Innovation-friendly regulation for biotechnological innovation

Abstract

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Dental caries? 'SMaRT' bacterial strain promises to fight the bacteria responsible for tooth deterioration. Blindness caused by glaucoma? Smart contact lenses might provide the answer to this problem. Smart regulation to ensure the timely and friendly commercialization of these innovations? We are very sorry to inform you that smart regulation has not emerged yet.

In the last decades, regulators such as the US Food and Drug Administration have been facing a complex dilemma: on the one hand, they must only authorize safe and effective medical innovation; on the other, they should avoid delaying the introduction of innovations in the marketplace due to morose investigations. The regulation of innovation through statutes and regulations has often been criticized and qualified as a true antithesis: innovation is a fast changing and fluid reality that does not go well with rigid top-down rules. However, even critics of the regulation of innovation admit that the former is necessary because, on the one hand, the lack of an effective legal framework can be a significant obstacle to innovation. On the other, 'a form of case-by-case-litigation can easily prove to be worse'.

In this paper, I focus on the challenges of biotechnological innovation for medical purposes and try to sketch a legal framework for 'innovation-friendly regulation' of this emerging technology. An 'innovation-friendly regulatory zone' is not only a place where hurdles are removed and biotechnology is given the freedom to fly towards more innovation. Instead, here biotechnology is given wings that will not 'melt' as it approaches the sun. Therefore, I argue that regulatory instruments are not necessarily obstacles to biotechnological innovation, but rather 'wings with licenses to fly' that if correctly designed, can have a positive effect on the advancement of innovation.

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In this paper, I analyze different types of regulatory approaches and instruments that could be more often used in the regulation of biotechnological innovation to create the mentioned 'innovation-friendly' zone, notably adaptive licensing with regional pilot products, temporary and experimental regulations, soft law, and 'contracts' between regulators and biotechnological companies to advance innovation. I draw inspiration from concrete examples (*e.g*. temporary regulation of experiments with stem cells in the Netherlands) and adopt the perspective that, despite the differences characterizing the diverse emerging technologies, regulatory learning is possible under specific conditions (*e.g.* can biotechnology draw lessons from the experience of nanotechnology with soft law?)

My paper aims to address the following questions: (i) What is the relevant definition of 'innovation' for the regulation of biotechnology? (ii) What are the specific challenges faced by regulators in the regulation of biotechnology? (iii) Can regulators be at the throttle of biotechnological innovation? (iv) What is 'innovation-friendly' regulation for biotechnology? (v) What regulatory approaches and instruments can ensure the timely introduction of biotechnological innovation while safeguarding potential risks to human health? (vi) Should preference be given to hard or soft law? (vii) Can regulators of biotechnological innovation learn from the successful regulation of other emerging technologies and are 'regulatory transplants' impossible?