a trade association seeking to require or 'enforce' specific licensing practices by its membership, the authors' suggestion that nonparties to a specific licensing transaction would have the information necessary to reasonably judge (presumably, after the fact) whether an exclusive agreement is or is not appropriate under the particular circumstances involved is simply not realistic, as much of the relevant information would likely be proprietary. In addition, BIO's membership is largely made up of therapeutic research and development companies, rather than the type of companies whose business models are the focus of the authors' critique.

In short, BIO never has denied that certain problems exist with respect to access to genetic diagnostic testing; we just disagree as to the causes of such problems and how best to fix them. BIO will continue its efforts to work with other organizations to help improve patient access to genetic testing, but will also continue to oppose—vigorously when necessary—any ill-considered and misguided proposals that would undermine the development of new diagnostics and therapies and do more harm than good for the patients of today and tomorrow.

COMPETING FINANCIAL INTERESTS
The author declares no competing financial interests.

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Robert Cook-Deegan, Subhashini Chandrasekharan, Misha Angrist, Bhaven Sampat, E Richard Gold, Julia Carbone & Lori Knowles reply:

We thank Tom DiLenge of BIO for his thoughtful comments. We agree with many points, but focus here on remaining points of disagreement.

First, although we agree there is no evidence of systematic and pervasive harm from patenting and licensing in DNA diagnostics, we reiterate that there is unequivocal evidence of problems in some cases. We agree there may well be a role for patent incentives in DNA testing; we do not believe, however, that this means *carte blanche* for patent holders. We are particularly wary of exclusive licensing to sole providers of genetic tests unless nonexclusive licensing will fail to bring a product to market. This is decidedly not the case in empirical studies to date. We say this for three main reasons. First, in instances where no test is available and yet patents are being enforced, as was the case with long-QT testing from 2002 to 2004, there are clearly access problems by any definition. These situations may be rare, and we hope they are, but denying a problem that has historically occurred is not a winning argument. The BIO letter is silent on such problems.

Second, it is simply not true that exclusive licensing needs to lead to monopolies. If a particular laboratory does not offer a particular form of service (e.g., prenatal testing), does not have a payment agreement with an insurer or health plan, or has already gotten paid to do a test, and the patient (or doctor) wants verification, then prudent business practice would suggest sublicensing, a permissive testing policy or some other way to ensure testing can be done by others. Policies on sublicensing or testing by others are under control of the patent holder and could be remedied by them without breaking patents. It is thus puzzling that patent-holders have not adopted such policies.

Third, although we agree that reducing the number of laboratories offering a test does not necessarily reduce patient access, there is a very consistent pattern revealed in our case studies and the survey of laboratory directors that we cited by Cho *et al.*[1]: the holder of exclusive patent rights is consistently not first to market with a genetic test. The effect of patents has been solely to reduce competition, not to create new products that would not otherwise exist. Suppression of competitors who have beaten the holder of exclusive rights to market is not what is usually observed with patents. Pharmaceutical firms and instrument companies generally do not enforce patents against universities and research institutions, for example, and yet this is what we find in DNA diagnostics in several cases. In this respect, diagnostics are unusual compared with other domains where patent exclusivity has a role. We agree the evidence of harms from exclusive licensing is not systematic, but the evidence of benefit from patents in genetic diagnostics historically is even weaker.

Finally, we appreciate there are indeed limits to BIO's actions when questions of antitrust would arise in enforcing the existing norms on patenting and licensing genomic inventions. The licensing norms developed by the Organization for Economic Cooperation and Development[2] (Paris), the US National Institutes of Health[3] and the 'Nine Points' document on university technology licensing[4] are all pro-competitive however, not anti-competitive. If a company is deviating from those norms, therefore, antitrust concerns would not arise; quite the reverse. We don't suggest BIO act when antitrust would loom as an issue, but commenting on policies—such as enforcing patents when no test is available to patients—would rarely confront antitrust policy.

The main underlying point is that problems with patents and exclusive licensing distinctive to diagnostics can be identified and dealt with, but only if the problems are acknowledged and acted upon. If BIO is turning its attention to these issues, then we will all benefit.

COMPETING FINANCIAL INTERESTS
The authors declare no competing financial interests.

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3. National Institutes of Health. "Best Practices for the Licensing of Genomic Inventions," Federal Register 70 (No. 68): 18412–18415.
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Stem cell clinics in the news

To the Editor:

As highlighted in a News Feature "Trading on hope" published in this journal[1], stem cell tourism is a growing and increasingly contentious phenomenon. By 'stem cell tourism', we refer to the emerging practice that sees patients travel abroad to receive (largely) unproven stem cell treatments that are generally not approved or available in their home country[2]. Although precise numbers are unknown, current information suggests that potentially thousands of patients each year from various countries are travelling around the world to receive stem cell therapies for a wide range of conditions[3–5].

The stem cell tourism phenomenon is highly controversial. The therapeutic possibilities promised by the clinics involved engage the hopes of often desperate patients and their families, including those who feel there are no other options. These individuals are understandably anxious to have a