Incentives, Intellectual Property, and Black Box Personalized Medicine

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Personalized medicine is reshaping the biomedical landscape. Where Big Data meets Big Health, it has been hailed as the next leap forward in health care, and is both a subject of health law and an object of innovation policy. Humans are inherently variable, and closely matching treatment to patients has the potential to save and extend lives by suggesting better treatments, to avoid unnecessary treatment, and to streamline the process of drug discovery and clinical trials - all important innovation goals. But the version of personalized medicine being implemented today is just an entrée into the realm of what huge amounts of data can tell us about our health and how to improve it. Current versions of personalized medicine rely on the simple relationships that we can explicitly identify and validate in clinical trials. But biology is complicated. This paper introduces into legal scholarship the concept of black box personalized medicine, which seeks to use more directly that biological complexity by finding and using more complex, implicit biological relationships within the troves of health data we are increasingly amassing. This new form of personalized medicine offers potentially immense benefits, but requires high investment in developing new data, models, and applications - all of which are hard to protect once they become public. The current set of intellectual property incentives, particularly after the Supreme Court's recent decision in *Prometheus*, fails to provide the necessary incentives for that investment, and instead pushes firms toward simple diagnostics paired with devices or trade secrecy and proprietary data. This paper addresses the concepts underlying black box personalized medicine, explains why the current intellectual property landscape provides incentives which are both inadequate and misdirected, and briefly suggests policy options to better align incentives.

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