

November 19, 2002

750 North Lake Shore Drive
Chicago, Illinois 60611
(312) 988-5598 FAX: (312) 988-5628
intelprop@abanet.org
www.abanet.org/intelprop

The Honorable Robert B. Zoellick
The United States Trade Representative
600 17th Street, N.W.
Washington, D.C. 20506

Paragraph 6 of the Doha Declaration on the
TRIPS Agreement and Public Health

Dear Ambassador Zoellick:

This letter is written to set forth the views of the American Bar Association Section of Intellectual Property Law concerning solutions to the potential problem identified in Paragraph 6 of the November 14, 2001 Doha Declaration on the TRIPS Agreement and Public Health -- the problem that WTO members which have little or no manufacturing capacity in the pharmaceutical sector may face in making use of compulsory licensing under the TRIPS agreement during national emergencies.

We hope that our practical experience may be helpful in understanding the role of the patent laws in such situations and in crafting an appropriate solution to a potential Paragraph 6 problem. The views in this letter, however, have not been considered by the Board of Governors or the House of Delegates of the ABA, and they should not be considered as representing policy of the Association.

There is no question about the gravity of the public health problems that result from epidemics in HIV/AIDS, tuberculosis and malaria and afflict many developing and least-developed countries. Nor is there any question that national and international action should be taken to address these epidemics.

The present issue is what can and should be done to address the Paragraph 6 problem, since the Ministers have determined, and we agree, that TRIPS can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and otherwise has sufficient flexibility to address public health crises, including national emergencies or other circumstances of extreme urgency. In short, in accord with the approach you are now taking, we believe that because intellectual property laws not only encourage private investment that leads to inventions, but also encourage private investment that implements and makes inventions available to the public, any exception to those laws should be the minimum possible. Creating any greater exception than is necessary will discourage private investment in developing and least-developed countries.

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Charles P. Baker
Fitzpatrick, Cella, Harper & Scinto
30 Rockefeller Plaza
New York, NY 10112-3801
(212) 218-2100
cbaker@fchs.com

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Banner & Witcoff, Ltd.
10 S. Wacker Drive
Chicago, IL 60606
(312) 715-1000
mtbanner@bannerwitcoff.com

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(312) 554-7934
rws@pattishall.com

SECRETARY

Joseph M. Potenza
Banner & Witcoff, Ltd.
1001 G Street, NW, Ste. 1100
Washington, DC 20001
(202) 508-9107
potenza@bannerwitcoff.com

FINANCIAL OFFICER

Mark K. Dickson
Howrey Simon Arnold & White, LLP
301 Ravenswood Avenue
Menlo Park, CA 94025
(650) 463-8234
dicksonm@howrey.com

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(713) 782-7821
jcgoldst@aol.com

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San Francisco, CA

(415) 369-7641

juilikema@thelenreid.com

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ipconsulting@msn.com

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Washington, DC 20005-1009

(202) 662-1772

FAX: (202) 662-1762

I. One of the Most Important Aspect of Intellectual Property to
Developing and Least-Developed Countries Is Its
Encouragement of Private Investment to Implement
New Technology

Private investment and technology transfer from developed countries into developing countries and least-developed countries cannot be mandated. They can only be encouraged. Intellectual property law systems provide that encouragement.

Many who suggest broad exceptions to deal with the Paragraph 6 issue fail to understand this. For example, a September 2002 Report of a British Commission on Intellectual Property Rights (the "CIPR Report") focuses incorrectly on whether intellectual property rights are a stimulus to inventors and to making inventions in developing countries. Intellectual property rights, however, are not only for inventors. They are also for investors – investors who could choose to invest in real estate, in established businesses or in other areas with little risk. The Report should have focused on whether intellectual property rights are a stimulus to invest in, develop and provide the infrastructure (distribution systems, education for use, etc.) for inventions that have already been made.

One conclusion of the CIPR Report is that developing countries need to adopt intellectual property rules that limit the extent of patenting and facilitate the introduction of generic competition, but the Report fails to deal with the fact that less incentive to invest will mean less private investment. The major problem for developing and least-developed countries is not the creation of new inventions. The major problem is encouraging private investments to make current technologies available in those countries.

The principal alternative to patents – a trade secrets system – would reduce the incentives for disclosure and transfer of new technology to developing and least-developed countries and would favor big and well developed countries, which would be able to maintain their markets and their manufacturing capability through sheer size and advanced technologies. Even for a pharmaceutical whose final ingredients are known from sales on the open market, the best manufacturing ingredients and methods may not be known. Developing and least-developed countries would find it difficult in a trade-secret-only system to obtain private investment in marketing or manufacturing innovations. We are convinced that the existence of exclusive rights in inventions is essential for developing and least developed countries to compete against large and developed countries for private investments in manufacturing and marketing of new technologies.

II. Any "Extra Costs" That May Be Associated with
Intellectual Property Laws Must Be Evaluated
In the Long Term

Many who question the value of intellectual property to lesser developed countries, including the CIPR Report in a number of places, presume expressly or implicitly that intellectual property laws grant a "monopoly" to the intellectual property owner, and hence there are "extra costs" associated with intellectual property rights. Matters are seldom that simple. While we have no specific knowledge about AIDS, tuberculosis and malaria treatments, when looked at carefully in specific instances, intellectual property rights seldom give rise to monopoly power. In the real world, patent claims seldom cover all relevant products in a market.

One cannot assume that there are always "extra costs" associated with intellectual property rights. It is difficult to provide appropriate incentives to potential suppliers of medicines who are asked to provide them at cheaper prices than the patentee. Even for the patent owner, the exclusivity of a patent may fail to provide enough incentive to implement or market an invention in a particular country, as evidenced by the fact that patents on many AIDS drugs are not obtained in countries where AIDS is a national emergency.

The same point applies to the need asserted in the CIPR Report for "counterbalancing and strengthening of competition policies globally." This need is a myth in the practical world. Almost without exception, new developments have competition from old ones, and, particularly in the pharmaceutical field, other new developments follow close behind. For example, we expect that today's apparently exclusive AIDS treatments will have competition from new ones in the near future. The period of true market power for any technological innovation is usually short to non-existent.

The CIPR Report asserts that the extra costs "imposed by IP rights may be at the expense of the necessities of life for poor people." Neither the patent laws or TRIPS, nor creating exceptions to the patent laws or TRIPS, can help people who are unable to pay for needed medicines or agricultural imports at any price.

A major fallacy of many who suggest that large exceptions be made to TRIPS, including the CIPR Report, concentrate too much on short term benefits (*e.g.*, the farmers' ability to exchange and informally sell seeds year-to-year), versus long term benefits -- multi-year protection which an investor wants before investing in the infrastructure (education about use, sales and distribution systems) that will bring new plant varieties and other inventions to fruition in lesser developed countries. We respectfully suggest that it is better for a country to encourage private investment by granting exclusive rights for a short period, with the subject matter being

developed and made available in the country for that period and becoming freely available at the end of that period, than for the country never to encourage that investment.

In summary, “extra costs” of patents, when looked at in the long term, are necessary costs. They pay for investment in developing the technology, and then they pay for implementing the technology – creating infrastructure and making the technology accessible. Such “extra costs” are related to the added benefits provided by the patented technology. Any country that would implement weaker intellectual property protection, as the CIPR Report suggests, would find itself out of the mainstream of world trade, with little or no private investment in infrastructure or in marketing of new technologies.

III. Broad Exemptions from Intellectual Property Laws Will Lead to Decreased Private Investment in the Areas Exempted

Some have suggested, including the CIPR Report, that the standards for compulsory licenses under TRIPS should differ for developing countries. Related suggestions include enabling lesser developed countries to exclude broadly, across-the-board such things as diagnostic and therapeutic methods, new uses of known products, certain subject matter (*e.g.*, patents on pharmaceuticals or, as the CIPR Report suggests, patents on agricultural biotechnology), or inventions that have a lesser stature (assuming for the moment that the stature of an invention can be determined, since in many cases the last step in a progression may seem small, but it may be the one step that makes all the earlier steps workable).

Several things would be wrong with these kinds of overly broad exemptions. First, generally speaking, the more intellectual property rights vary between countries, the more the objectives and the benefits of a world trade organization are defeated.

Second, to the extent a single global economy in any particular market becomes a fact of life, a country that adopts IP laws that are substantially different for that market from the rest of the world may find itself omitted from that market.

Third, viewed simply from the viewpoint of a single country, declining to grant patents in certain new technologies, or on inventions that have a lesser stature than others, will have the effect of discouraging private investment in the factories and in the sales, distribution and support systems, that will bring an already made invention to life in a lesser developed country. To the extent any exception is made for a particular subject matter, there would be less private investment in innovation and more reliance on trade secrets, neither of which would be good public policy for the country involved. Stated conversely, if a pharmaceutical or an agricultural biotechnology invention is novel and non-obvious, shouldn't the WTO want to

encourage private investment within all its members to develop the innovation and make its benefits available?

In this argument, as in its others, some of which are mentioned elsewhere in this letter, we find the CIPR Report generally unpersuasive in its conclusions. We would be glad to go into this in more detail if you would like.

IV. To Encourage Private Investment in Developing and Least-Developed Countries, Waivers or Moratoriums of Patent Laws or Rights Should Be Limited to Specific Products, Companies and Countries, for Specific Times

Intellectual property laws are perhaps the best way to encourage private investment in implementing new technologies. Conversely, exceptions to intellectual property laws discourage such investment. To the extent such exceptions are made more frequently than necessary under TRIPS, those exceptions will tend to erode confidence in intellectual property law systems and discourage investments in new technologies. Therefore, any exemptions authorized by TRIPS should be limited to the specific countries, producers, requirements diseases, and health related technologies involved, for the limited time an emergency lasts, and should be consistent with TRIPS. If used more than that, compulsory licensing will defeat the overall public good of encouraging private investment in new technologies. Indeed, the more the possibility of granting compulsory licenses is talked about unnecessarily, the more doubt is cast on intellectual property laws, and the less effective those laws are in encouraging investment in new infrastructures and new jobs.

We understand that the TRIPS waiver process is transparent. The more patent owners know about when waivers are granted and what the circumstances are, the more they will retain their confidence in the system. Compulsory licenses or exceptions of unknown kinds and extent can only weaken the intellectual property system, discouraging investment in new technologies.

In summary:

1. Private investment and technology transfer cannot be mandated; they can only be encouraged. Without uniform and strong intellectual property protection in lesser developed countries, private investment to implement new technologies is less likely to occur.

2. To resolve any Paragraph 6 issues, the most limited and transparent approach is the best approach for preserving as much as possible the incentive of patents to encourage private investment in health infrastructure.

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3. We understand that waivers or moratoriums are the most limited and transparent approach under TRIPS, and hence they should be used to resolve Paragraph 6 issues. In determining whether waivers or moratoriums should be granted for that purpose, many factors should be taken into account, including issues related to distribution and administration of patented health technologies within the country for which a Paragraph 6 need has been identified. Also, any grant should be limited to the specific countries, producers, requirements, diseases, and relevant health-related technologies involved, for the limited time a national emergency, or other circumstance of extreme urgency, lasts, and should be consistent with the purposes of the Doha Declaration and with TRIPS.

Thank you for considering these views. If you would like more detail, or if you would like us to address other matters, please let us know.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark T. Banner", with a long horizontal flourish extending to the right.

Mark T. Banner
Chair
ABA Section of Intellectual Property Law