Intellectual Property and Electronic Health Records: A Review of the 2019 Interoperability Rulemaking

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"Earlier this year, the Office of the National Coordinator for Health Information Technology (ONC, part of the Department of Health and Human Services) released a 187-page notice of proposed rulemaking on interoperability of electronic health records. Perhaps unexpectedly, the rulemaking includes a substantial discussion of intellectual property licensing, in fact going so far as to provide specific rules and procedures for FRAND-like licensing of IP necessary for health care record interoperability.

As I and others have observed, intellectual property can conflict with government regulatory objectives, in this case public policy favoring portability of health records, in ways such that compliance with the regulatory scheme triggers infringement of a patent or copyright. In most cases, the regulating agency is unaware of or chooses not to deal with that conflict, leaving regulated entities in an unfortunate place. In the case of the interoperability rulemaking, though, ONC not only recognizes the conflict but makes an explicit effort to balance interests between intellectual property holders and the government's objectives. The ONC proposed rulemaking thus offers a unique opportunity to observe how a government agency, faced with and aware of that conflict, addresses it through regulatory policy.

Looking at ONC's proposal from an intellectual property policy lens reveals important successes and shortfalls. On the one hand, the proposal draws from private industry experiences such as standard-essential patent policies, as well as from the case law that has developed around those policies. In parts the agency mirrors private industry practice, and in others the agency—unconstrained by the antitrust concerns that private standard-setting organizations face—is able to deviate.

The proposed rulemaking is furthermore a case study on the limits of agencies to deal, ex ante, with the holdup issues that arise from the combination of intellectual property protection and regulation. Among other things, the agency is limited to sanctioning firms that fall within the agency's regulatory purview of certifying electronic health record systems; the alienable nature of intellectual property rights could greatly vitiate the teeth of the agency's enforcement as a result. Furthermore, given the possibility of "standard-essential copyrights" in view of the Oracle v. Google litigation, ONC may end up in a position of having to deal with a larger swath of intellectual property protections than it originally contemplated in its proposed rulemaking. I will consider some ways that ONC can address these issues. But these limitations more importantly demonstrate an increased need for ex post adjustment of intellectual property rights by courts when faced with an overlap between intellectual property and regulation."