

**SEPARATE STATEMENT OF CHAIRMAN ROBERT PITOFSKY, AND
COMMISSIONERS JANET D. STEIGER, ROSCOE B. STAREK, III,
AND CHRISTINE A. VARNEY**

in Ciba-Geigy, Ltd., C-3725

We write to respond to Commissioner Azcuenaga's suggestion that the Commission erred by requiring licensing rather than divestiture in order to remedy competitive problems in the gene therapy markets.

The Commission's Complaint in this matter alleges that the merger of Ciba-Geigy Ltd. ("Ciba") and Sandoz Ltd. ("Sandoz") may substantially lessen competition or tend to create a monopoly in several gene therapy markets, including "gene therapy technologies" and "research and development of gene therapies" as well as specific gene therapy product markets.⁽¹⁾ No gene therapy product is currently marketed or even approved by the Food and Drug Administration, and none is expected to obtain regulatory approval until the year 2000. The Complaint notes, however, that sales of gene therapy products are projected to reach \$45 billion by 2010.⁽²⁾ The Complaint emphasizes that patent rights to proprietary inputs sufficient to provide a firm in this industry with reasonable assurances of freedom to operate are necessary for the firm to reach advanced stages of development.⁽³⁾ Moreover, the Complaint alleges not only that Ciba and Sandoz "are two of only a few" entities capable of commercially developing gene therapy products, but also that they "control the substantial proprietary rights necessary to commercialize gene therapy products" and "control critical gene therapy proprietary portfolios, including patents, patent applications, and know-how."⁽⁴⁾ We are left with a post-merger picture of potentially life-saving therapies whose competitive development could be hindered by the merged firm's control of substantially all of the proprietary rights necessary to commercialize gene therapy products. Preserving long-run innovation in these circumstances is critical.

Commissioner Azcuenaga argues that the Commission should have required the divestiture of Ciba's or Sandoz's gene therapy businesses, rather than licensing, in order to "preserve the competition that existed before the merger."⁽⁵⁾ Of course, an injunction or divestiture is often the remedy chosen to resolve competition problems arising from mergers and acquisitions. In this case, however, patent licensing not only alleviated the competitive problems but also avoided divestiture's potentially disruptive effects on the parties' ongoing research.

As the Commission explained in the Analysis to Aid Public Comment that accompanied acceptance of the proposed consent agreement in this case, licensing was as effective in preserving competition as the traditional remedy of divestiture:

The Commission believes that licensing, rather than divestiture of assets, is sufficient because access to certain key intellectual property rights held by the merged firm is a crucial component of successful commercialization of many potential gene therapy products. Competitors already have (to varying degrees) the hard assets, e.g., production facilities, researchers and scientists, needed to compete. Rivals and other scientists confirm that licensing would enable them to develop gene therapy products and replace the competition lost due to the merger.⁽⁶⁾

Licensing was preferable to divestiture in this case because an asset divestiture "might create substantial disruption in the parties' research and development efforts."⁽⁷⁾ Not a single comment was submitted during the public comment period questioning this analysis, despite the invitation in the statement that Commissioner Azcuenaga issued when the Commission accepted the proposed Order for public comment.

Commissioner Azcuenaga asks why the Commission could not have ordered a divestiture of Sandoz's wholly-owned Gene Therapy, Inc. ("GTI") subsidiary or Ciba's partially-owned Chiron Corporation subsidiary. It may be appealing to call for divestiture of businesses acquired only two or three years ago -- as both GTI and Chiron were -- particularly when one such business is only partially owned. Ciba and Chiron, however, have numerous joint efforts that would have to be unraveled to separate the two companies. And GTI's U.S. clinical development is being closely coordinated with trials that Sandoz is conducting in Europe. Divestiture in this case would not be simple. To divest a business that would have such extensive continuing entanglements with the merged firm -- its principal competitor -- not only could hamper efficiency but also could be less effective in restoring competition if it led to coordinated interaction or left the divested business at the mercy of the merged firm.⁽⁸⁾

Instead of divestiture, the Order requires the merged firm to license gene therapy technology and patent rights to Rhone-Poulenc Rorer Inc. ("RPR"), so as to put RPR in a position to compete against the combined firm. In this way, RPR will be able to continue its research to develop HSV-tk gene therapy products for cancer and graft versus host disease. Commissioner Azcuenaga suggests that this relief only creates a potential "clone" that "may follow identical [research] tracks."⁽⁹⁾ We can not agree. This licensing package will give RPR the intellectual property that it likely could have obtained but for this merger's effect in reducing Novartis' incentive to license, so that RPR may continue to research and develop products on its own. Given RPR's ongoing research efforts, there is no basis for the assertion that this licensing package will turn RPR's efforts into a "clone" of the merging firms'.

In addition, the Order mandates that the merged firm license specific patents of Ciba and Sandoz to any interested person at a reasonable royalty. The dissent seems to suggest that such relief is ill-advised because it is based on some notion of the "essential facilities" doctrine, it usurps the role of the Patent and Trademark Office, and the setting of a royalty rate puts the Commission in the position of a price regulator.

First, it is not accurate to suggest that this remedy flows from the essential facilities doctrine. The Commission is not saying that Sandoz's *ex vivo* patent and associated cytokine patents are so important that they "ought" to be shared with everyone. Instead, the remedy is a response to a *merger* in which the merging parties possessed competing technologies. Before the merger, if developers of potential gene therapies were unable to reach agreement with Sandoz to license the *ex vivo* and associated patents, in many instances they could have worked with Ciba and used other technologies that did not infringe the *ex vivo* patent.⁽¹⁰⁾ The merger has eliminated that option. Granting the right to sublicense was necessary to restore access to the critical patents for other developers of many gene therapies.

Second, although the Commission alleges in its Complaint that both Ciba and Sandoz control portfolios of issued patents and patent applications "of uncertain breadth and validity,"⁽¹¹⁾ the Commission does so not as a patent tribunal but as a body charged with evaluating how market reality -- including firms' perceptions of their own and others' positions -- affects competitive behavior. Ciba and Sandoz each controlled a variety of patents and patent applications, and their merger combined alternative technologies and approaches to research and development. Whereas before the merger third parties might have had the option of licensing one party's patents or challenging the validity of the other's, the Commission was concerned that the merger created a "killer" patent portfolio so broad as to eliminate that option. As a result, the merger created a disincentive for Novartis to license third parties.⁽¹²⁾ Broad licensing of the *ex vivo* patent and the cytokines resolves these concerns. Simply stated, licensing of these patents preserves the innovation competition that would otherwise be lost as a result of the merger.⁽¹³⁾

Third, the Commission must always think long and hard before it enters an order which sets a price. But that cautionary rule should not be turned into an absolute. The Commission believes that a compulsory license was a more focused and effective remedy than divestiture. If there is to be a compulsory license, there must be a price, and that price cannot be too high.⁽¹⁴⁾ In this case the price was set at a level that would not interfere with the restoration of competition, and was commensurate with similar kinds of licenses negotiated in similar situations in the free market.

In short, requiring Novartis to license the key gene therapy patent rights is the best way to maintain competition and preserve the efficiencies gained in this transaction.

1. Complaint ¶ 9.

2. *Id.* ¶ 10.

3. *Id.* ¶ 26.

4. *Id.* ¶¶ 14, 15; see also *id.* ¶¶ 16-19.

5. See Statement of Commissioner Azcuenaga at 1.

6. Analysis to Aid Public Comment at 7.

7. Id.

8. Divestiture of the type that Commissioner Azcuenaga favors also might have disrupted or even ended the merging firms' ongoing collaborations with academic researchers.

9. Statement of Commissioner Azcuenaga at 3.

10. Analysis to Aid Public Comment at 6 ("Although Ciba/Chiron and Sandoz had substantial individual intellectual property portfolios pre-merger, they had the incentive and did act as rival centers from which others could obtain needed intellectual property rights. Ciba/Chiron and Sandoz would grant limited intellectual property rights to other developers and researchers in return for receiving marketing or other valuable rights back from them.").

11. Complaint ¶ 31 f.

12. Complaint ¶¶ 15, 31 f, g. See W. Tom and J. Newberg, "U.S. Enforcement Approaches to the Antitrust/Intellectual Property Interface," in Competition Policy, Intellectual Property Rights, and International Economic Integration.

13. The dissent appears to suggest the that licensing remedy called into question the decision of NIH to license the *ex vivo* patent to Sandoz on an exclusive basis. Statement of Commissioner Azcuenaga at 5. That criticism is inapt since NIH's license grants Sandoz the full authority to sublicense the patent.

14. In previous cases the Commission has had concerns with royalty payments in licenses meant to restore competition eliminated by merger. There are two reasons for such a concern: (1) royalties can lead to information exchanges facilitating collusion, and (2) royalties can interfere with firms' incentives to compete vigorously. The Order issued today minimizes the exchange of competitively sensitive information through use of an independent auditor to collect and aggregate royalty payments. Moreover, the relatively low royalty rate is unlikely to affect development of potential "blockbuster" drugs. See Analysis to Aid Public Comment at 8.