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Gloria Blue
Executive Secretary
TPSC
Office of the USTR
600 17th Street, NW
Washington, DC 20508
Attention: U.S.-Chile Free Trade Agreement

Dear Ms. Blue:

Essential Action and the Consumer Project on Technology submit these comments in response to a request from the Office of the U.S. Trade Representative for public comment on negotiating objectives for the proposed U.S.-Chile Free Trade Agreement (FTA) (Federal Register, December 14, 2000).

Essential Action is a corporate accountability group that focuses especially on international issues. The Consumer Project on Technology is a consumer group that brings a consumer perspective on emerging policy debates on technology issues. Both groups are Ralph Nader-founded organizations. We have been involved in trade and intellectual property policy debates for more than a decade.

Our comments focus on the potential intellectual property provisions of a U.S.-Chile Free Trade Agreement (FTA), and particularly on provisions relating to access to medicines and compulsory licensing.

THE CASE FOR EXCLUDING INTELLECTUAL PROPERTY FROM THE U.S.-CHILE FTA

There is no reason for inclusion of intellectual property provisions in the U.S.-Chile FTA. Both the United States and Chile are members of the World Trade Organization and have committed themselves to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS establishes a comprehensive international standard for intellectual property protection, with a heavy tilt towards the interests of intellectual property (IP) holders.

The TRIPS rules constitute a floor of IP protection. With TRIPS already establishing a high level of IP protection in every Member country, there is no reason to include IP rules in bilateral agreements among TRIPS Members.

Efforts to incorporate enhanced IP protection ("TRIPS-plus") in bilateral agreements are not only unnecessary, but, as discussed below, dangerous and injurious to public health.

THE JORDAN FTA PRECEDENT AND COMPULSORY LICENSING

The provisions in the recently concluded U.S.-Jordan FTA include requirements that signatory countries grant IP protections over and above those mandated by TRIPS. As the United States enters FTA negotiations with Chile, the intellectual property provisions of the U.S.-Jordan FTA must not be used as a template for negotiations with Chile (or any other trade negotiations).

Especially troublesome is Article 20 of the U.S.-Jordan FTA, which limits the grounds for compulsory licensing for non-public use far more than does the TRIPS agreement. Compulsory licensing, a critical policy tool to prevent price-gouging and promote competition, enables a government to instruct a patent holder to license the right to use its patent to a company, government agency, or other party. Compulsory licensing lowers prices to consumers by creating competition in the market for the patented good. Its impact is similar to the introduction of generic competition at the end of a drug's patent term -- prices come tumbling down.

In the case of AIDS drugs, for example, a three-drug cocktail may cost consumers, including in developing countries, \$10,000 - \$12,000 a year. These costs are obviously far out of reach for all but a tiny few in developing countries, and especially in Africa, where the AIDS epidemic is most severe. Generic producers report that they could lower the price for triple-drug therapy into the \$250-a-year range. Compulsory licensing would allow these savings to be realized -- and hundreds of thousands, or more, to access therapies that are now out of their financial reach. The experience of Brazil in making affordable generic medicines available to people with HIV/AIDS illustrates the spectacular public health and humanitarian achievements that are possible with compulsory licensing and making affordable generic products available to people with HIV/AIDS.

Chile's per capita income is less than \$5,000, according to the World Bank. Even with its small HIV-positive population -- estimated by UNAIDS at 15,000 -- providing combination therapies would be a heavy annual burden of \$150 million. If compulsory licensing were able to bring prices down to even \$500 a year, the national cost of providing anti-retroviral therapy to Chile's HIV-positive population would be a very affordable \$7.5 million.

Under the model of the Jordan FTA, compulsory licensing to achieve this public health aim -- even in case of a national emergency -- would only be permissible if the licenses were granted to "government entities or legal entities operating under the authority of a government."¹ Under the more permissive TRIPS arrangement, by contrast, compulsory licenses could as a matter of course be granted to private parties for commercial, non-public use,² so long as TRIPS procedures and rules, including payment of reasonable compensation to the patent holder, were complied with.

¹ U.S.-Jordan FTA, Article 20(b).

² It will still remain possible under the Jordan FTA for private parties to gain licenses if "they are operating under the authority of a government." For example, it would be government use for a compulsory license to be issued to a private party producing a drug on behalf of a public health agency. See footnote 1.

Article 20 of the Jordan FTA permits compulsory licensing only in three cases: to address anti-competitive practices; for public non-commercial use, including emergencies; or to address failure to meet working requirements.³

By contrast, TRIPS Article 31 contemplates compulsory licensing as part of the basic schema of the intellectual property system, not as a limited set of exceptions. Article 31(b) permits compulsory licensing generally, so long as certain procedural conditions are met.⁴

Of course, compulsory licensing can be used for other essential medicines and other products besides AIDS medications. But the AIDS medicines example clearly highlights the life and death consequences of IP provisions in trade agreements. It would be unconscionable to include IP provisions in the Chilean FTA or any other trade agreement that would consign thousands of people to preventable death.

THE BROADER CONSEQUENCES OF REPLICATING THE JORDAN FTA LANGUAGE ON COMPULSORY LICENSING

Indeed, perhaps the most serious consequence of inclusion of Jordan FTA-style TRIPS-plus language in a U.S.-Chile FTA would be its precedential effect for other trade agreements. The establishment of anti-compulsory language as a standard feature of trade agreements is likely to infect negotiations of the Free Trade Agreement of the Americas, and perhaps other trade agreement negotiations, including renegotiation of the TRIPS. Generalizing Jordan-style restrictions on compulsory licensing could be devastating to public health.

The IP provisions of the Jordan FTA also appear to conflict with existing U.S. law, and would conflict with various legislative proposals recently introduced in Congress. For example, 42 USC Sec 2183 permits compulsory licensing of atomic energy inventions. In the 106th Congress, Representative Sherrod Brown introduced HR 2927, which would permit compulsory licensing of pharmaceuticals and patented medical inventions.⁵ Also in the 106th Congress, Representative Dennis Kucinich introduced HR 4739, which would permit compulsory licensing of patents on reformulated gasoline.⁶ Compulsory licensing is likely to become increasingly important in the United States in the field of

³ Under Article 20, "Neither party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances:

a) to remedy a practice determined after judicial or administrative process to be anti-competitive;
b) in cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or
c) on the ground of failure to meet working requirements, provided that importation shall constitute working."

⁴ These conditions include: a prior effort by the proposed user to obtain authorization from the right holder on reasonable commercial terms (TRIPS Article 31(b)), that the compulsory license be granted for a specific purpose only (TRIPS Article 31(c)); that the license be non-exclusive, non-assignable and predominantly for use in the domestic market (TRIPS Article 31 (d), TRIPS Article 31 (e), TRIPS Article 31 (f)), that the license be terminated if the conditions giving rise to it cease (TRIPS Article 31 (g)), that the legal validity of the license and the terms of remuneration be subject to appeal to a judicial or administrative authority (TRIPS Article 31 (i), TRIPS Article 31 (j)).

⁵ The bill was co-sponsored by Representatives Thomas Allen, Thomas M. Barrett, Marion Berry, Danny Davis, Dennis Kucinich, Major Owens, Bernard Sanders, Janice Schakowsky, Fortney Pete Stark, Ted Strickland and Albert Wynn.

⁶ The bill was co-sponsored by Representatives John Elias Baldacci, Thomas M. Barrett, William Lipinski, Cynthia McKinney, Eleanor Holmes Norton and Frank Pallone, Jr.

biotechnology, where patents on foundational inventions and multiple overlapping patents on single consumer products have the potential to seriously impede medical progress.

Compulsory licensing is a valuable policy tool in the United States. It should not be sacrificed in trade negotiations, especially when it is the United States, not the nation's trading partners, which is pushing for compulsory licensing restrictions.

LINKING MARKETING APPROVAL TO PATENT STATUS

The Jordan FTA and the recently released U.S. negotiating guidelines for IP for the Free Trade of the Americas Agreement (FTAA) include other inappropriate TRIPS-plus measures or proposals that will set back the goal of making essential medicines affordable and accessible.

Under the U.S. government FTAA proposal, the United States proposes to link marketing approval for a drug -- based on a finding of safety and efficacy, or bioequivalence to a safe and efficacious product, granted by FDA-equivalent agencies -- to patent expiration.⁷

This arrangement establishes drug safety agencies as *de facto* IP enforcement agencies. In practice, this kind of arrangement is likely to yield unjustified patent extensions, as drug safety agencies, operating outside of their field of competence, improperly deny marketing approval to generic competitors.

In the United States, where marketing approval is linked to patent expiration, the FDA almost automatically grants 30-month monopoly protection to patent holders who claim a new patent on claims related to dosage levels or similar grounds of renewed patents for drugs nearing the end of patent protection. In deference to these patent claims, the FDA denies marketing approval to generic companies -- even though many are subsequently found illegitimate. The result is that consumers are denied the benefits of competition, and lowered prices, for two-and-a-half years.

There should be no linkage between marketing approval and patent term. If a generic company markets an on-patent drug without license, under TRIPS the patent holder has adequate remedy at law. Stated differently, linkage can only serve to protect invalid IP claims -- valid claims receive protection through normal judicial means.

Again, it bears emphasizing that the artificial inflation of the price of medicines that stems from such misuses of the IP system is often a life-and-death matter. Seemingly obscure IP provisions will have enormous consequences for how much preventable suffering is averted or endured by the poor.

IMPROPER GRANTS OF DATA EXCLUSIVITY

⁷ " The U.S. proposal also addresses the limited situation in which generic pharmaceutical or agricultural chemical manufacturers can make, use or sell a patented product or process to obtain government marketing approval during the term of the patent so that they can compete with the patent owner soon after the patent expires. Under the U.S. proposal, FTAA countries would agree that so long as the patent remains valid the product or process may be made, used, or sold in their country by competitors only to meet marketing approval requirements." USTR, "FTAA Negotiating Group on Intellectual Property, Public summary of U.S. Position," <http://www.ustr.gov/regions/whemisphere/intel.htm> (No date, but released January 17, 2001).

Article 39.3 of the TRIPS agreement requires members to grant "reasonable" protection to "undisclosed" pharmaceutical test data, the study data showing safety and efficacy. To gain marketing approval, generic companies typically show their product is bioequivalent to a patented product, and then rely on the patented product's safety data to earn approval.

In many instances, if a generic company cannot use the already-generated registration data, it will not introduce a generic version of the patented product; the price of generating the data may be too high, or, just as important, take several years to replicate. If the company does choose to re-generate the data, consumers suffer from the delay in the introduction of the generic product that occurs while the generic firm re-conducts the relevant tests. Moreover, from a social point of view, retracing old tests to reach an already-known result is a tremendous waste of resources.

In those countries that establish set terms for registration data exclusivity (5 years in the United States, 10 years in the European Union), the period of exclusivity typically runs shorter than the patent term. Thus, registration data protections are not normally an impediment to the introduction of generics.

They are an issue, however, for new drugs that are not patent-protected or in cases of compulsory licensing. Where a compulsory licensing is granted for a drug for which registration data exclusivities remain in force, the data exclusivity can block the generic from gaining market approval.

An effective system of compulsory licensing must permit compulsory licensing of registration data.

The Jordan FTA includes TRIPS-plus language on registration data that requires Jordan to provide exclusivity for the same period as granted by the country where the data was filed, if it was filed outside of Jordan.⁸ Thus Jordan may be made to honor U.S. terms of protection -- or even the longer term of protection afforded in the EU, which is not a signatory to the U.S.-Jordan FTA, and requires a longer exclusivity period than the United States -- without specified exceptions.

Similarly, the U.S. negotiating position for the FTAA seeks to establish for the entire hemisphere a minimum exclusivity period of five years for registration data.⁹

⁸ "It is understood that, in situations where there is reliance on evidence of approval in another country, Jordan shall at a minimum protect such information against unfair commercial use for the same period of time the other country is protecting such information against unfair commercial use." U.S.-Jordan FTA, Article 22, footnote 11.

⁹ "The U.S. proposal also serves to clarify Article 39.3 of the TRIPS Agreement, which requires governments to protect against 'unfair commercial use' any undisclosed test data they receive as part of an application to market a new pharmaceutical or agricultural chemical product. The U.S. proposal makes clear that to implement this requirement, FTAA countries must prohibit any firm other than the company that produced the data from using or relying upon them without the latter's consent to obtain marketing approval for generic versions of the new product for at least five years after the country has granted marketing approval for the new product."

"Some FTAA countries currently do not have the capacity to review data for purposes of granting marketing approval and instead rely on marketing approvals in other countries. Accordingly, for purposes of complying with TRIPS Article 39.3, the U.S. proposal clarifies that FTAA countries will prohibit companies from submitting evidence of marketing approval for a new product in another country as a basis for seeking marketing approval in their country for a generic version of that product for at least five years after marketing approval for the new product was granted in the other country, unless the firm that obtained marketing approval in the other country consents to use of the evidence. In addition, the U.S. proposes that FTAA countries agree to prohibit non-consensual use of evidence of foreign government marketing

TRIPS language itself is quite vague on registration data.¹⁰ It only covers "undisclosed" data, stipulates protection from "unfair" commercial use, does not address the issue of reliance upon published studies or foreign government drug approvals, and sets out no standards for how governments should protect against unfair commercial use.

It is unacceptable for trade agreements to contain language that increases monopolistic protection for registration data beyond that contained in TRIPS. Such measures may significantly impede efforts at compulsory licensing of pharmaceuticals.

EXTENSION OF THE PATENT TERM

Both the Jordan FTA and the U.S. FTAA negotiating position call for patent extensions to offset delays in marketing approval for pharmaceuticals.¹¹ The result will again be extended monopoly protection for drug manufacturers and gouging of consumers.

TRIPS obligates member countries to grant 20-year patents. Those patents provide a two decade monopoly on inventions. Patent terms seek to create a balance between providing incentives for inventors and the public interest in maintaining and promoting competition. The 20-year term manifested such a balance -- albeit one tilted in favor of the corporate patenting sector -- taking into account the known delays sometimes associated with marketing approval. Adding additional time to the patent term after a balance has been struck improperly tips the IP scheme too significantly for patent holders.

The United States should not seek to extend the patent terms in negotiations for the U.S.-Chile FTA, and it should abandon such efforts in the FTAA.

OTHER INTELLECTUAL PROPERTY CONCERNS

The Jordan FTA and the U.S. FTAA negotiating position contain other TRIPS-plus provisions which should not be part of the U.S. negotiating objectives for the U.S.-Chile FTA.

Both the Jordan FTA and the U.S. FTAA negotiating position include specific language on enforcement that goes beyond TRIPS and improperly limits enforcement approaches available to countries, and the Jordan FTA contains enforcement provisions that do not clearly respect due process rights.¹²

approval in support of an application to market for a new use of an existing agricultural chemical or pharmaceutical product." USTR, "FTAA Negotiating Group on Intellectual Property, Public summary of U.S. Position," <http://www.ustr.gov/regions/whemisphere/intel.htm> (No date, but released January 17, 2001).

¹⁰ "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that data are protected against unfair commercial use." TRIPS, Article 39.3.

¹¹ Jordan FTA, Article 23(a); USTR, "FTAA Negotiating Group on Intellectual Property, Public summary of U.S. Position," <http://www.ustr.gov/regions/whemisphere/intel.htm> (No date, but released January 17, 2001).

¹² Including, for example, a presumption against defendants even in criminal copyright infringement cases as to where copyright subsists. Jordan FTA, Article 27.

The Jordan FTA and the U.S. FTAA negotiating position also inappropriately require the extension of patent protection to products and processes that are not required to be covered under TRIPS. Both require the patenting of genetically modified plants and animals,¹³ removing fundamental moral (as well as agricultural, environmental and economic) decisions from national decision-making -- both in U.S. trading partners and in the United States itself. The Jordan FTA also requires the patenting of business methods,¹⁴ even though these do not meet the basic patentability requirement of inventiveness and are subject to frequent abuse in the United States.¹⁵

The United States should not seek in its negotiations with Chile to force such unmerited expansion of patent monopolies.

CONCLUSION

Discussion of the specific problematic provisions in the Jordan FTA and the U.S. FTAA negotiating position should emphasize rather than obscure the fundamental issue: Expansion of intellectual property rights is not a proper subject for inclusion in an FTA between two WTO members, and should not be included in the U.S.-Chile negotiations. The only purpose of such inclusion is to advance a TRIPS-plus agenda which is improperly biased to IP holders and against the public interest and the public domain, and which threatens dire public health consequences.

If intellectual property is to be addressed at all in new international agreements, it should be to address concerns regarding the public's rights in intellectual property. For example, the agreement between the United States and the United Kingdom to put basic data about genes in the public domain should be expanded to other countries, and international agreement should also be reached to avoid overly broad and anti-competitive patents on e-commerce or the Internet. International agreement should clarify that trademark rights should not be used to stop persons from comparative advertising, criticism, parody or other legitimate uses of a company name, for example, in Internet domains. There should also be an agreement on the minimum rights for educators, researchers and others on a wide range of "fair use" issues, to protect U.S. fair use traditions in intellectual property in the new global trading regimes.

Sincerely,

Robert Weissman

James Love

¹³ The permissible exclusion on plants and animals in TRIPS Article 27(b) is absent from the Jordan FTA and U.S. negotiating position category of permissible categories of patent exclusions.

¹⁴ "Memorandum of Understanding on Issues Related to the Protection of Intellectual Property Rights Under the Agreement Between the United States and Jordan on the Establishment of a Free Trade Area," Article 4.

¹⁵ Prominent among many examples of such abusive business methods patents is Priceline.com's claim to a patent on internet auctions. See Mark Gimein, "Jay Walker's Patent Mania," Salon, Aug. 27, 1999, <http://www.salon.com/tech/feature/1999/08/27/priceline/print.html>. For a broader look at the issue, see <http://www.cptech.org/ip/business/ipurchasing.html>.

There are similar controversies over the appropriateness of using patents for software, a product that is protected also by copyright, trade secret and contracts. Many feel that patents should not be granted for software, due to the availability of other mechanisms for protection, the inability of patent examiners to provide adequate patent examination or evaluate prior art, and the potential for anti-competitive use of patents, for example to cover fundamental technologies and standards used in Internet communications.