Biosimilars and Manufacturing Trade Secrets

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The rapidly increasing role of biologics in the national health care budget created the political pressure necessary to implement a "generic" pathway. The extent to which this pathway will actually succeed in reducing costs is unclear, however. Processes for making biologics are notoriously complex, and an enormous literature testifies to the costs that firms aiming to make biosimilars will face. What this literature generally ignores is the reality that the information to make biosimilars (or perhaps even the holy grail of "interchangeables") does of course exist - with the firms that have made the pioneer biologics. To some extent, because of regulatory filings, the FDA also has this information. The obvious challenge is how to make at least some of this information publicly accessible without damaging innovation incentives. Perhaps enablement requirements for biologics patents should be applied more strictly. Indeed, using existing but underutilized statutory authority, the PTO could ask FDA experts to assist in making enablement determinations. Because pioneer biologics firms have 12 years of regulatory exclusivity, however, such a move may cause pioneer firms to avoid patents altogether and rely even more heavily on trade secrecy. Alternatively, regulators could use the carrot rather than the stick, offering additional rewards to those who disclose trade secret information. Information release through carrots and sticks could feed into nascent public efforts to create a general purpose knowledge base for biologics manufacture. From a broader theoretical standpoint, the role of trade secrecy in biologics manufacturing illuminates not only how firms make choice between patents and trade secrecy but also debates regarding the disclosure function of patents and the complex intersection between patents, trade secrecy, and the regulatory state.

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