The U.S.-Australia Free Trade Agreement (FTA) The Intellectual Property Provisions

Report of the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3)

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Advisory Committee Report to the President, the Congress and the United States Trade Representative on the U.S.-Australia Free Trade Agreement

Prepared By the

Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3)

I. <u>Purpose of the Committee Report</u>

Section 2104 (e) of the Trade Act of 2002 requires that advisory committees provide the President, the U.S. Trade Representative, and Congress with reports required under Section 135 (e)(1) of the Trade Act of 1974, as amended, not later than 30 days after the President notifies Congress of his intent to enter into an agreement.

Under Section 135 (e) of the Trade Act of 1974, as amended, the report of the Advisory Committee for Trade Policy and Negotiations and each appropriate policy advisory committee must include an advisory opinion as to whether and to what extent the agreement¹ promotes the economic interests of the United States and achieves the applicable overall and principle negotiating objectives set forth in the Trade Act of 2002.

The report of the appropriate sectoral or functional committee must also include an advisory opinion as to whether the agreement provides for equity and reciprocity within the sectoral or functional area.

Pursuant to these requirements, the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3) hereby submits the following report on the U.S.-Australia Free Trade Agreement ("AFTA").

II. Executive Summary of Committee Report

This is the first FTA in the recent series of FTAs that has been agreed to with a country in an advanced stage of development. IFAC-3 believes that, taken as a whole, this agreement is very strong and commends the U.S. negotiators for a job well done. This agreement is broadly consistent with the negotiating goals and objectives contained in the Trade Act of 2002 and those of the U.S. intellectual property-based industries, creators and innovators. IFAC-3 strongly supports the chapter on intellectual property and believes that, on the whole, it establishes key precedential provisions to be included in the other FTAs now being negotiated, including the FTAA. IFAC-3 wishes to underscore the importance that it attaches to a close working relationship between IFAC-3 and industry, on the one hand, and U.S. negotiators, on the other, in ensuring that the model FTA intellectual property text, which has been carefully developed

¹ This report is based on a review of AFTA agreement dated March 1, 2004. This text is not the "final" text, which at a minimum must undergo a legal "scrub" before it is submitted to the Congress and to the President. Accordingly, the final agreement may be different from the text upon which IFAC-3 has made these comments.

through the course of negotiation of six FTAs, continues to form the basis for these other agreements.

III. Brief Description of the Mandate of IFAC-3

As part of its mandate to provide detailed policy and technical advice, information and recommendation on trade-related intellectual property matters, IFAC-3 advised U.S. negotiators during the course of the negotiation without, however, reviewing draft texts of AFTA intellectual property chapter, which had not been presented to it for review until the conclusion of the negotiations. However, IFAC-3 did evaluate these FTA provisions during the course of the preparation of this report in the context of the IP-related objectives contained in the Trade Act of 2002 and the objectives and achievements of other U.S. multilateral and bilateral initiatives on intellectual property.

IV. Negotiating Objectives and Priorities of IFAC-3

The negotiating objectives and priorities for IFAC-3 reflect those contained in the Trade Act of 2002 (Pub. L. No. 107-210, 116 Stat. 995 (codified at 19 U.S.C. Sec. 3802(b)(4) (2002), trade promotion authority legislation) which also provided the fast-track authority under which this Free Trade Agreement will be reviewed and voted on. Specifically, IFAC-3's objectives and priorities seek to further promote the adequate and effective protection of intellectual property rights on a global basis. To accomplish this goal, the Committee works with the U.S. government to ensure full implementation of not only the substantive obligations in the TRIPS agreement but also the enforcement obligations as well. The latter is assuming increasing importance as countries improve their substantive standards of protection and especially in the context of increasing global trade in information and other innovative and creative products subject to intellectual property protection. The Committee also seeks to ensure that these standards of protection and enforcement keep pace with rapid changes in technology, including establishing that right holders have the legal and technological means to control the use of their works through the Internet and other global communication media, and to prevent the unauthorized use of their works. The Committee seeks to ensure the full range of protections for patented innovations, to eliminate any discrimination against U.S. right holders by any of our trading partners, and to secure deterrent enforcement against piracy, counterfeiting, cyber squatting and other infringements through significant improvements in civil and criminal remedies and penalties. Finally, the Committee seeks to establish strong precedents in these FTAs in order to raise the global level of protection and enforcement, nationally and in regional and multilateral agreements.

V. <u>Statement as to Whether Agreement Provides for Sectoral or Functional</u> Equity and Reciprocity

The concept of sectoral equity and reciprocity is not relevant to the development of rules such as those in the chapter on intellectual property. With the exception of the certain unilateral commitments by Australia contained in a side letter to the agreement, the provisions on intellectual property apply equally to both Parties. IFAC-3 expects that

Australia will equitably implement all of the intellectual property-related provisions of this agreement, but will not hesitate to recommend U.S. action under the provisions of the dispute settlement chapter should Australia's implementation of the agreement fall short of its commitments made in this agreement.

VI. Advisory Committee Opinion on Agreement

Introduction:

AFTA builds on the standards already in force in the TRIPS agreement, the NAFTA agreement, the Jordan, Singapore and Chile FTAs, updating the TRIPS/NAFTA standards to take into account the wealth of experience operating under those agreements since their coming into force in 1995, 1992, 2001 and 2003 respectively. It also takes into account the many years of experience gained from bilateral engagement with countries under the Special 301 trade process through which the U.S. Trade Representative has sought to leverage both legal and enforcement reforms in countries posing particular intellectual property problems for U.S. industry and for the U.S. economy. Perhaps most important, AFTA takes into account the significant legal and technological developments that have occurred since the TRIPS and NAFTA agreements entered into force and mirrors, as closely as possible, the Singapore and Chile FTAs in order to establish clear precedents for future FTA negotiations.

IFAC-3 is particularly gratified that AFTA preserves these strong precedents set forth in these other agreements and now, with high-level agreements with both small developing countries in the CAFTA and a strong and mature developed country like Australia, it will prove much easier to convince future FTA countries that strong intellectual property protection is in the interest of <u>all</u> countries <u>regardless of their economic circumstances</u>. Accordingly, IFAC-3 urges the U.S. government to keep this in mind when negotiating with countries such as those in the SACU, which have much to gain from maintaining the high levels of protection negotiated to date.

IFAC-3 applauds the U.S. negotiators for the incorporation within this agreement of the obligations set forth in the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT) which are so critical to creating the legal infrastructure for e-commerce, for the distribution and transmission of protected materials over the Internet and for products in digital format generally. In particular, it applauds the negotiators for convincing Australia to adhere to, and come into full step with, key provisions of those treaties consistent with the manner these were implemented in the U.S. in 1998 in the DMCA.

Accordingly, IFAC-3 welcomes, indeed applauds, the successful negotiation of AFTA. While IFAC-3 recognizes that the negotiation of FTAs with individual countries and regions is labor-intensive, especially when compared with the negotiation of a multilateral agreement among the 146 Members of the WTO, FTA negotiations provide the most effective approach currently available to the United States for improving global intellectual property protection. The negotiation of an individual FTA provides the opportunity to deal with specific intellectual property concerns that U.S. industry may have in the particular negotiating

partner. The resultant level of intellectual property protection that it contains should set a new baseline for future FTAs, including the FTAA. This baseline is continually reflected in the model FTA text which is constantly updated based on what industry and government learn through negotiating each of the FTAs.

IFAC-3 recognizes that, to a large extent, the negotiation of FTAs has become the primary focus of the U.S. trade agenda and supports the use of all policy tools to gain worldwide improvement in intellectual property protection. IFAC-3 urges U.S. negotiators to ensure that FTAs remain part of a coordinated, multi-dimensional program that not only includes multilateral and regional initiatives but also focuses on substandard intellectual property protection and enforcement in countries that are not parties to FTA negotiations.

IFAC-3 views the TRIPS Agreement as reflecting minimum international norms of intellectual property protection that most countries should already have in place. The role of the FTAs is to clarify, where necessary, those obligations and to improve upon them by enhancing the level of intellectual property protection in the negotiating partner.

The FTAs that the United States has negotiated since 1999 have facilitated national implementation of the TRIPS obligations and have provided the vehicle both for improved standards of intellectual property protection and enforcement and for significant clarifications of TRIPS obligations in the FTA partners. The continuum of intellectual property protection that links these FTAs has sent an important signal to future FTA partners about U.S. intellectual property expectations.

IFAC-3 urges the U.S. government to continue to maintain a strong bilateral program to deal with IPR deficiencies in non-FTA countries, many of which are critical markets for our industries and which may never be FTA candidates. It is therefore essential that traditional trade tools such as Special 301, Section 301, the unilateral trade preference programs and WTO dispute settlement be aggressively employed to lift levels of intellectual property protection in those countries. Many of these countries have failed to recognize the clarifications and new standards that U.S. negotiators have been able to achieve in the FTAs, while others may not be implementing these clarifications and new standards lest they lose bargaining chips in any future FTA with the United States. IFAC-3 further notes that negotiating FTAs is highly resource intensive and has an impact on the effectiveness of the overall bilateral program including with non-FTA countries.

IFAC-3 believes that, taken as a whole, this agreement is very strong and commends the U.S. negotiators. Accordingly, IFAC-3 strongly supports the chapter on intellectual property and believes that the agreement, on the whole, establishes key precedential provisions to be included in the other FTAs now being negotiated, including the FTAA. IFAC-3 wishes to underscore the importance that it attaches to a close working relationship between IFAC-3 and industry, on the one hand, and U.S. negotiators, on the other, in the development of a model FTA intellectual property text, which formed the basis of this agreement and for the negotiation of these other agreements to come.

IFAC-3 also wishes to highlight its expectation that the U.S. will insist, in any future FTA negotiations with countries that have yet to implement fully their TRIPS obligations, that they

not only do so before the launch of the negotiations but also provide a standstill specifically with respect to the approval of generic copies of pharmaceutical products.

IFAC-3 strongly supports Congressional approval of this agreement.

The following summarizes the main provisions of the intellectual property text and highlights both the provisions that we believe provide strong protection and those few provisions which IFAC-3 views as deficient and which should be improved upon in future FTAs.

General Provisions

These provisions acknowledge that both countries have already ratified and acceded to the major IPR treaties. An exception are the WIPO "Internet" treaties, which Australia agrees to adhere to by the entry into force of the FTA. These general provisions also contain the national treatment and other general provisions governing all of Chapter 17.

IFAC-3 is pleased with the general breadth of the national treatment provisions but is particularly disappointed that the agreement carves back such treatment and subjects to reciprocity the treatment of radio broadcasts and analog communications of sound recordings. Neither the Singapore FTA nor CAFTA permitted any national treatment derogations and it is critical that this or other derogations not be continued in other FTAs or in the FTAA. The U.S. has always supported the principle of full national treatment in intellectual property agreements and it is particularly vexing, that in a bilateral context, where access to the U.S. market is so critical, that full national treatment was not obtained.

Trademarks and Geographical Indications

Article 17.2.2 indicates that sounds and scents may be capable of constituting a mark. This view of what can constitute a mark is beneficial to trademark owners whose goods are distinguished based on sounds or scents.

Article 17.2.3 reaffirms TRIPS Article 20 that the use of one's trademark shall not be encumbered. Thus, the Article clarifies and enhances existing TRIPS obligations prohibiting interference with the use of trademark rights in products such as pharmaceuticals that are also subject to requirements regarding the use of the generic or common name of the product.

Article 17.2.6 provides a broadened view of well-known marks and the scope of protection. This Article extends protection of such marks to dissimilar goods and services, whether registered or not, with the proviso that the expanded protection is based on an association between the goods/services and the owner of the well-known mark and when the interests of the trademark owner are likely to be damaged. In view of the frequency of infringements of well-known marks, the ability of well-known trademark owners to protect their marks on unregistered and dissimilar goods and services is critical to protecting these valuable assets.

Although this agreement provides for greater scope of protection for well-known marks, it does not have a provision that is found in the Chile FTA, which provides for owners of well-

known marks to prohibit or cancel trademark registrations of marks that are identical or similar to the well-known mark. Rather the Agreement contains only the general provisions for opposing or canceling a registration with no specific mention regarding well-known marks.

17.2.10 eliminates the trademark license recordal requirement. While this is a positive provision for trademark owners, more explicit language as found in the Singapore FTA is preferred as it is clearer in stating that trademark license recordals shall not be required to establish validity of the license or to assert any rights in the trademark. Industry would prefer that future provisions eliminating the trademark license recordal requirement clearly state that there shall be no license recordal requirement to establish validity of the license or to assert any rights in the trademark, by either the trademark owner or license.

Geographical indications are dealt with in Article 17.2. As opposed to the Chile FTA, the provisions relating to geographical indications are part of the article dealing with trademarks. Conceptually, this is not a problem provided, as is the case here and as more fully set forth below, the critical elements related to geographical indications are included, namely: that registered trademarks may block the use of confusingly similar geographical indications, that the proper relationship (prior right takes precedence over the later right) between trademarks and geographical indications is established and that systematic examination of and opposition to applications for protection of geographical indications are provided for.

As with the Chile and Singapore FTAs, Article 17.2.4 requires that the owner of a registered trademark have the right to prevent the use, in the course of trade by third parties, of confusingly similar signs, including geographical indications.

AFTA text, like the Chile FTA text, then improves upon this language by also including a specific provision which would prohibit the protection or recognition of a geographical indication that is confusingly similar to a previously used, applied for or registered trademark, thereby unequivocally protecting prior trademarks against later geographical indications (Article 17.2.12(b)(v)). This is consistent with U.S. law and policy on the subject of the relationship of geographical indications and trademarks and is also consistent with the TRIPS agreement. As with the Chile FTA, to the extent that it lends clarity to the issue, the language in AFTA is a welcome addition to the Singapore FTA language.

To the extent that a Party allows for an application and registrations system for the recognition of geographical indications, AFTA text provides a clear framework required for the procedures involved in the process. AFTA text requires a very systematic and fair opportunity to object to the protection of geographical indications. One of the major problems with the protection of geographical indications is the lack of a clear mechanism to determine whether a geographical indication should be granted protection. AFTA, as with the Chile FTA, provides clear language requiring such a mechanism in cases where application and registration of geographical indications are allowed.

Finally, in footnote 5, AFTA broadens the definition of a geographical indication to allow for the protection of geographic indicia other than the actual names of geographic places (such as the

outline of a state). This provides the opportunity to protect geographic indicia as geographical indications, which will benefit those organizations that seek such protection. Provided that the above-mentioned relationship between trademarks and geographical indications remains clear, the broadened definition for geographical indications is likewise welcome.

Domain Names on the Internet

AFTA provides two provisions regarding domain names: Article 17.3 requires that each Party shall provide for Uniform Domain Name Dispute Resolution Procedures for the country-code top level domains (ccTLDs) of the Parties. This Article also requires that each Party provide public access to a "reliable and accurate" database of contact information for each domain name registrant. These provisions combine to combat the problems of copyright and trademark cyber-piracy and are welcome. IFAC-3 prefers, however, (and mentioned this in its Chile FTA report) that there be a specific reference to the "Whois" database and any additional contact information elements as available in the gTLDs namespace. Inclusion of this direct reference would clarify the type of information this database must contain. Reference to "Whois" was included in the Singapore FTA.

IFAC-3 wishes to underscore that the provisions regarding the establishment of Uniform Domain Name Dispute Resolution Procedures for ccTLDs in AFTA address only trademark cyber-piracy, and not other alleged abuses such as the use in domain names of geographical terms. IFAC-3 commends the fact that challenges based upon the use of geographical terms as, or as part of, a domain name are not included.

Copyright and the Protection of Certain Satellite Signals

The United States is the world's largest producer and exporter of copyrighted materials and at the same time loses more revenue from piracy and other inadequate copyright protection than any other country in the world. High levels of copyright protection and effective enforcement mean more revenue and more higher-paying jobs benefiting all Americans. The copyright industries account for over 5% of U.S. GDP and have employed new workers at over three times the rate of the economy as a whole over the last 25 years.

The goal for AFTA intellectual property negotiations was to achieve, for the first time with a developed country and a key trading partner, a level of protection that in some areas improved on the standards in TRIPS and in others clarified provisions in those agreements. In addition, it was critical to achieve Australia's agreement to adhere to, and fully implement the provisions of, the WCT and WPPT, along the same lines as the U.S. had in the DMCA in 1998. Unfortunately, in consideration of these issues in the last three years, Australia had strayed in a particularly key area from what industry and the U.S. government considered to be full and correct implementation of the obligations of those treaties. Finally, industry and the U.S. negotiators sought to clarify and build upon provisions of the TRIPS enforcement text in light of the U.S. copyright industries' wide experience with copyright enforcement globally. While enforcement in Australia was by no means as serious a problem as in many other countries in the region, there were some key improvements that industry believed would make a major difference in that market. These objectives were, in almost all instances, achieved.

While the text does not repeat obligations already found in the TRIPS agreement, it does contain detailed provisions that require implementation of the new obligations provided in the WCT and WPPT to which Australia is not currently a member. While Australia, as part of its Digital Agenda initiative, has implemented many of these provisions, AFTA ensures that it does so fully and in harmonization with the U.S. implementation in 1998. These provisions include:

- Clear language assuring that temporary and transient copies (such as those made in the RAM of a computer) are nevertheless copies and fully subject to the reproduction right. This treatment is critical in a digital, networked world in which copyrighted material can be fully exploited without a permanent copy ever being made by the user (Article 17.4.1);
- The right to control any technological manner of transmitting works, including interactive transmissions over electronic networks, like the Internet, with only minor exceptions for sound recordings and performances recognized in U.S. law (Articles 17.5 and 17.6.3);
- The requirement that Australia revise its current implementation providing protection for technological protection measures (TPMs) used by right holders to protect against unauthorized access and exploitation of their works to do so in the same manner as did the U.S. in the DMCA in 1998. In addition the text provides for a list of narrowly crafted exceptions in close consistency with how the U.S. Congress crafted those exceptions in U.S. law. A principal objective of the negotiation was to close a damaging loophole that Australia had enacted. This was done², is a significant gain and bodes well for the implementation by other countries of their TPM provisions in a manner closely similar to the way it was achieved in U.S. law (Article 17.4.7);
- Full implementation of the WCT and WPPT provisions on prohibiting the removal or alteration of electronic rights management information along the lines set out in the DMCA (Article 17.4.8);
- Implementation of those specific provisions of the WPPT that seek to harmonize the rights afforded sound recordings with most of the rights afforded all other protected works, though Australia, like the U.S. already protects sound recordings as works. (Article 17.6);
- A repetition of the three-step test for circumscribing the scope of exceptions to copyright protection found in the TRIPS Agreement and the WCT and WPPT (Article 17.4.10(a));
- Reiteration of the TRIPS and WIPO treaties' obligation ensuring the full term of protection for pre-existing works (Article 17.4.5).

Other key provisions clarifying or, in some cases, going beyond the existing TRIPS obligations include:

• New language to ensure that Australia may not subject retransmission of television signals to a compulsory license; such uses are subject to exclusive rights afforded the right holders of the subject matter contained in such signal, subject to a provision in a

 $^{^2}$ In a side letter, discussed below, Australia is given a short transition period to implement this important loophole-closing change.

side letter, discussed below. (Article 17.4.10(b));

- Unfortunately, the text does not contain a provision which follows U.S. law (17 USC §602) providing for the right of a copyright owner to prevent parallel imports of its products manufactured outside Australia that are not intended for distribution in that country. The failure to obtain such important protection is a deficiency in the copyright text; and the absence of such protection in certain sectors in Australia has caused great difficulty including facilitating the importation of pirated goods;
- In a major advance, Australia has agreed to extend its term of protection closer to that in the U.S.—to life of the author plus 70 years for most works. While industry sought to have the term of protection for sound recordings and audiovisual works extended from 50 years from publication to a term matching the U.S. law's 95 years, a compromise was struck at 70 years. We urge that future agreements move that level to the full 95 years (Article 17.4.4);
- The text incorporates the important "contractual rights" provisions of the NAFTA agreement ensuring that Australia will give effect to transfers of rights and the treatment of monetary benefits resulting from such transfers that are contained in U.S contracts. This safeguards the freedom of contract and ensures that Australian law may not undermine the intent of the parties to such contracts. This has been a controversial issue, with the European Union (and some other countries, though not with Australia to date), and we hope the agreement of Australia to this language will help establish a global precedent in this important area (Article 17.4.6);
- The text contains an all-important requirement that the two governments issue decrees or other similar orders mandating use of legal software by government agencies. The U.S. has already issued such an Executive Order and it is critical for all governments, Australia included, to ensure that their software use is fully licensed and that effective software management systems are established (Article 17.4.9);
- Finally, the substantive text adds provisions, based upon a similar provision in the NAFTA, protecting against the theft of encrypted satellite signals and the manufacture of and trafficking in tools to steal those signals. The Singapore FTA made it a criminal offense to manufacture and trade in these tools and to "receive or further distribute" such encrypted signals. AFTA follows this model but adds the words "receive and make use of and further distribute." This is an acceptable change. (Article 17.7).

Other than the specific shortcomings noted, and in particular the unacceptable limitations on national treatment with respect to the rights of performers and record producers, the substantive copyright text achieves all that U.S. industry sought in this negotiation and the negotiators are to be commended in achieving this most important result that expands U.S. economic opportunities for some of America's most competitive industries.

Patents

IFAC-3 notes that strong and effective patent regimes that provide a legal framework for the protection of technology stimulate not only innovation but delivery to the market of new products and services. As a general rule, the level of patent protection found in the industrial

countries, and especially the level of patent protection found in the United States, provide an appropriate level of incentives for these goals.

In that regard, IFAC-3 notes that AFTA is the first FTA, in the current series of FTAs, which was negotiated with a developed country that already provides many of the clarifications and additional provisions that enhance the patent and undisclosed information standards of the TRIPS Agreement that were included in earlier FTAs. Nevertheless, the FTA repeats a number of those clarifications and additional protections found in the earlier FTAs. IFAC-3, however, hastens to add that the absence from AFTA of a number of other clarifications and additional protections should not be misconstrued as setting any precedents for the negotiation of future FTAs, especially since the current candidates are all developing countries with lower standards of intellectual property protection when measured not only with those found in Australia but also with those found in the TRIPS Agreement.

IFAC-3 believes that it should be the U.S. objective in the FTA negotiations to ensure that our negotiating partners adopt a level of patent protection found in the United States, as called for in the Congressionally-mandated Trade Promotion Authority. Similarly, with regard to regulated products, the protection for undisclosed information available under U.S. law ensures a fair return on investment in the expensive research and development process for pharmaceutical and agricultural chemical products. IFAC-3 believes that it should be the objective of U.S. negotiators in the FTA to ensure a similar level of protection in FTA partners, notwithstanding their level of economic development, as in the United States. It is in light of these objectives that IFAC-3 provides its comments on the provisions relating to patents and to measures related to certain regulated products.

As in other FTAs, the patent section clarifies and improves on the standards contained in the TRIPS Agreement. The inclusion of these provisions is most welcome.

Certain of the obligations establish strong new precedents for the global standards applicable to patents. For example, AFTA, in noting the adherence of both countries to the Patent Cooperation Treaty, recognizes that this well-accepted international application regime has delivered benefits to patent applicants. Incorporating PCT adherence as a mandatory obligation of U.S. FTAs extends the procedural benefits of this treaty to patent applicants seeking to obtain protection on a global basis.

IFAC-3 notes with satisfaction that AFTA confirms that patents will be available for all products and processes and for any uses or methods of using a known product. The obligation, which includes patents on plants and animals, reinforces the standards that exist today in Australia and validates the importance of extending, without exclusion, broad patent eligibility for biotechnology products. The FTA, however, continues to permit Australia to exclude patents on surgical, diagnostic and therapeutic methods and for technology that may not be commercially exploited in the territory (i.e., consistent, respectively, with Articles 27.3(a) and 27.2 of the TRIPS Agreement). (Article 17.9.1 and .2)

IFAC-3 is also pleased to see that provisions were included in the FTA to enhance the ability of patent owners to prohibit international exhaustion of patent rights. IFAC-3 believes that it is critical that the FTAs include provisions that restrict the authority of countries to provide

for international exhaustion of patent rights, including, as was done in the Australian agreement, by protecting the right of the patent owner to prevent the unauthorized importation of goods subject to the patent put on another market by the patent owner or its agent. AFTA does so by providing a right of action to enforce contractual provisions that are violated outside the territory of each Party. IFAC-3 notes that the underlying right being protected is implicitly acknowledged to be the right of the patent owner to exercise its exclusive right to prohibit importation of products subject to the patent. While IFAC-3 welcomes the formulation found in AFTA, it continues to urge that future agreements explicitly provide this understanding. (Article 17.9.4)

AFTA appropriately restricts the grounds for the revocation of a patent to those that would have justified a refusal to grant the patent or on the basis of fraud, misrepresentation or inequitable conduct. In addition, IFAC-3 notes that a side letter permits Australia to provide that a patent may also be revoked on the basis that the patent is used in a manner determined to be anticompetitive in a judicial proceeding. IFAC-3 notes that, while AFTA does not prohibit third party opposition to the grant of patents prior to the issuance of the patent, industry has not found the practice in Australia to have led to the type of inordinate delays in patent grant that is found in other countries with pre-grant opposition. IFAC-3 expects that U.S. negotiators will continue to include the prohibition of pre-grant opposition in all future FTAs where the potential for abuse exists. (Article 17.9.5)

AFTA places restrictions on how a third party may use a patented invention to generate data needed for the marketing approval of generic pharmaceutical products (so-called "Bolar"-type use) by limiting its use specifically to purposes related to meeting marketing approval requirements, and if export of the generic pharmaceutical product is permitted, to permit such export only for purposes of meeting marketing approval requirements. In view of the additional provisions that require Australia to restore the term of patent lost due to the time necessary to obtain initial marketing approval of a product, these restrictions generally reflect the standards found in U.S. law and practice. (Article 17.9.6)

AFTA imposes restrictions on a country's authority to grant compulsory licenses to situations that are needed to remedy anti-trust violations, national emergencies or other circumstances of extreme urgency, and for public non-commercial use. With respect to cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, the FTA specifies that such unauthorized use is to be limited to use by the government or third parties authorized by the government; that the patent owner is provided with reasonable compensation for such use and manufacture; and that Australia shall not require the patent owner to transfer undisclosed information or technical "know how" related to the patented invention that had been subjected to the involuntary use authorization. While these limitations clarify a country's authority to use compulsory licensing and are most welcome, IFAC-3 notes that the substance of these restrictions are already found in the TRIPS Agreement and the Paris Convention. (Article 17.9.7)

AFTA recognizes the delays that patent owners face in the issuance of their patents by the patent office and requires patent term adjustments to compensate for these delays. IFAC-3 expects that implementation of these provisions into the Australian patent regime will

correspond to U.S. practices. Since neither Australia nor the United States provides for the grant of a patent based on an examination of the invention conducted in another country, AFTA does not include the provision that requires patent term extension in such cases. Since, as a general rule, developing countries provide for such reliance, IFAC-3 believes that it is critical that the inclusion of such an obligation be included in FTAs with countries that provide for reliance on third country examinations. (Articles 17.9.8)

The FTA requires (in Article 17.9.9) Australia to treat public disclosures of an invention that occur within twelve months prior to the filing date of the application in Australia to be non-patent defeating. The formulation requires the pre-filing disclosure of the invention to have emanated in some form from the patent application, which is a slightly narrower authority than U.S. law.

Article 17.9.10 through Article 17.9.13 of AFTA provide procedural definitions that will facilitate patent examination and ensure the transparency of that process. Article 17.9.14 calls on the two countries to reduce the differences in law and practice between their respective systems, with specific reference to differences in determining the rights to an invention, the prior art effect of applications for patents and the division of an application containing multiple inventions. Both countries also agreed to participate in international patent harmonization efforts, including those underway in the WTO dealing with the reform and development of the international patent system. Pursuant to Article 17.9.15, both countries will seek to establish a cooperative framework between their respective patent offices as a way to make progress towards the mutual exploitation of search and examination work. The inclusion of such procedural provisions is particularly germane to an FTA between two countries that provide high levels of patent protection. Nevertheless, IFAC-3 believes that such procedural safeguards are equally relevant to FTAs with countries that have less mature levels of intellectual property protection and urges U.S. negotiators to replicate the provisions in all future FTAs.

IFAC-3 believes that it is critical that future FTAs include, at a minimum, all of the additional patent protections and clarifications found in AFTA as well as those that were not included because of the special circumstances posed by Australia's developed country status and its resultant current high standards of patent protection. For example, the United States should take the opportunity of future FTA negotiations to clarify that no disclosure requirements beyond those in Article 29 of TRIPS may be imposed on patent applicants. Such a provision would explicitly prohibit countries from imposing special disclosure requirements regarding the origin of genetic resources or comparable grounds that could be used as a basis either to refuse to grant the patent or to invalidate it. Future FTAs should also include provisions that will provide for the grant of pipeline protection, especially in FTA candidate countries that currently do not provide patent protection for pharmaceutical products. Finally, the United States should include an obligation on countries engaged in FTA negotiations to prevent the loss of rights due to actions taken by the negotiating partner prior to the conclusion of the FTA negotiations that permit third parties to enter the market in advance of the entry into force of new obligations contained in the FTA.

Measures Related to Certain Regulated Products

The provisions of AFTA clarify the obligations contained in TRIPS Article 39.3 with respect to data exclusivity and provide for additional protection with respect to pharmaceutical products subject to a patent.

To give effect to the data exclusivity obligations of Article 39.3 of TRIPS, AFTA imposes an obligation of "non-reliance" on either the pioneer approval or the pioneer data package itself for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product. (Article 17.10.1(a) and (b))

In addition, AFTA explicitly provides protection in cases where regulatory approval is conditioned on the demonstration of prior marketing approval in another territory by requiring the deferral of the date of any marketing approval to third parties not having the consent of the party providing the information in the other territory for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product in Australia or in the other territory, whichever is later. Footnote 18, however, notes that both Australia and the United States do not currently permit such filings nor will they permit such filings at the time that the agreement enters into force. (Articles 17.10.1(c))

AFTA seeks to ensure that the term "new product" that is used in Article 17.10 is not confused with the "novelty" requirement for patentability found in Article 17.9.1 that an invention must be "new." IFAC-3 welcomes the regulatory-related definition of a "new product" contained in Article 17.10.1(d) as being a product that does not contain a chemical entity that had been previously approved in Australia as providing an important clarification of the term "new chemical entity" found in TRIPS Article 39.3.

Article 17.10.1(e) essentially clarifies the obligation found in TRIPS Article 39.3 that, if a government or a government entity (in this case, Australia) discloses undisclosed information provided by the originator for gaining marketing approval of a pharmaceutical or agricultural chemical product, it shall protect the information from unfair commercial use, by specifically providing that such protection must be done in a manner set forth in Article 17.10.1, that is, through non-reliance.

Article 17.10.2 requires Australia to provide additional periods of non-reliance of three years from the date of marketing approval in Australia or the other territory, whichever is later, for new clinical information (other than information related to bioequivalency) or evidence of prior approval of the product in another territory that requires such new information, which is essential for the approval of a pharmaceutical product that uses a previously approved chemical component. Footnote 19, however, grandfathers Australia's current system for protecting information submitted in connection with the approval of a pharmaceutical product that utilizes a previously approved chemical component from unfair commercial use by indicating that it may retain such system, notwithstanding the obligations of Article 17.10.2.

In addition, AFTA explicitly restricts Australia from terminating the data protection period with the expiration of the underlying patent. (Article 17.10.3)

While these provisions on data exclusivity do not impose any additional obligations beyond those contained in TRIPS Article 39.3, they do serve to clarify the intent of the negotiators of the TRIPS Agreement.

AFTA also imposes a second set of obligations that provides patent term restoration for the unreasonable curtailment of the patent term as a result of the marketing approval process (Article 17.10.4); prohibits generic drug approvals during the term of the patent covering the pharmaceutical product (i.e., "linkage"); and requires the mandatory disclosure of the identity of the generic applicant that seeks marketing approval to enter the market during the patent term. (Article 17.10.5)

IFAC-3 is, however, troubled, by the recognition, in paragraph 1 of Side Letter 2, of Australia's current practice to permit the export by a third party of a pharmaceutical product covered by a patent during the period of patent term extension permitted under Article 17.10.4 for purposes of meeting the marketing approval requirements of another territory as well as of Australia. IFAC-3 believes that there should not be any differentiation between the protections provided pharmaceutical patents during the initial patent term or during the extension, as is the current practice in the United States.

IFAC-3 welcomes these provisions with respect to certain regulated products contained in AFTA and urges that they be retained in all future FTAs.

Enforcement

IFAC-3 wishes to underline the importance that it attaches to the effective enforcement of the full panoply of intellectual property rights afforded in this agreement, which build upon the existing enforcement obligations in the TRIPS agreement. The updated protections afforded in this agreement will be of little value to U.S. companies without the capability and willingness of the Australian government – any government for that matter – to enforce those standards, particularly against commercial piracy and counterfeiting (and other infringements) that cause such a drain on the U.S. and Australian economy.

Today, eight years after the WTO TRIPS enforcement obligations became effective in the developed world and four years after they became effective in the developing world, the U.S. companies and industries benefiting from this agreement continue to suffer billions of dollars in losses due to global piracy, counterfeiting and other infringements of the rights provided in TRIPS and in this agreement – primarily due to ineffective enforcement by our trading partners. While, for the most part, the substantive provisions of the TRIPS Agreement have been implemented in these countries, it is crystal clear that the enforcement obligations are not being met by many countries. The continued development and importance of new technologies, such as the Internet, and the accompanying greater ease with which piracy and counterfeiting can be accomplished, have made this situation even more acute. In addition, the alarming increase in the international trade in counterfeit pharmaceutical products is raising public health concerns, especially in developing and least developed countries. It was the

objective of the U.S. government, of IFAC-3 and of the entire U.S. intellectual property community to use the opportunity offered by the FTA process (the Doha Round in the WTO will not be considering changes in the TRIPS enforcement text) to use our enforcement experience over this period to improve and strengthen these enforcement obligations, with the goal of having them adopted on a global basis.

IFAC-3 notes that this task was particularly challenging since governments are most reluctant to bind themselves to specific performance standards in the area of enforcement. But it is precisely the day-to-day operation of the enforcement system and its ability to "deter further infringements" (the TRIPS standard) which will bring back to the U.S. and to other countries the billions of dollars lost globally to rampant piracy and counterfeiting, including counterfeiting of pharmaceutical products.

While, as noted, above, piracy rates are far lower and the enforcement system better than in many countries in the region, this agreement makes some significant advances toward the broader goal of setting high standards and good precedents for the future and for other FTAs. But again, even in Australia, the proof will lie in the implementation of these new standards on the ground in the country, by police, prosecutors, judges and administrative agencies responsible for enforcement and implementation of intellectual property rights.

Some of these advances (clarifying or building upon existing TRIPS standards) and some areas where needed improvements were not achieved include:

General Obligations on Enforcement

- These general provisions clarify and expand, for the most part, existing TRIPS obligations;
- Article 17.11.3 requires both parties to publicize information "that the Party may collect" with respect to their enforcement efforts including making available enforcement statistics, if kept by each country. The keeping and publicizing of enforcement information is a key to deterrence and permits industry and governments to evaluate performance and educate the public about the importance of intellectual property rights, and the risks attendant upon their infringement. IFAC-3 would prefer that this obligation be stronger, including provisions that would "require" the keeping of statistics on cases brought and outcomes reached;
- Article 17.11.4 is a very significant advance for the copyright industries and completes the process of fixing a serious problem in the Australian enforcement system. This provision lays out detailed presumptions that must be implemented in national law concerning the subsistence and ownership of copyright in all protected subject matter. Proving these preliminary issues in court, without the benefit of presumptions, makes enforcement difficult, expensive and causes long and unnecessary delays, all to the detriment of expeditious and effective enforcement against the run-of-the-mill piracy and counterfeiting that causes most of the losses globally. IFAC-3 notes, however, that the provision only requires the defendant to provide "evidence" to rebut the presumption. IFAC-3 urges that the Parties to the FTA must interpret this to mean "credible" evidence, not just "any" evidence. The latter interpretation would be only a slight, and unacceptable, advance from what existed at one time under Australian law,

namely, the requirement that the defendant merely had to plead denial of ownership or subsistence to defeat the presumption. This latter manner of dealing with presumptions had caused great difficulties for right holders in Australia. In addition, the presumption on subsistence is limited to "all the factual elements necessary under the law of that Party." IFAC-3 prefers the simpler formulation in the other FTAs which does not draw any distinction between factual and legal elements for establishing this presumption.

Civil and Administrative Procedures and Remedies

- Article 17.11.6 is intended to clarify and expand upon TRIPS obligations, to make clear that civil damages, at least in the area of copyright piracy and trademark counterfeiting, must actually compensate the right holder for the damages suffered, including payment of the infringer's profits not taken into account when calculating actual damages. However, Paragraph 3 of Side Letter 2 of the FTA would permit Australia to maintain its current provisions on calculation of damages. This side letter provision would allow Australia to retain its provision whereby the right holder must elect between damages and the infringer's profits and its provision entitling the right holder to only recover the infringer's profits in the case of innocent infringement. Finally, Australia can retain its provision providing for no damages to the right holder of a trademark that is not being used. IFAC-3 would have preferred that the simple provision in the Singapore and other FTAs would have been included in this FTA and urges that these exceptions not be permitted in future FTAs. Article 17.11.6(b) also requires the courts, upon submission from the right holder, to "consider" "any legitimate measure" of the value of the infringed upon product, including the suggested retail price of the legitimate product as a measure of the loss to the right holder. Industry prefers stronger language that damages "be based upon" this measure;
- Article 17.11.7, "at least" with respect to copyright piracy and trademark counterfeiting, makes the option to provide for statutory (or "pre-established") damages in the TRIPS Agreement mandatory following the Singapore FTA text. However, the Australia provision permits it to retain its system of "additional damages" as an alternative with a requirement to implement a system of statutory damages if the existing system does not work. We hope that this provision succeeds in solving this problem. The difficulty of proving "actual" damages in a piracy or counterfeiting case is well known; the U.S. has long had a statutory damages regime. It is a major goal of industry to see an effective statutory damages regime established in every country;
- Articles 17.11.8-12 elaborate on and make mandatory many discretionary remedies from the TRIPS Agreement including payment of reasonable attorney's fees to the prevailing party; making clear the right of judicial authorities to order the seizure of all suspected infringing goods, implements, other materials and documents used in the commission of the infringement; making mandatory the destruction of infringing goods, except in exceptional circumstances; requiring destruction of implements used in the commission of an infringement even if the predominant use (TRIPS test) may have been for legitimate purposes; making mandatory that the removal of a trademark from infringing goods will never be sufficient to permit their release back into commerce; and, most important, mandating that the courts have the authority to order

the infringer to identify accomplices, suppliers and others involved in the infringement, at the risk of fines or imprisonment for failure to do so. The latter is particularly critical given the role that organized crime plays in today's piracy and counterfeiting. These provisions are strong and follow the Singapore FTA formulation;

- Article 17.11.13 extends the panoply of civil remedies for copyright infringement to circumventing technological protection measures and tampering with rights management information. Destruction of devices is mandatory;
- Article17.11.15 adds that, if expert witnesses are required by the court and must be paid for by the right holder, the charges be related to the work performed, and not deter recourse to such relief. This seeks to remedy abuses found in many countries.

Provisional Measures

- Article 17.11.16 reflects the TRIPS requirement for *ex parte* provisional relief in civil cases and requires that such orders be issued "expeditiously." Quick *ex parte* search orders are critical to meaningful civil enforcement against infringements. Industry prefers that this provision contain a more precise guideline for the time period for a search order request to be acted upon or denied, such as within10 days, except in exceptional circumstances;
- Article 17.11.17 again builds upon TRIPS by providing that any security required of the plaintiff be "reasonable" and not "deter" recourse to these procedures (experience in many countries is that the right to require bonds and security has been abused).

Special Requirements Related to Border Measures

The provisions relating to enforcement at the border include improvements over the TRIPS text.

Articles 17.11.19 et seq. streamline the border enforcement measures and clarifies and expands TRIPS border enforcement powers. First, Article 17.11.19 states that right holders must provide sufficient information to identify goods to establish a prima facie case but it is clarified that this information need not go beyond what is reasonably expected to be in the right holder's possession. Moreover, the requirement to provide such information must not unreasonably deter recourse to these procedures. The provision also provides that an application to suspend the import of goods will remain in effect for not less that one year. These are welcome clarifications. Second, Article 17.11.20 provides that right holders put up security but that the amount of such security be reasonable and not unreasonably deter recourse to the procedures. Third, Article 17.11.21 requires that the competent authorities have the power to order the infringers to provide the right holder with information regarding the consignee, consignor and importer of infringing goods. TRIPS does not require that the competent authorities have this power and this is a welcome addition. Fourth, customs authorities must act ex officio and without a right holder complaint but the AFTA text limits this obligation only to imports. IFAC-3 prefers that ex officio authority extend to exports and transshipment as well.

Australia did not agree to cover transshipment which is a deficiency in the text;

- Article 17.11.23 outlines the treatment and disposition of pirate and counterfeit goods found by the authorities at the border. Unlike TRIPS, AFTA outlines these measures and indicates that counterfeit and pirate goods shall be destroyed except in exceptional circumstances. It strengthens the disposition requirements for trademark counterfeit goods, clearly indicating that the simple removal of unlawfully affixed trademarks is not sufficient to permit release into channels of commerce and that in no event shall authorities permit export of counterfeit or pirated goods;
- Article 17.11.25 includes a provision new to the FTA texts calling for exchange of technical advice and for bilateral and regional cooperation. This is also a positive development.

Criminal Procedures and Remedies

- Article 17.11.26 again builds on the TRIPS provisions in this area. For the copyright and trademark industries, criminal remedies and effective border measures are key to reducing losses globally. The critical concept of piracy or counterfeiting "on a commercial scale" is clarified to include infringing acts without a profit-motive or commercial purpose but which cause damage "on a commercial scale" the proper reading of this term in TRIPS. Thus, even where the person posting infringing material on the Internet is not charging a fee to the downloader/viewer/listener, such acts cause great damage to those right holders and must be covered. The text in Article 17.11.26 includes this concept (as does the NET Act in the U.S.). IFAC-3 would have preferred the "more than *de minimis*" threshold in the CAFTA than the requirement for "significant" willful infringements in the AFTA text. It will be important to ensure that the threshold adopted by Australia is low.
- Article 17.11.27 seeks to reach one of the most serious problems for right holders globally—the failure of judges or other enforcement authorities to actually impose penalties at a real deterrent level. The text is more specific with respect to the remedies that must be available and includes reference to penalties being sufficiently high to provide a deterrent and "consistent with a policy of removing the monetary incentive of the infringer," as in the Singapore FTA. However the text appears to draw a distinction between what is in the law and what judges do in practice. In the latter situation, the text only requires Australia to "encourage" judges to impose deterrent penalties. The language from the CAFTA referring to "guidelines" including sentencing guidelines is not contained in this text.
- Article 17.11.27(b) is a very positive provision requiring seizure of infringing goods, implements, related materials, assets traceable to the infringing activity and relevant documentary evidence. These obligations are unqualified. An associated footnote deals with an endemic problem of the seizure by authorities of only product named in a search order even though other clearly infringing products are at the search site. The footnote repeats the CAFTA language that products to be seized need not be specifically identified but need only fall into general categories named in the warrant or search order. Search orders in many countries are written too narrowly and the text remains ambiguous whether this provision would require seizure of pirate videogames, music, software or books found in a search requested by the movie

industry looking for pirate DVDs, videos etc. It is incumbent upon right holders, judges and the governments implementing this provision to permit broad search orders that facilitate seizures of all pirate and counterfeit material found at a raid site.

- Article 17.11.27(c) expands on TRIPS and requires the destruction of counterfeit and pirated goods, except in exceptional cases, and with respect to copyright piracy, any implements or other materials used in accomplishing the infringement. This is to be commended. However, in view of the magnitude of product counterfeiting, industry prefers that the destruction of materials and implements be extended to those used for production of counterfeit trademarked products. It also provides for the forfeiture of any assets traceable to the infringing activity, but limits this obligation only to indictable offenses. This is also welcome and not provided in TRIPS. We assume that indictable offenses in Australia will accompany any serious piracy crime, such that assets may be forfeited;
- Article 17.11.27(d) is a key advance, requiring criminal authorities to act *ex officio* against piracy and counterfeiting. Many countries require a right holder to make a formal complaint, which is a major enforcement impediment and should be eliminated on a global basis. Piracy and counterfeiting must be "public" crimes;
- Article 17.11.28 adds an additional offense, not found in TRIPS, making it a crime to deal in counterfeit labels for certain products. This is also a positive advance.

Limitations on Liability of Service Providers

• Article 17.11.29 governs the key issue of the liability of, and limitations on the liability of, service providers that are involved in the hosting and transmission of infringing material over their facilities. The result of the negotiation follows what was achieved in Singapore, Chile and CAFTA and is an excellent set of provisions that establishes the basic functional equivalent of the concepts and provisions embodied in U.S. law as found in Section 512 of the DMCA. We commend the negotiators for obtaining these specific obligations in a country as important as Australia. IFAC-3 believes it is essential that these provisions be replicated in other FTAs, if U.S. protected material is to find its way safely into global e-commerce to the great benefit of the U.S. economy and to U.S. jobs. It is also our understanding that Australia already has in place a strong system of secondary liability which does, and will, provide an effective mechanism for addressing piracy through networks and in ensuring cooperation between service providers and content owners.

Transitional Provisions

• Article 17.12 contains transitional provisions. As noted above, all obligations of the FTA become effective upon entry into force. However, because the anticircumvention provisions in the FTA will require Australia to amend its law to remove the loophole in its existing law regarding the trafficking in circumvention devices for certain "permitted purposes" in its law, Australia has a two year transition period to close this loophole and in the interim is obligated not to apply any new exceptions to those provided in Article 17.4.7(a). We again commend the negotiators for ensuring that this loophole is repealed and that it not be permitted to be a

precedent for future FTAs.

Side Letters

- Side Letter 1 contains the details of an effective notice and takedown process modeled on the DMCA provisions. IFAC-3 strongly supports these procedures;
- Side Letter 2 contains some specific unilateral provisions asked for by Australia. These include:
 - (a) For patents and certain regulated products, the first provision recognizes Australia's current practice to permit the export by a third party of a pharmaceutical product covered by a patent during the period of patent term extension permitted under Article 17.10.4 for purposes of meeting the marketing approval requirements of another territory as well as of Australia. IFAC-3 is troubled by the recognition of Australia's current practice and believes that there should not be any differentiation between the protections provided pharmaceutical patents during the initial patent term or during the extension, as is the current practice in the United States.

The fourth provision permits Australia to provide for the revocation of a patent on the basis that the patent is used in a manner determined to be anticompetitive in a judicial proceeding.

- (b) The second provision adds on to the prohibition against Internet transmissions of television programs and provides that Australia would have the right to move from a regime of exclusive rights in this area if technology becomes available that would limit such transmissions to not being receivable outside Australia. IFAC-3 is strongly in favor of exclusive rights in this area and would not like to see Australia or any other country take advantage of this or any similar Internet exception which does not afford full exclusive rights to right holders;
- (c) As noted in the discussion above of Article 17.11.6, paragraph 3 of this Side Letter would permit Australia to maintain its current provisions on calculation of damages. This side letter provision would allow Australia to retain its provision whereby the right holder must elect between damages and the infringer's profits and its provision entitling the right holder to only recover the infringer's profits in the case of innocent infringement. Finally, Australia can retain its provision providing for no damages to the right holder of a trademark that is not being used. IFAC-3 would have preferred that the simple provision in the Singapore and other FTAs would have been included in this FTA and urges that these exceptions not be permitted in future FTAs.

VII. <u>Membership of the IFAC-3</u> <u>Committee</u>

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