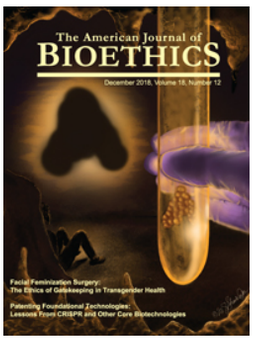

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Fair Governance of Biotechnology: Patents, Private Governance, and Procedural Justice

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PATENTS AND PRIVATE GOVERNANCE

In their article "Patenting Foundational Technologies: Lessons From CRISPR and Other Core Biotechnologies," Feeney and colleagues (2018) provide a critical analysis of Farrelly's (2016) take on patents. Patents serve to encourage investments needed to get new biotechnologies on the market, yet may also raise distributive justice concerns by delaying development and limiting access to the patented technology, as Feeney and colleagues (2018) point out. Such inequality in access is particularly problematic for what they refer to as "foundational" technologies, given their great promise for both fundamental research and therapeutic applications. To mitigate these concerns, a number of ways are suggested to curtail the exclusivity afforded by patents on foundational technologies so as to increase access to these technologies. In doing so, the authors adopt a nonideal perspective toward patents, taking a real-world starting point.

As Feeney and colleagues (2018) discuss, patents are "rights of exclusivity" and can thus also be employed to achieve private governance. Private governance occurs when certain phenomena, such as the use of new biotechnologies, are regulated by private agents rather than through governmental policies. Correspondingly, exclusive rights can give patentees the power to direct others' use and research for private good, but also for societal good through so-called "ethical licensing" (Sherkow 2017). The license that Editas Medicine, Inc. (Editas), the surrogate licensee to which the Broad Institute has outsourced its licensing and commercialization rights, granted to Monsanto (recently acquired by Bayer) is an example of such ethical licensing. In this license, specific applications were expressly prohibited, such as the creation of sterile "terminator" seeds or the conduct of research aimed at commercializing tobacco products (Feeney et al. 2018). Similarly, Kevin Esvelt proposed using gene drive patents to prevent others from using this technology without disclosing their research plans and accompanying safety and ethical issues (Guerrini et al. 2017; Regalado 2016).

While we are sympathetic to the nonideal perspective adopted by Feeney and colleagues (2018) and agree that it is important to address the distributive justice concerns of biotechnology patents, their approach fails to address concerns of procedural justice raised by the use of exclusivity rights for private governance. Like Feeney and colleagues (2018), we consider it praiseworthy that patentees such as Editas aim to pursue a socially responsible approach in their licensing agreements, but we argue that using property rights in this way raises concerns beyond the mere issue with the voluntariness of adopting a socially responsible approach that they bring forward. In what follows, we discuss why this is the case, why procedural justice matters, and propose a potential solution to mitigate these concerns.

PRIVATE GOVERNANCE AND PROCEDURAL JUSTICE

Foundational technologies such as CRISPR (clustered regularly interspaced palindromic repeats) are exceptional not only in terms of the promises they hold for fundamental research and therapeutic applications, but also in terms of the discussion and disagreement they generate about what would constitute "socially

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responsible" or "ethical" use of these technologies. As there is no widely accepted, independent criterion to determine this, such value pluralism poses a legitimacy problem: Who should be allowed to decide this, and under what conditions?

By leaving the determination of what is "socially responsible" or "ethical" to the sole discretion of the patentee, ethical licensing through private governance raises not just distributive justice concerns, but also concerns related to the fairness of this decision-making process: concerns of procedural justice. Given the absence of a widely accepted criterion to determine what counts as a "socially responsible" or "ethical" application of new foundational technologies, ethical licensing should foster broad debate about whether and when these epithets apply, rather than leaving it solely up to the patentee to determine this.

We contend that the societal importance of foundational biotechnologies provides a rationale not only to impose obligations on patentees to increase access to these technologies, but also to safeguard the fairness of regulatory processes for the use of these technologies. A fair process can provide a legitimization for the way in which decisions about the use of these technologies are made (Daniels 2008), even though it has been argued that a fair process does not guarantee that the resulting outcome is just.

Although it is beyond the scope of this commentary to specify necessary and sufficient conditions to achieve procedural justice in ethical licensing, such a process should at a minimum allow a broader group of stakeholders, other than just the patentee, to have insight and influence in those terms of the license that govern acceptable uses of the technology. Furthermore, the debate about these restrictions should be made as transparent as possible, allowing the community at large to hold patentees and licensees accountable for the arrangements made.

ADDRESSING THE PROCEDURAL JUSTICE CONCERNS IN ETHICAL LICENSING

In the field of genome editing broadly construed, the need for stakeholder engagement in the discussion about the governance, applications and use of these technologies is widely acknowledged. Among others, Jasanoff and Hurlbut (2018) have proposed a "global observatory," an international network of different stakeholders that should deepen and enrich the debate about biotechnologies. Similarly, patent scholars have come up with proposals to increase responsiveness to societal interests. Howe (2013), for example, has defended a community-oriented concept of patents that entails obligations for patentees on green technologies to contribute to a better environment, the so-called "stewardship" model.

We acknowledge that different strategies may be employed to increase procedural justice in ethical licensing. One solution might be to allow democratically chosen governments to control or oversee licensing conditions. Given their democratic legitimacy, such governmental involvement could increase procedural justice. Nevertheless, we believe this solution poses two problems. First, this approach would strongly compromise the rights of patentees and thereby threaten the further development of these technologies in the first place, raising distributive justice concerns as patentees would be less likely to invest in new technologies. Second, it would result in internationally fragmented policies, as different governments will likely come to different regulatory frameworks. A second solution, advanced here, circumvents these problems by acknowledging that patents incentivize research investments in biotechnologies (Farrelly 2016). At the same time, this solution diminishes problematic characteristics of private governance by allowing other stakeholders to have insight and influence in decision making about acceptable use of these technologies, thereby optimizing the balance between procedural justice and distributive justice.

Specifically, we suggest creating a platform akin to the Creative Commons platform in the creative industry. Creative Commons unites different stakeholders from the creative industry to formulate a model license, reflecting what the stakeholders agreed is a fair balance between the rights of creators and the public. Although the use of a Creative Commons license is not mandatory and may be tailored to the wishes of the copyright holder, it has set a "gold standard" for open licensing of creative content. Adherence to this gold standard can have important reputational benefits for copyright holders, in addition to encouraging widespread dissemination of their work.

A similar process could be facilitated by a platform that brings together stakeholders from the CRISPR community, including scientists, research institutes, patient organizations, and pharmaceutical companies, such as the one proposed by Jasanoff and Hurlbut (2018). Even in the absence of full agreement on the ethical use of a technology such as CRISPR, these stakeholders could jointly formulate a guideline in which consensus is specified. As mentioned previously, this platform should be open to the public to the extent possible to allow public scrutiny of (debates on) the contents of the guideline. The best practices thus formulated could become a guideline for ethical use of CRISPR technology and a model license for those wishing to license the technology.

Of course, the voluntariness of committing to such a platform's blueprint license poses problems. These problems might be alleviated by making government grants conditional on the recipient's commitment to the platform's principles, among other solutions. Moreover, the shift toward more openness and societally responsible use of intellectual property that has been observed over the past years in various industries, such as the publishing industry, stems hopeful. Within the CRISPR community, the example of Editas shows that also in this

industry, patentees are receptive to societal interests and appear willing to take them into account in the execution of their rights.

CONCLUDING REMARKS

By leaving the determination of "socially responsible" use of foundational technologies to the sole discretion of the patentee, ethical licensing through private governance raises concerns of procedural justice. It is imperative to urge the pursuit of policies that encourage broader insight and influence in this process, such as the one advanced here, to ensure legitimate decision making on technologies that have broad societal impact.

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Is CRISPR Different? Considering Exclusivity for ResearchTools, Therapeutics, and Everything In Between

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Feeney and colleagues (2018) identify an issue that has been widely discussed in the literature: the potential impact of patents on the dissemination and use of CRISPR gene editing technology (Contreras and Sherkow 2017; Contreras 2018). By looking at the manner in which two earlier technologies—recombinant DNA and the polymerase chain reaction (PCR)—were handled, they seek to derive "recommendations for realistic and workable guidelines for patenting and licensing" of CRISPR technology (36). Throughout, they seek to rebut Farrelly's argument (2016. *Biologically Modified Justice*. UK: Blackwell) that patents serve a moral function by incentivizing the development of socially valuable innovations.

Feeney, et al. begin by characterizing CRISPR as a "foundational technology" (36), which they define as a technology that "rarely yield[s] direct societal benefit, but constitute[s an] important tool[] for further research" (37). In the literature, such technologies are commonly referred to as "research tools"—basic scientific

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