Reply to Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences

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A brief reply is in order to clarify our position on the patenting of research tools.

We stand by the statement that "there are reasons to be wary of patents on research tools," but that statement should not be understood as a broad condemnation of patents on research tools in all contexts. Indeed, immediately after the cited language our opinion letter acknowledges that withholding patent protection from research tools could undermine private incentives to develop research tools and to make them available to investigators or lead to greater reliance on trade secrecy. Unlike the government, which purports to pursue patent rights for the purpose of facilitating technology transfer, private firms pursue patents in order to earn a return on investments in R&D that would otherwise be unprofitable. Thus, even in cases where patents do nothing to facilitate technology transfer, private firms may invoke justifications for their claims of proprietary rights in the results of research that they have paid for. These justifications have considerably less force when applied to the results of research paid for by the government.
Nonetheless, we disagree with Dr. Chambers' statement that "[p]atents that cover research tools are no more dangerous than patents that cover any other aspect of human endeavor."

The primary difficulty with patents or other proprietary rights in research tools is that they can be used to restrict access to discoveries that are likely to have the greatest social value if they are widely disseminated to researchers who are taking different approaches to different problems. True believers in intellectual property might argue that if widespread dissemination is socially valuable, patent owners will be well motivated to disseminate their research tools widely through licensing. Indeed, in many cases, owners of patents on research tools will perceive researchers as customers for their patented products. For example, owners of patents on research reagents will generally maximize their profits by making the reagents widely available to anyone who wants them in anonymous market transactions. Even when researchers are not ordinary consumers of a patented invention, patent owners may welcome the use of their inventions by researchers, perhaps hoping that their research efforts will enhance the value of the patented inventions.

But there are reasons to fear that we can not always rely on a market for licenses to achieve optimal dissemination of research tools. For one thing, not all research tools are of a character that permits widespread distribution in an anonymous market. Sometimes face-to-face negotiations will be necessary in order to secure a license and, in these cases, researchers may be called upon to disclose what it is that they plan to do with the patented research tools before they are ready to do so. Researchers who do not want to disclose the directions of their research in its early stages may be reluctant to tip their hand by requesting a license.

Moreover, a significant research project might require access to a great many research tools. If each of these tools requires a separate license and royalty payment, the costs and administrative burden could mount quickly. This could be a particularly unattractive outcome for an institution such as NIH that may find itself in the position of royalty-payor in its role as research sponsor at least as often as it finds itself in the position of royaltee-

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payee in its role as patent holder. More troubling still, owners of patents on research tools may find it more lucrative to license their patents on an exclusive basis rather than on a non-exclusive basis, a strategy that could choke other research efforts before they get off the ground.

Dr. Chambers suggests that the downside risk of patents on research tools is minimal because the courts have the equitable power to withhold injunctive relief against researchers. But in spite of the equitable character of injunctive relief, there is only a small handful of cases in which courts have withheld permanent injunctions once patent infringement is proven, and researchers would be foolish to count on getting such a break. And even if at the end of the day researchers are able to beat the odds and avoid injunctive relief, the prospect of a damage remedy alone can be expected to deter socially productive uses of research tools.

We concede that proprietary rights may enhance incentives to develop further research tools in the private sector, and it may be that on balance the research enterprise will benefit more from the development of these new tools than it loses by allowing those who develop research tools to restrict access to them. Surely it is better to have research tools available on a restricted basis than it is to have them entirely unavailable because they don’t exist. But this argument is only persuasive to the extent that, in the absence of patents, research tools would not be developed.

When the government is picking up the tab, it may be better still to have research tools freely available in the public domain. Government is uniquely situated to enrich the public domain, a fact that we should not lose sight of in the prevailing climate of enthusiasm for private appropriation of government-sponsored research discoveries.

We do not urge these considerations upon the PTO in its determinations of what is patentable, but we believe they are appropriate considerations for a public institution such as NIH to weigh in deciding when it should pursue patents on its own discoveries, and when it would be wiser to dedicate those discoveries to the public domain.