THE CENTER FOR THE
ADVANCEMENT OF
CAPITALISM

August 8, 2002

Donald S. Clark, Esq.
Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, N.W., Room 159-H
Washington, D.C. 20580

Re: Comments of the Center for the Advancement of Capitalism to the proposed Consent Agreement and Order in *In Re Amgen, Inc. and Immunex Corporation,* File No. 021 0059 (Docket No. C-4053).

Dear Mr. Clark:

On July 12, 2002, the Federal Trade Commission (FTC) issued a proposed consent order (order) in the matter of *In re Amgen, Inc. and Immunex Corporation*, File No. 021 0059. The Center for the Advancement of Capitalism[1] (CAC) files the following public comments in response to the terms of the proposed consent order.

CAC is a District of Columbia non-profit corporation which seeks to promote the welfare of the nation by advocating a moral foundation for individualism and economic freedom. In pursuance of our goals, CAC has consistently opposed the enforcement of U.S. antitrust laws, because we believe such laws are incompatible with the protections provided by the constitution and violate the right of all individuals to engage in voluntary action free of government coercion.

In the instant case, CAC believes entry of the proposed consent agreement would not be in the public interest for three reasons. First, we believe that the FTC is improperly

The Center for the Advancement of Capitalism
P.O. Box 16325
Alexandria, VA 22302-8325
VOX: (703) 625-3296 FAX: (703) 997-6521
E-mail: info@moraldefense.com

punishing the respondent corporations for actions which the United States itself is responsible for, especially the Food and Drug Administration (FDA). Second, we believe that the terms of the agreement requiring respondent Amgen to license certain patents is a violation of their rights under Article I of the Constitution, and thus would cause injury to the people of the United States and their interest in maintaining a constitutional government. Third, CAC believes the consent agreement will harm the public interest by impairing full, fair and free competition in the biotechnology industry. For these reasons, CAC would respectfully request the FTC to withdraw from the proposed consent order and dismiss their complaint against the respondents.

I

By its own express admission, the FTC is holding the respondents liable for an "anticompetitive" marketplace which exists solely because the United States has enacted significant barriers to entry. For example, in the case of the neutrophil regeneration factors market, the Commission states that FDA approval for entry into the marketplace takes "6 to 10 years and cost over $200 million. The FDA must approve all phases of development, including extensive preclinical and clinical work. *The most significant barriers to entry* include technical, regulatory, patent, clinical and production barriers. (emphasis added)[2]"

In all of the barriers stated by the FTC, not one of them involves any coercive, deceptive or fraudulent act on the part of the respondents. Not once does the FTC allege

[1] CAC was formerly the Center for the Moral Defense of Capitalism.
[2] Analysis to Aid Public Comment, 67 Fed. Reg. 48,475 (2002).

that the respondents used any kind of force to gain or maintain its position in the market. Quite the contrary, the respondents and every other corporation were arbitrarily barred by the FDA from entering the market until they could satisfy requirements prescribed by the United States. Now that the respondents have cleared all those "regulatory" barriers, the FTC has seen fit to reward their hard work by assaulting their right to enjoy the profits of their labor.

If there is truly a lack of competition in the relevant markets defined by the FTC in its complaint, than that is the responsibility of the FDA, and not of the respondents. For the Commission to impose punitive relief upon the respondents as a result of actions that they are not responsible for (1) renders the law itself non-objective, since there is no longer a clear standard of *conduct* for companies and individuals to follow to avoid sanction, (2) rewards the FDA for its own anticompetitive behavior, (3) harms the public interest by allowing arbitrary and capricious regulation by the United States (through the FTC and FDA) to thwart the research and development efforts of private corporations, like the respondents, whose work is likely to produce scientific creations of substantial value.

II

An integral requirement of the consent agreement forces the respondents to license certain patents so as to render them essentially meaningless.[3] In forcing this outcome as a condition of settlement, the FTC has acted in direct violation of its

[3] *See* Decision and Order (proposed). .

obligation as an executive agency to uphold the Constitution and the laws of the United States.

Article I, Section 8 of the Constitution provides, in relevant part, "The Congress shall have Power…To promote the Progress of Science and Useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Pursuant to this charge, the Congress has enacted and revised federal laws providing for the recognition of patents[4]. Such action is consistent with the intent of the Constitution's framers, who believed, "The right to useful inventions seems with [reason] to belong to the inventors. The *public good* fully coincides…with the claims of individuals[5] (emphasis added)."

The importance of protecting intellectual property rights can hardly be overstated. Unlike real property rights, which are attached to a tangible object or parcel, intellectual property rights are claims to the practical application of knowledge. The physical manifestation of these ideas are not essential to the right, only the author's ability to prove that he was, in fact, the creator of the idea. In the realm of biotechnology, patent rights are indispensable. In the absence of ownership, new technologies would cease to develop, because there would be no incentive for the men who would create them to produce; all creators, be they individuals or large corporations, after all, seek to produce as much for profit as they do for the self-satisfaction of invention. These are, however, complementary goals, contrary to what the FTC would appear to believe.

[4] *See* 35 U.S.C. §1 *et seq*.
[5] THE FEDERALIST NO. 43 (Alexander Hamilton).

In requiring the respondents to license their patents, the consent agreement seeks to undo the practical effect of 200-plus years of American intellectual property law. The FTC is, in our opinion, quite aware of this, and yet has chosen to proceed with this form of remedy for the express purpose of accomplishing that which they cannot do overtly—collectivizing patent rights under a government-directed regime. Rather than recognize and protect the labor of one's mind, which is the essence of intellectual property, the Commission would prefer to arbitrarily assume responsibility for deciding which companies should be allowed to manufacture which technologies; that one company can demonstrate a *right* to a particular technology based on their own labor is irrelevant to the FTC, which instead preaches the Gospel of "competition" to be the supreme Law of the Land.

The immediate problem, we believe, is that such a policy on the FTC's part directly contradicts the clear and unambiguous intent of the Founders as stated in the Constitution. Whereas the FTC attacks patents on the grounds that they are "anticompetitive," and thus repugnant to the Commission's mission, the Constitution clearly authorizes individuals like the respondents to exercise the "exclusive Right"[6] over their inventions. In other words, it permits a private monopoly of limited scope and duration on the basis of merit. While the FTC appears confused over the place of such monopolies in a world where antitrust law exists, the Constitution sees no conflict whatsoever: The antitrust laws are, at best, a vague pronouncement of federal authority, and their wholesale reliance on the Commerce Clause cannot justify overruling the clear and unambiguous intent of the Patent Clause. Otherwise, one would have to conclude that

the Executive (or Judicial) Branch can unilaterally overrule some clauses of Article I, Section 8, simply by invoking another unrelated clause. One provision of the Constitution cannot be used to negate another provision, especially when such negation relies the opinion of a single administrative agency. We believe the Framers did not draft the Constitution in such a disjointed and illogical manner.

Admittedly, the FTC is trying to reconcile the mixed constitutional messages being broadcast by the Congress. But even though Congress was in error for assigning to the FTC functions and powers which contradict the Constitution's mandate, that does not absolve the Commission of its own constitutional responsibilities[7]. Specifically, by pursuing this matter and seeking the relief that it has, the FTC has acted contrary to the letter and intent of Article II, Section 3, which provides that the executive branch shall "take Care that the Laws be faithfully executed." In this case, just the opposite has occurred, as the FTC has deliberately impeded execution of the patent laws of the United States in order to further an objective of nebulous constitutional and statutory authority. At a minimum such conflicts should, as a matter of fairness, be resolved in favor of the clear and unambiguous provision. Such an interpretation in favor of intellectual property owners would be of far greater benefit to the public interest than diluting the respondent's rights in the name of antitrust enforcement.

---

[6] U.S. CONST. art. I, §8, cl. 8.

[7] Nor does the fact that "[t]he Supreme Court has on numerous occasions confirmed the constitutionality of the FTC Act by sustaining Commission orders prohibiting unfair methods of competition," a point raised by the FTC in replying to a previous CAC comment letter, mean that the FTC can simply act without independently assessing their own constitutional authority. The FTC must be able to defend its own actions, not simply hide behind citations of court precedent, when it comes to antitrust cases brought before it as an administrative agency.

III

Finally, the terms of the proposed final judgment will harm the public interest by restricting full and free competition in the biotechnology market. As has been discussed above, the primary cause of the "anticompetitive" markets described by the FTC in this case is the FDA and its approval process for permitting new drugs to be sold to the public. Because the FDA operates on the principle that only the government is able to answer the scientific question of a drug's safety and effectiveness prior to marketplace entry, many drugs are delayed or even prohibited from benefiting consumers, simply because the government has paternalistically decided that they should not have access to them.. "The FDA's product approval process, while usually scientifically rigorous, is strongly biased against risk taking.[8]" This bias acts against individual interest, leading some people to seek alternatives not available in the "legitimate" marketplace. Consequently, "[r]ather than submit to the Food and Drug Administration's extreme risk aversion, for example, Americans can more easily use the Internet to buy medicines approved in other countries.[9]" Clearly, the public interest does not like to sit and wait for the government to tell them it's okay to proceed with bringing innovation to the pharmaceutical marketplace.

In spite of the FDA, some companies do manage to bring new and beneficial medicines to the American public. As noted by the FTC in its complaint against the respondents, there is a great monetary cost expended in bringing new technologies to the market under FDA auspices. This makes it all the more imperative that these companies

[8] Virginia Postrel, THE FUTURE AND ITS ENEMIES 24 (1998).
[9] *Id*., at 146.

The Center for the Advancement of Capitalism
P.O. Box 16325
Alexandria, VA 22302-8325
VOX: (703) 625-3296 FAX: (703) 997-6521
E-mail: info@moraldefense.com

be allowed to reap the profits of their work. To do provide otherwise would be to provide a perverse incentive *not* to innovate, but instead wait for some other manufacturer to develop a new drug, than swoop in on the FTC's wings after the fact claiming "unfair competition" when the innovator tries to collect his just reward.

The proposed consent agreement requires a number of divestitures, both of patents and physical assets, that in effect reward competitors of Immunex that have done *nothing* to promote innovation in the fields affected by the FTC order. The FTC is not only punishing competition by doing this, it is encouraging "bottom feeding" by less able competitors, a kind of parasitism that a truly capitalist system would reject, much like an immune system rejects a virus.

Nothing in the proposed final judgment or the accompanying Competitive Impact Statement provide any kind of explanation for why the FTC would want to reward non-achievement. In the absence of any reason, CAC is left to speculate, and none of our permutations bode well for the FTC's character. Perhaps the Commission is motivated by a desire to regulate human achievement, in which case the FTC is simply acting out of envy of the respondents' ability to produce something of value. Alternatively, the FTC could be acting in the name of groups hostile to the respondents' interests, as was the case in the Department of Justice's prosecution of Microsoft Corporation. Or maybe the FTC honestly concluded that impeding the marketplace's ability to act according to its own interest would genuinely benefit the public, in which case the Commission is simply wanting for basic intelligence.

Whatever the reason, CAC cannot identify any which would show that the terms of the consent agreement benefit competition. Given the multiple harms to the market

The Center for the Advancement of Capitalism
P.O. Box 16325
Alexandria, VA 22302-8325
VOX: (703) 625-3296 FAX: (703) 997-6521
E-mail: info@moraldefense.com

that would be created, the entry of the final judgment would not serve any identifiable public interest. For this reason, and the other reasons stated herein, CAC calls on the FTC to withdraw the proposed consent agreement and dismiss the complaint against the respondents.

Respectfully Submitted,

S.M. Oliva
Director of Federal Affairs
The Center for the Advancement of Capitalism

The Center for the Advancement of Capitalism
P.O. Box 16325
Alexandria, VA 22302-8325
VOX: (703) 625-3296 FAX: (703) 997-6521
E-mail: info@moraldefense.com