Intellectual and Regulatory Property

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Conventional accounts of the relationship between IP and FDA law depict distinct regimes at crosspurposes with each other. By these accounts, public welfare regulations compel inventors of medical technologies to incur costs that the government offsets with grants of IP rights. Yet this simplistic framing breaks down upon closer examination. Public interest concerns cabin IP protection, and regulation erects barriers to competition that benefit innovators. Moreover, a broad conception of innovation encompasses not only the creation of new inventions, but also the accumulation of new information about the benefits and risks of existing technologies. On this view, IP and FDA regulation interoperate at different points in technology development timelines to create incentives to develop socially valuable information. This Article adds to the burgeoning literature on legal structures that encourage innovation beyond IP by explaining how ostensibly conflicting IP and regulatory regimes actually perform overlapping, complementary functions as parts of a composite legal scheme to govern technological knowledge production. It uses the term "regulatory property," in contradistinction to regulatory takings (and givings) of preexisting property, to highlight the ways in which regulatory oversight gives rise to the creation of new information resources. IP exerts a pulling effect on would-be inventors, while FDA regulation pushes developers to move nascent discoveries downstream along innovation pathways. As regulatory property is generated, various federal and state laws manage its allocation across proprietary and public domains. The Article examines the interplay between patents, trade secrecy, and FDA regulation, and offers a framework for developing more holistic biomedical innovation policy. More broadly, it suggests that drawing distinctions between intellectual and regulatory property can aid in developing coherent governance schemes for all potentially beneficial, risky technologies.

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