Inter-Agency Conflict And Cooperation In Patent Litigation

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Traditionally, Congress and commentators view administrative law as having little to do with patent litigation. There has been a recent increase, however, in various types of patent litigation that involve regulatory determinations, such as Hatch-Waxman Act patent litigation, section 337 proceedings in the ITC, standard essential organization (SEO) licensing lawsuits, and “biosimilar” cases. And, where regulations do play a role in the administration of these suits, multiple agencies are often involved: the FDA, the FTC, the ITC, and, of course, the PTO.

Although a long-standing problem in the law, scholars have only recently begun to develop theoretical and political models of agency-agency interaction. This scholarship can be synthesized into broad groups of agency conflict and cooperation that may prove useful to agency interaction—or the lack thereof—in regulatory-heavy patent litigation. A model of “divided authority,” for example, occurs where Congress divides authority for a single statutory scheme among competing agencies. “Overlapping authority” exists where Congress gives multiple agencies administrative powers over several, related statutory schemes. “Primary authority” is present where Congress has given one agency primary control over multiple statutory schemes that affect other agencies. And “ministerial authority” exists where one agency must administer a particular statutory scheme without any substantive rule-making power.

Hatch-Waxman Act litigation serves as a representative example for how these models could be applied to better agency decision-making in patent litigation. The FDA, for example, has only ministerial authority over Orange Book listings, which has proven to be a cause of regulatory gamesmanship. Using a model of divided authority, Orange Book listings could be improved by employing the PTO’s expertise. Nor does the FTC employ the PTO’s expertise in reviewing “reverse payment” settlements between branded and generic pharmaceutical manufacturers, even though determining the strength of the patents-at-issue is crucial. A model of overlapping authority may prove fruitful. Similarly, the FTC does not consult the FDA regarding settlement-related business transactions in the pharmaceutical industry, such as manufacturing agreements, mergers, and transfers of New Drug Applications (NDAs), even though the FDA could provide some insight into such practices. Here, a model of primary authority could be deployed in such decision-making. This approach could similarly be used for other varieties of patent litigation, such as “biosimilar” litigation, section 337 ITC petitions, and standards essential or FRAND licensing disputes.

Employing models of inter-agency conflict and cooperation to patent litigation should alleviate regulatory gamesmanship as well as market inefficiencies in politically feasible, easy-to-administer packages of rule-making. These changes, crafted well, should ultimately make agency decision-making better, easier, and more efficient, and should enable innovators speedier access to the marketplace.