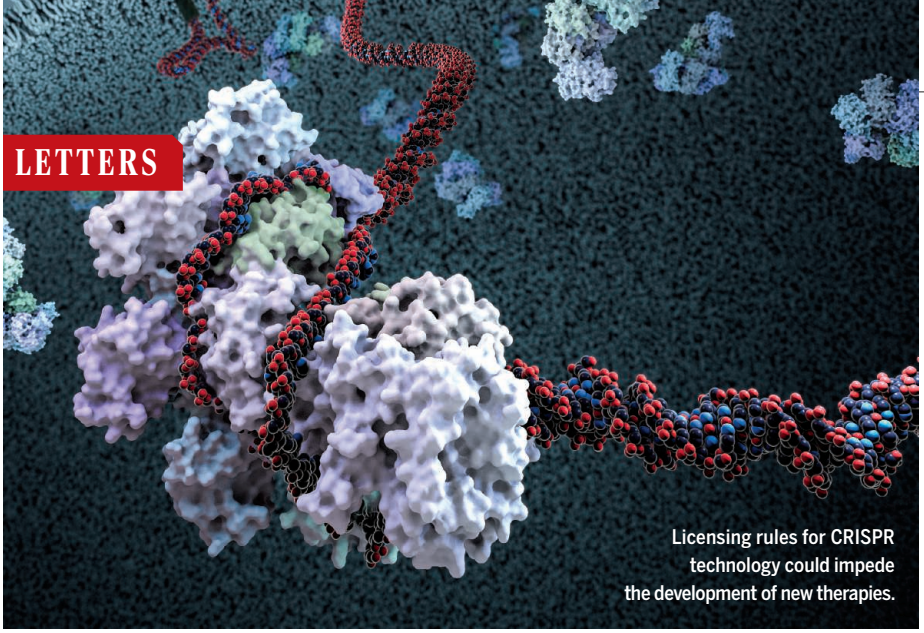

Licensing rules for CRISPR technology could impede the development of new therapies.

Edited by **Jennifer Sills**

Patent pools for CRISPR technology

J. L. CONTRERAS and J. S. Sherkow's Policy Forum "CRISPR, surrogate licensing, and scientific discovery" (17 February, p. 698) suggests that exclusive licenses granted by the foundational patent holders "could rapidly bottleneck the use of CRISPR technology to discover and develop useful human therapeutics." To address this problem, Contreras and Sherkow call for the institutions that control patent rights to "ensure…exclusive licenses are narrowly drawn to specific genes." An independent patent pool like those successfully deployed in the consumer electronics industry would provide a more competitive and effective solution.

Pooling the foundational CRISPR patent rights for licensing to industry on nonexclusive, cost-effective, transparent, and nondiscriminatory terms, including royalty-free research by universities, would expand and accelerate commercialization of CRISPR-based products and therapies by providing developers easy access to a package of essential patent rights in a single licensing transaction, thereby allowing them to focus on creation of new products that compete on technological innovation, product quality, service, and marketing. At the same time, the foundational patent owners would be rewarded for their investment from their fair share of reasonable royalties from the pool.

As a voluntary market-based business solution to the patent-access problem tailored to balance, incentivize, and resolve competing market and public interests, an independently managed patent pool is superior to solutions imposed from on high, such as march-in rights or compulsory licensing. The pool also would afford yet greater opportunity for all licensees, including those who abrogate limited exclusivity to free up patents for licensing through the pool, to gain broad access to related CRISPR technologies.

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Response

IT APPEARS THAT Horn concurs with our assessment of the potential development bottlenecks arising from the current CRISPR licensing model. We welcome his creative thinking about further ways to open CRISPR technology to a broader market.

We are aware that patent pools have been successfully deployed in the consumer electronics and other markets, but we question whether patent pooling would offer the optimal balance of openness and incentive for CRISPR therapeutics. Intellectual property licenses exist along a spectrum of exclusivity (*1*) ranging from the public domain, such as the DNA sequence data generated by the Human Genome Project (*2*), to complete exclusivity, such as Johns Hopkins's exclusive licenses of some of its stem cell patents to Becton-Dickinson and Baxter International (*3*). As we described in our Policy Forum, CRISPR surrogate licensing falls somewhere between these poles. It is currently characterized by exclusive rights for all human therapeutics across all human genes, with other uses, such as academic research, agricultural applications, and tool development, licensed on a nonexclusive basis.

Both antitrust law and industry custom require patent pools to make licenses available to all applicants on comparable terms that are "fair, reasonable, and nondiscriminatory" (FRAND) (*4*). Pools thus offer broad market access to enabling technologies on terms that are affordable and accessible to most market participants. In this sense, pool licenses are more restrictive than the broad royalty-free licenses that are offered with respect to fundamental Internet and connectivity technologies such as TCP/IP, http, Bluetooth, and USB (*5*), but less restrictive than even narrowly drawn exclusive licenses.

Notwithstanding their potential benefits, only a handful of patent pools have been formed in the biopharma sector, consisting mostly of humanitarian efforts seeking to benefit the economically disadvantaged (*6*). We believe that the lack of commercial patent pooling and FRAND licensing in the biopharma sector is due to the high cost of product development, clinical trials, and regulatory approval required to market new drugs and treatments (*7*). In many cases, private-sector firms that incur these costs will be profitable (and viable) only if they can leverage the market exclusivity afforded by patent rights for a limited period. Indeed, this is an animating concern behind much of the lengthy and costly development of cancer therapeutics today (*8*). Because patent pools do not lend themselves to exclusive licensing, even when commercially desirable in narrow fields, we question whether patent pooling for CRISPR would ultimately be successful.

This is not to say, however, that we support the breadth of exclusive rights granted for CRISPR. As we argued in our Policy Forum, today's CRISPR surrogate licenses effectively cede an entire field of investigation to one or two companies, thereby bottlenecking socially useful commercial development. We still believe that the greatest development of new CRISPR-based human therapies is likely to occur only if limited exclusive rights covering specific genes and disease targets are granted to companies having the means and intention to develop them. We would applaud any efforts to tailor patent pooling to fit such a regime. In either case, we hope that private and public benefit can be balanced so as to maximize social welfare using this promising new technology.

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Specimen collection crucial to taxonomy

IN THEIR LETTER "Photos belong in the taxonomic *Code*" (24 February, p. 805), A. R. S. Garraffoni and A. V. L. Freitas argued that, due to the problem posed by organisms whose diagnostic characteristics quickly deteriorate after specimen preservation, a revised version of the *International Code of Zoological Nomenclature* should allow taxonomic descriptions of newly discovered species based merely on photographs or videos, without preserved specimens. The concerns expressed by Garraffoni and Freitas are legitimate; however, their suggested solution to the problem ignores the harmful effects of taxonomic descriptions that lack preserved specimens. Such descriptions can obstruct scientific progress, and critics consider them inadequate, unnecessary, and potentially harmful for the biological sciences (*1*).

Contrary to Garraffoni and Freitas's assertion that the *Code* does not allow species descriptions lacking preserved specimens, the *Code*'s Article 73.1.4 (*2*) does allow the description of new species based only on illustrations (of any kind). This Article enables the nomenclatural availability of species names established without preserved specimens before the maturity of taxonomy (*1*), but, unfortunately, in some instances has also been used to justify modern descriptions in absence of preserved specimens (*3*).

Modern taxonomic descriptions lacking preserved specimens should not be allowed by the *Code*. High-quality illustrations (paintings, photographs, and videos) can show important aspects of the appearance of an animal; however, many characteristics of the animal are impossible to be adequately, or at all, represented in them—for example, minuscule body features, aspects of the animal's internal anatomy and, of course, its DNA. Although a researcher might consider that a given set of illustrations shows characteristics that he/she deems sufficient to distinguish a presumably new species from all other species that have been described until that moment, further research can show that other species with those same characteristics exist (including new, unnamed species). When at least one physical specimen is available (even a severely damaged, fragmentary, or dissolved one), it is often possible to find useful characteristics that could distinguish it from another species. This task is enormously facilitated by current sequencing technologies that have enabled scientists to obtain whole genomes, even from fragmentary and degraded biological material that is hundreds of thousands of years old (*4*) or that has been fixed with formalin (*5*). Moreover, it is to be expected that new technologies will also aid in new, efficient methods to preserve specimens.

The concern expressed by Garraffoni and Freitas with regard to organisms that deteriorate quickly after specimen preservation is attempted (such as comb jellies) has been pointed out in the past (*6*), but so far no suitable solution has been proposed. For the aforementioned reason and additional arguments provided by a number of colleagues (*1*, *7*–*10*), the proposal that a revised version of the *Code* allow species descriptions lacking preserved specimens is unlikely to, and should not, be accepted by the great majority of taxonomists. An alternative solution that should be considered could be that, for such organisms, a revised version of the *Code* would require high-quality drawings, photographs, or videos in addition to, but not as a replacement for, a preserved type specimen.

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