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## Gene therapy and the 14th century Karelians

*To the editor:*

As the staff attorneys in the Ciba-Sandoz merger investigation, we are writing to respond to your editorial satirizing the FTC's consent order that requires Ciba, Sandoz, and Chiron to license several gene therapy patents and patent applications in order to remedy anticompetitive effects of the merger in five gene therapy markets (*Nature Biotechnology* 15:109, February 1997). These comments do not reflect the views of the FTC or any individual commissioner.


While condoning the FTC's actions in the flea control and corn herbicide markets, your editorial assumes a tone of incredulity and disparages the FTC's capability to adequately comprehend the "baffling and intricate technological endeavor" of gene therapy "in just a few months time." The derisive tone implies that the FTC should not meddle in anything as technologically complex as gene therapy, presumably allowing all gene therapy and biotechnology companies to form a "cabalistic synarchy" (commonly referred to in the agency as an oligopoly, duopoly, or even a monopoly). Your editorial, which fails to identify even one factual error in the FTC investigation or consent order, is misguided and ill-informed about the sources of the evidence that forms the basis for all FTC actions.

The FTC is authorized under various federal antitrust laws to investigate proposed mergers and determine whether they will likely harm consumers. Although FTC staff are not technical experts in all industries, the attorneys and economists investigating the Ciba-Sandoz merger possess extensive experience analyzing pharmaceutical mergers. We are very familiar with analyzing R&D pipelines, FDA approval process, and intellectual property portfolios. Moreover, where the FTC staff lacks technological expertise, we rely on industry participants and experts to educate us. We increase our understanding of every industry by reading tens of thousands of pages of documents relating to technology, patents, and market analysis. The FTC's subpoena power gives us access to sources of confidential information unavailable to others, including proprietary patent applications and competitive assessments by all industry participants. By the end of the investigation, the FTC has more information than any single entity in the industry. In the Ciba-Sandoz investigation, this accumulated information showed us that the merger was likely to cause consumer harm by reducing or delaying the development of gene therapy treatments for fatal diseases such as cancer, hemophilia, and AIDS.

Information gathered in the FTC investigation cannot be disclosed. But, even a cursory examination of publicly available information, including the FTC consent order, Analysis to Aid Public Comment and Complaint; issued US patents and published international patent applications; Recombinant Advisory Committee reports and gene therapy protocols approved by the National Institutes of Health and the FDA; press releases by industry members; SEC filings; and published scientific papers, supports the conclusions of the FTC. We recommend that you examine this public information and notify us of any facts that lead you to conclude the consent order is in error.

In addition, your editorial erroneously criticizes the FTC for "anticipat[ing] that legal challenges to Novartis's intellectual property position in gene therapy would not occur or fail" and for "rapidly judg[ing] what is and what is not potentially dominant intellectual property position." The editorial fails to recognize that the consent order takes into account the indeterminate validity of the Anderson ex vivo patent by expressly providing that royalties will be paid only to the extent that the patent "is valid and enforceable" (consent para IX.C). We readily admit that the FTC cannot predict the outcome of patent litigation; however, the consent order is drafted approximately to account for this.

Furthermore, the consent order does not imply that "pharmaceutical companies. . .have misguidedly wasted huge sums of money on gene therapy investments when it must have been obvious that Ciba and Sandoz, separately or combined, would dominate completely." The FTC has explained in the consent order, Analysis to Aid Public Comment and Complaint that it is the merger of Ciba and Sandoz's competing gene therapy businesses that will likely harm gene therapy innovation because of the combination of their respective gene therapy businesses. Prior to the announcement of the merger, the pharmaceutical industry had no reason to investigate the market power of a combined Ciba and Sandoz gene therapy entity. These companies could not have accumulated the confidential patent information that the FTC did in order to conclude that without the licenses required by the consent order, competitors in the gene therapy markets would have to either invent around or declare invalid a greater array of patents in the merged firm, or pay significantly higher licensing fees.

In the Ciba-Sandoz investigation, the FTC carried out its duties to protect American consumers. The learning curve was steep, but not so different from many other FTC investigations of technologically complex defense, computer, or telecommunications industries. We would have abandoned our responsibilities to American consumers (in this case, critically ill patients awaiting gene therapy treatments) if we avoided difficult investigations because they involve new or complex technologies, especially as rapid innovation becomes more important to successful competitive strategies in increasingly technical and global markets.

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PS. While the FTC staff does not include "a panel of world authorities on the dialectical inflections of the 14th century Karelians and their relationship to the ancient Magyar languages," we believe that the inflections of the 14th century Karelians would resemble the Magyar languages in vowel harmony and constancy of stress upon the first syllable of the word as these are generally the inflections of the Ural-Altaic languages, including the Finno-Ugric subfamily that contains the languages spoken by the Magyar and Karelians. Had this answer been relevant to a merger investigation, we would have invested the necessary resources to verify it with an appropriate expert.

*Naure Biotechnology replies:*

We don't doubt that FTC investigation of gene therapy was thorough. Equally, we are convinced that FTC can haul itself up the very steepest of technical learning curves. What continues to surprise us is that the FTC managed to reach so definite a conclusion on future outcomes in the gene therapy market. Most other organizations looking at the field—from individual investors to corporate acquisitors—have spread their bets around, unable to predict which combinations of technical tools will work clinically (at all, let alone optimally) or who, in the absence of legal judgments, owns them.

## Erratum

In "Beyond the letter of the law: The US Federal Circuit interprets §271(g)(1)" (*Nature Biotechnology* 15:86–87, January 1997), the sentence on page 87 regarding the Federal Circuit two-phase test should have read: "If it turns out that there are none, then the analysis is over—there is infringment."