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

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 Rh ne-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)]

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 rie edh -1.15 T(t)-2(e)-1Tf 0 Tc 0 Tw(o)1(es.)TJ ET

11. Complaint 31 f.

12. Complaint 15, 31 f, g.