Working Through the Patent Problem

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Patents provide important incentives for biomedical innovation (*1*–*3*). There is increasing concern, however, that, by raising the costs of access, growing numbers of patents on research tools may now be retarding the pace of biomedical discovery (*4*–*7*). Further, broad patents on foundational discoveries may unduly limit their use in subsequent research (*8, 9*).

To probe these potential challenges to biomedical research, we conducted 70 interviews with: intellectual property (IP) attorneys, scientists, and managers from 10 pharmaceutical firms and 15 biotech firms; university researchers and technology transfer officers from six universities; and other IP attorneys and government and trade association personnel (*10*). This purposive sampling was designed to solicit information about the different activities and institutions associated with biomedical research and drug development (*11*).

All respondents reported that the patent landscape has indeed become more complex, with more patents per innovation (including patents on research tools). Also, the patenting of upstream discoveries (such as targets for drug intervention) has increased, potentially limiting access for follow-on research. Nonetheless, almost none of our respondents reported worthwhile projects being stopped because of issues of access to IP rights to research tools. Moreover, although we do not have comparably systematic evidence on projects never undertaken, our interviews suggest that IP on research tools, although sometimes impeding marginal projects, rarely precluded the pursuit of worthwhile projects. Why? Our interviews reveal that university and industrial researchers have adopted "working solutions" that allow their research to proceed. These include licensing, inventing around patents, going offshore, the development and use of public databases and research tools, court challenges, and simply using the technology without a license (i.e., infringement).

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Licensing is routine in the drug industry, and this suggests that the problem of access to patented research tools or upstream discoveries can often be settled contractually (*12*). Although identifying and licensing relevant patents take time and money, the 10 industry respondents who offered concrete estimates reported that, for a given project, usually fewer than a dozen outside patents require serious consideration, and the number of licenses required is much fewer, often none.

In addition, most respondents said that infringement of research tool patents, especially by university researchers, is common. A third of the industrial respondents (and all nine university or government lab respondents) acknowledged occasionally using patented research tools without a license. Infringement of research tool patents is hard to detect, and because of the long drug development process, the 6-year statute of limitations may expire before infringement is discovered. However, respondents mostly justified such infringement by invoking a "research exemption."

On the other side, all the industrial IP holders who addressed the issue reported tolerating academic research infringing their IP on research tools [with the exception of patents on diagnostic tests used in clinical research (*13*)], partly because it can increase the value of the patented technology. In addition, the industrial respondents agreed that the small prospective gains from a lawsuit were not worth the legal fees, the risk of the patent being narrowed or invalidated, and the bad publicity from suing a university. There is also a reluctance to upset the norms of open access in this community of academic and industrial researchers for fear of losing the goodwill of one's peers and the associated access to materials and information (*14*). Yet, the firms we interviewed were willing to defend against competitors' infringement of their core patents, especially those on potential therapeutics.

Firms also reported avoiding research tool patents by using the patented technology offshore. Firms considering this strategy may be emboldened by a recent court ruling that neither offshore use of a domestically patented screening method nor domestic sales of products discovered using that method violate the patent (*15*, *16*).

Public and private sector responses have helped increase access to research tools as well. For example, with substantial public, private, and foundation support, public and quasi-public databases (e.g., GenBank or the SNPs Consortium) have been created, making genomic information widely available. The NIH has funded initiatives and instituted new guidelines for grantees to promote access to research tools (*17*). The NIH has also negotiated with owners of foundational technologies, such as stem cells or genetically altered mice, to ease publicly funded researchers' access to important upstream discoveries (*18*). Scientific journals have pushed authors to deposit sequences in publicly available databases as a condition of publication.

Notwithstanding these "working solutions," aggressive assertions of IP can still threaten scientific research, as recent experience with genetically altered mice and diagnostic tests suggests (*10*). Thus, we anticipate a continuing need for active defense of open science. Moreover, the effective elimination of the research exemption by the recent Circuit Court *Madey* v. *Duke University* decision (*19*) may undermine the informal exemption that, as our interviews suggest, is important for open science. Thus, policy-makers should ensure an appropriate exemption for research intended for the public domain.

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20. The Science, Technology, and Economic Policy Board of the National Academies commissioned and supported this research. The NSF and the Abe Fellowship Program also provided support. We thank J. Cohen for editorial and J. Conde, W. Hong, J. Lee, and M. Saegusa for research assistance.