patent-related law and policy. Legal scholars have recognized this reality. Thus we have seen a number of studies of the International Trade Commission, an independent agency that has quasi-judicial authority to issue exclusion orders against imported goods that it finds infringe U.S. patents. Scholars have also investigated the institutional role of the antitrust agencies (the Federal Trade Commission ("FTC") and DOJ's Antitrust Division) in formulating policy at the patent-antitrust interface.

Less recognized is the manner in which executive branch actors other than the PTO have influenced decisions on core questions of patent *validity* – that is decisions on such fundamental issues as how the patent statute's broadly worded requirements of patentable subject matter, utility, non-obviousness, and adequate disclosure should be interpreted. This lack of recognition is perhaps not surprising – after all, the PTO is the only executive branch agency given the power to adjudicate the validity of patent applications. Additionally, unlike some other agencies, the PTO (as contrasted with the Department of Justice) typically takes the lead in litigating non-Supreme Court cases to which the PTO is a party. Similarly, with respect to the filing of U.S. government amicus briefs in patent validity cases, the PTO (through its Solicitor's Office) typically takes the lead.

At least in the life sciences, however, agencies other than the PTO have, over the last 20 years, significantly influenced the evolution of the rules and standards that govern patent validity. In the early 1990s, the National Institutes of Health ("NIH") first raised the question of whether innovation goals would be served by patents on gene-related research that was several steps upstream from a full gene of known biological function. By the late 1990s, NIH had come to a conclusion. As large numbers of patent applications drawn to gene fragments of unknown biological function began to be filed, NIH sounded an alarm over the transaction cost impediments requirements to license numerous upstream patents would pose for subsequent research.

Although the PTO was initially resistant, an apparent consequence of consistent NIH pressure was PTO guidelines that raised the patentability bar posed by the utility requirement. These guidelines (subsequently upheld by the Court of Appeals for the Federal Circuit, the appellate court that hears all patent cases) allowed the PTO summarily to reject all claims to gene fragments of unknown biological function.

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Particularly given contemporaneous Federal Circuit case law that effectively eliminated the non-obviousness requirement in genomics, the utility guidelines arguably forestalled the development of a genomic patent thicket. More recently, in the context of the ongoing litigation challenging on patentable subject matter grounds the DNA patents held by the diagnostic firm Myriad, executive branch actors other than the PTO have had a prominent role.

As a normative matter, investigating the role of executive branch actors other than the PTO has significant payoffs for the debate over institutional choice in patent policy. Critics of a policymaking role for the PTO have legitimately been concerned about capture. The capture concern may be mitigated by the reality that, at least in significant life science cases, PTO decision making is embedded in the larger institutional apparatus of the executive branch. Although debate among knowledgeable agencies with different perspectives may not always yield the right conclusion, it is likely to reach conclusions that are at least plausible. Certainly these conclusions will be less subject to criticism regarding capture than determinations made solely by the PTO.

Of course, for purposes of thinking more globally about a PTO role in policymaking over patent validity, the reality that substantial intervention by other executive branch actors may be limited to the life sciences (and a sometimes overlapping category of litigated cases in which the Solicitor General is heavily involved) represents an obvious limitation. On the other hand, one might imagine creating institutional structures that would allow agencies other than the PTO to play a mor*e systematic role.

A more systematic role *ex ante* may be particularly useful. As the patentable subject matter example illustrates, when agencies get involved *ex post*, in the context of litigation disputes, the policy space is likely to be more constricted. Courts that adjudicate disputes may legitimately be quite concerned about the retroactive effects of their decision making on large numbers of existing patents. Conversely, as the utility example illustrates, even though the PTO does not have rulemaking authority over questions of patent validity, and the Federal Circuit does not give validity guidelines that it issues any formal deference, guidelines that have been in place for years may have considerable weight.