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

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 isnt s5(F)1(T)49(e)-1s/w 21.10 21.10tisisi 1iac

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).