STATEMENT OF COMMISSIONER MARY L. AZCUENAGA,
CONCURRING IN PART AND DISSENTING IN PART,

in Ciba-Geigy Limited, Docket C-3725

The order in this matter seeks to remedy the alleged anticompetitive effects of the merger of Ciba-Geigy Limited and Sandoz Ltd. in several product markets, corn herbicides, flea control products, and various gene therapy markets. I concur in the requirements of the order that the merged firm, Novartis, divest the corn herbicide business and the flea control product business that belonged to Sandoz. I do not concur with the order in the gene therapy markets, in which the Commission has bypassed the obvious, simple and effective remedy of divestiture in favor of a complex regulatory concoction that promises to be less effective and more costly.

Given the allegations of the complaint, the obvious remedy in the gene therapy markets is to require the divestiture of the gene therapy business of either Ciba-Geigy or Sandoz. A divestiture of GTI[(1)] or of Ciba-Geigy's interest in Chiron[(2)] would eliminate the alleged anticompetitive overlaps in the gene therapy markets[(3)] and preserve the competition that existed before the merger. It is a remedy that would be simple, complete, and easily reviewable. Normally, divestiture would be the remedy of choice, and no persuasive reason for a different remedy has been presented in this case.

The order of the Commission instead imposes licensing requirements that do not necessarily preserve the competition that existed before the merger. The only explanation offered for preferring licensing over an asset divestiture is the assertion in the Analysis To Aid Public Comment that a divestiture "might create a substantial disruption in the parties' research and development efforts."[(4)] What this means is not clear. Any divestiture is likely to involve substantial disruption, and if concerns about "disruption" were sufficient to avert a divestiture, that remedy would never be used. No doubt the parties prefer the negotiated licensing arrangement, but the preferences of the parties should not define the remedy.

The implication that divestiture in this case somehow would be counterproductive does not ring quite true. This is an industry in which cooperative research and development often is undertaken and in which innovative companies frequently change hands. Indeed, Ciba-Geigy and Sandoz only recently acquired their interests in the gene therapy field.[(5)] The gene therapy products at issue require years of research, and the FDA approval process also takes years. If the respective acquisitions by Ciba-Geigy and Sandoz in 1994 and 1995 of gene therapy companies did not hamper ongoing and future R&D projects, one must wonder why a divestiture in 1997 of one of those companies would be problematic.

Also, the licensing requirements imposed by the order are somewhat different from what we previously have seen. In the HSV-tk gene therapy markets, the complaint on which the order is based alleges that Ciba-Geigy and Sandoz, after the merger, could "combine alternative technologies, and reduce innovation competition"[(6)] and that "[o]nly two companies [presumably Ciba and Sandoz] are capable of commercially developing"[(7)] the HSV-tk gene therapies at issue.[(8)] The order permits Ciba-Geigy and Sandoz to combine their research and development projects in the HSV-tk gene therapy markets and requires them to license their combined

intellectual property to an entity approved by the Commission. Instead of preserving the premerger competition between Ciba-Geigy and Sandoz, the order allows the allegedly anticompetitive combination to stand, as long as it clones its intellectual property.[9] Novartis remains free to "combine alternative technologies," as alleged in the complaint. The diversity of research projects is an element of the pre-merger competition between Sandoz and Ciba-Geigy that is worth preserving,[10] but the order does not ensure that it is preserved.

The remedy in the market for Factor VIII gene therapy for the treatment of hemophiliacs offers two alternatives for licensing.[11] It is not clear how these alternatives will eventually work out, but neither of them necessarily preserves the competition that existed before the merger. A divestiture of either GTI or of Ciba-Geigy's interest in Chiron would have preserved the diversity of competition that existed before the merger.

The complaint also alleges a market for "the research and development of gene therapy," in which Ciba-Geigy and Sandoz are "two of only a few entities capable of commercially developing gene therapy products" and in which they control "critical gene therapy proprietary portfolios."[12] In this overall market for the research and development of gene therapy, the merger allegedly would "heighten barriers to entry by combining portfolios of patents and patent applications of uncertain breadth and validity" and "create a disincentive in the merged firm to license intellectual property rights"[13] to others. The remedy for the alleged violation is to require the licensing of intellectual property rights at a "low"[14] royalty rate stipulated in the order.[15]

Remedies that require the Commission to police prices generally are disfavored as highly regulatory, difficult to enforce and likely to distort the normal functioning of the market. They should be particularly disfavored in cases such as this in which a clean, simple divestiture of a gene therapy business is readily available and would not impede consummation of the remainder of the transaction, which is neutral or procompetitive. This agency often has been in the forefront in opposing government price controls, which makes this part of the order particularly mystifying.

The compulsory licensing requirement applies to the so-called ex vivo or Anderson patent.[16] The ex vivo patent, issued in 1995, is owned by the National Institutes of Health (NIH) and licensed by NIH exclusively to Sandoz. To commercialize a gene therapy product, a researcher would need either a license from Sandoz under the ex vivo patent or a different mode of transduction.[17]

The requirement to license the ex vivo patent does not follow, as in the usual case, from ownership by the merger partner of competing technology. There is no substitute for the ex vivo patent, and Sandoz is the exclusive licensee under the patent. The question, then, is what links the compulsory licensing requirement to the violation alleged in the complaint. One possibility is that the compulsory licensing requirement reflects a judgment that the ex vivo patent is excessively broad. The complaint alleges that the merger will "combin[e] portfolios of patents and patent applications of uncertain breadth and validity." This is a curious allegation for a complaint under Section 7 of the Clayton Act and one that is not explained. Antitrust can provide the basis for challenging the use or combination of patents in some circumstances, but patent

law, not antitrust law, customarily applies to assess the breadth and validity of patents. As far as I am aware, we have neither standards nor evidence by which we might conclude that the breadth or validity of the ex vivo patent provides a basis for liability under Section 7 of the Clayton Act.

One authority has identified the ex vivo patent as a "broad" patent that "cover[s] enormous areas of technology" and suggested that compulsory licensing would encourage follow-on invention in the field.[(18)] Others maintain that broad patent protection for inventions is necessary to encourage groundbreaking research and disclosure and that compulsory licensing would harm those incentives. These are important public policy issues, but they are not elements of a violation under Section 7 of the Clayton Act.

Even if some might think the ex vivo patent is too broad, it was granted to NIH by the U.S. Patent and Trademark Office, also an agency of the U.S. government, and licensed by NIH to Sandoz. It would seem curious for this agency, charged with enforcing Section 7 of the Clayton Act and Section 5 of the FTC Act, to call into question the breadth and validity of a patent granted by the Patent Office to another federal agency. It also would seem curious to call into question the decision of NIH to license the patent on an exclusive basis. To the extent that such a decision entails evaluation of the potential for advancing scientific research in aid of human health, the National Institutes of Health would appear to have qualifications superior to the FTC. The fact that the respondents agreed to this remedy tells us nothing about its competitive implications. We must look elsewhere for an explanation of the requirement to license the ex vivo patent.

A theme running through the complaint is that the ex vivo patent is "essential" to commercializing a gene therapy product.[(19)] But the courts and the Commission consistently have held that a patent holder has no obligation to deal and is free to refuse to grant licenses,[(20)] even if some believe that the patent is "essential" to follow-on inventors. There being no apparent basis for the compulsory licensing of the ex vivo patent under Section 7 of the Clayton Act, perhaps the majority selected this remedy in the belief that it serves the public good. The patent was developed with tax dollars, it is owned by a government agency, and access to the patent could be useful to follow-on inventors. Put another way, the majority may believe it is protecting the public health or even saving lives. These are powerful arguments, but Congress heard them and decided instead to encourage the patenting of inventions resulting from government-sponsored research and the licensing of the patents to private industry as an incentive for industry to make the significant investments to bring a product to market.[(21)]

A divestiture of the gene therapy business of either Ciba-Geigy or Sandoz would resolve the alleged anticompetitive overlap in all the gene therapy markets. It would preserve the competition in research and development that existed before the merger, without compulsory licensing under order, without the mandating by the Commission of "reasonable" fees, and without creating possible disincentives for innovative research.

I dissent from the order in the gene therapy markets.

1. Sandoz participated in the gene therapy market through its wholly-owned subsidiary Gene Therapy, Inc. (GTI), a corporation headquartered in Maryland that Sandoz acquired in 1995.

2. Ciba-Geigy participated in the gene therapy market through Chiron Corporation, a company headquartered in California, in which Ciba-Geigy acquired a 46.5% interest in 1994. Chiron acquired Viagene, Inc., a U.S. gene therapy firm, in 1995.

3. See Complaint ¶¶ 31.d through g.

4. Analysis To Aid Public Comment at 7. The Analysis, published with the proposed consent order, states that its "purpose . . . is to facilitate public comment on the proposed Order, and it is not intended to constitute an official interpretation of the agreement and proposed Order or to modify in any way its terms." Id. at 17.

5. See notes 1 & 2 supra.

6. Complaint ¶ 31.d.

7. Complaint ¶¶ 16 & 17.

8. The complaint alleges HSV-tk gene therapy markets for the treatment of cancer and for the treatment of graft versus host disease.

9. In addition, at the option of the licensee of the intellectual property, Novartis (but not Chiron, see note 2 supra) is required to provide "technical information, know-how or materials . . . necessary to enable" the licensee to research and develop HSV-tk products. Order ¶ IX.A.2.

10. See FTC & DOJ, Antitrust Guidelines for the Licensing of Intellectual Property ¶ 3.2.3 (1995), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,132.

11. Order ¶ IX.D requires Sandoz to convert its exclusive license to the partial Factor VIII hemophilia gene to a nonexclusive one or to license certain of its relevant intellectual property ("Hemophilia License," defined in Order ¶ I.PP).

12. Complaint ¶¶ 14 & 15.

13. Complaint ¶¶ 31.f & g.

14. Analysis To Aid Public Comment, supra note 4, at 8.

15. Order ¶¶ IX.B & C.

16. Order ¶ IX.C. As I understand it, the two modes of delivery (called "transduction") for gene therapies are ex vivo and in vivo. Ex vivo delivery involves removing, modifying and replacing the patient's cells and has been used in the majority of gene therapy trials. In vivo delivery involves delivery of genetic material directly into the patient.

17. The need to invent around existing patents can be a significant incentive for invention. To the extent that the compulsory licensing required by the order may reduce this incentive, it may reduce the research and development of alternative means of transduction for gene therapy.

18. John Barton, Global Hearings Tr. 3409 (Nov. 29, 1995) (suggesting at Tr. 3415 that compulsory licensing for follow-on investors is "an anathema in the United States"); see FTC Staff Report, "Anticipating the 21st Century: Competition Policy in the New High-Tech, Global Marketplace," Ch. 8, at 13-14 (May 1996).

19. The "essential facilities" doctrine ordinarily is triggered by a refusal to deal by a monopolist and is not part of an analysis under Section 7 of the Clayton Act.

20. See Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 426-30 (1908); see also Hartford-Empire Co. v. United States, 323 U.S. 386, 432-33, clarified, 324 U.S. 570 (1945); SCM Corp. v. Xerox Corp., 645 F.2d 1195 (2d Cir. 1981), cert. denied, 455 U.S. 1016 (1982); United States v. Westinghouse Elec. Corp., 648 F.2d 642, 647 (9th Cir. 1981); E.I. duPont de Nemours & Co., 96 F.T.C. 705, 748 & n.40 (1980). See also FTC & DOJ, Antitrust Guidelines for the Licensing of Intellectual Property § 2.2 (1995), reprinted in 4 Trade Reg. Rep. (CCH) § 13,132 ("The Agencies will not presume that a patent . . . necessarily confers market power upon its owner. . . . If a patent . . . does confer market power, that market power does not by itself offend the antitrust laws. . . . Nor does such market power impose on the intellectual property owner an obligation to license the use of that property to others.").

21. 35 U.S.C. §§ 200-211; 15 U.S.C. §§ 3701-3714. See Eisenberg, "Symposium: A Technology Policy Perspective on the NIH Gene Patenting Controversy," 55 U. Pitt. L. Rev. 633 (1994).