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We often overlook at the time those events to which history will later give great weight. On January 1, 1995, one such event occurred—the genesis of the World Trade Organization (WTO). To be sure, very few, if any, New Year’s revelers that year were toasting the creation of the WTO. Indeed, few people anywhere even took note of what had transpired. There were no fireworks displays; no medals were struck, no national or international proclamations made. Yet the agreements that the WTO administers, including the Agreement on the Trade Related Aspects of Intellectual Property—better known to lawyers and policy wonks everywhere as TRIPs—now govern virtually all aspects of trade and commerce in the global economy and affect the lives of literally billions of this planet’s residents. And, with few exceptions having to do with specialized issues like trade in civil aircraft, the WTO is unique among international bodies in that all WTO Agreements bind all WTO Members.
While perhaps a shade less awe-inspiring than sliced bread, we think it is fair to say that the TRIPs Agreement is one of the central achievements of the Uruguay Round for the United States because intellectual property is one of this nation’s greatest competitive advantages. Not to sound too jingoistic, but popular phrases like “American know-how” and “Yankee ingenuity” really do reflect a generally profound and widely-held respect around the world for the creativity and innovation that emanates from America’s shores, and more importantly, Americans’ minds. The TRIPs Agreement ensures that our national creativity and innovation are as protected abroad as they are at home, and perhaps even more importantly, that other nations are encouraged to develop their own national spirit and economy based on creativity and innovation.4

The United States is now both the world’s largest exporter and largest importer. Those exports and imports represent more than $2 trillion worth of goods and services annually.5 Thus, the jobs of millions workers both in the U.S. and other countries directly depend on open and stable markets worldwide. Beyond our own national economic and trade interests, we recognize that a strong trading system helps to give all participating nations a stake in international stability and prosperity.

This is the foundation of the leading role the U.S. has taken in the development of the trading system for over fifty years. Since the creation of the General Agreement on Tariffs and Trade in 1948, eight rounds of global trade negotiations have been concluded.6 Each successive Round has opened markets and helped to advance basic principles of rule of law, transparency and fair play in the world economy.

Intellectual property protection is a critical component of U.S. trade policy. Piracy of U.S. owned intellectual property has been

WTO agreements are obligatory for all members).

4 See Marie Wilson, *Trips Agreement Implications for Asean Protection of Computer Technology*, 4 ANN. SURV. INT’L & COMP. L. 18, 23 (1997) (noting the protection of intellectual property under the TRIPs agreement and the effects it has on developing nations).


6 See John Zarocostas, *A Summit Triumph; Trade Officials Hope ’96 Information Technology Deal Will Be Followed by More in 1997*, J. COMM., Jan. 6, 1997, at 28C (stating that there have been eight rounds of negotiations since GATT was created).
and continues to be a serious problem in many countries. The U.S. copyright industries estimate that they suffer total annual global losses in the range of $20-22 billion, not including losses due to Internet piracy.\(^7\) Our patent-dependent pharmaceutical industry estimates that it too loses billions of dollars annually in two major markets alone.\(^8\) Other U.S. industries dependent on patents, trademarks, trade secrets, industrial designs and other forms of intellectual property suffer similar losses.\(^9\) Of course, piracy exists in the United States -- just walk down Broadway south of Houston to Canal Street any weekend to see piracy hard at work -- but the problem is most severe in developing countries and countries in transition to a market economy, where some of the best growth opportunities would otherwise exist for our intellectual property-dependent industries.

The TRIPs Agreement will help to reduce significantly these levels of intellectual property piracy and counterfeiting because the Agreement established for all WTO Members minimum standards of protection for copyrights, trademarks, geographical indications, industrial designs, patents, integrated circuit layout designs, and trade secrets.\(^10\) Equally important is that the Agreement imposes standards for civil and criminal enforcement of intellectual property and for border enforcement with respect to copyright pirated goods and goods bearing counterfeit trademarks.\(^11\) And over the past several years, the U.S. Government has pressed countries wherever possible to accelerate implementation of their obligations through bilateral


\(^8\) See Mark J. Murphy, International Bribery: An Example of an Unfair Trade Practice?, 21 BROOK. J. INT'L L. 385, 416 (1995) (estimating the annual losses in the pharmaceutical industry to be between $25 and $100 million due to patent piracy).


negotiations and persuasion.12

The TRIPs Agreement also is the first truly multilateral agreement that provides for enforcement of obligations between governments, through the provisions of the WTO’s Understanding on Dispute Settlement.13 The United States has been very aggressive in using WTO dispute settlement to ensure that our trading partners implement their obligations fully. Beginning with the first case we initiated against Japan, we have initiated an additional thirteen additional cases, primarily concerning obligations related to copyrights, patents, and enforcement.14

The United States has two main objectives with regard to the TRIPs Agreement’s existing obligations. First is to ensure that all WTO Members fully implement their obligations under the Agreement.15 The second is to encourage accession of new WTO Members while ensuring that they have fully implemented the obligations of the TRIPs Agreement by the date of their accession.16 This is one component of a larger four-part U.S. WTO agenda, and our approach with regard to TRIPs and the new round of negotiations initiated by the Doha Ministerial Declaration reflects these objectives.

So where does TRIPs fit with regard to the new Round? As you have heard earlier, there is only one negotiating mandate in the Doha Ministerial Declaration that relates to the TRIPs Agreement.17 But it is nothing new—that mandate was already

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15 See generally Joel P. Trachtman, The Boundaries of the WTO: Institutional Linkage: Transcending “Trade and . . . ”, 96 AM. J. INT’L L. 77, 78 (2002) (discussing one of the U.S. goals regarding the TRIPs Agreement is to encourage other countries to enhance their intellectual property laws).


17 See generally Divya Murthy, Note: The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health, 17 AM. U.
part of the TRIPs Council's built in agenda and the Council began negotiations in 1999 to establish a multilateral system for notification and registration for geographical indications for wines and spirits.\textsuperscript{18}

The negotiations to date have been difficult because those WTO Members that currently have long-established formal, legislative regimes for recognition of domestic appellations of origin and enforcement of product standards, have proposed a formal registration system, resembling that of the Lisbon Agreement for the Protection of Appellations of Origin and Their International Registration, to be established in the WTO.\textsuperscript{19} Those Members, the United States included, that protect geographical indications through a variety of other legal regimes, including trademark law, unfair competition laws, and, in some cases, labeling laws, have proposed instead the creation of a database that would facilitate such protection by participating Members under their various legal regimes.\textsuperscript{20} The database would provide information, not easily accessible currently, in a convenient and reliable form so that participating Members can use the information in making determinations that related to geographical indications.

There is no reason to believe that requiring, as the Ministers did in the Doha Declaration, that negotiations be completed by the Fifth Ministerial Conference, scheduled for 2003 in Mexico, will make the negotiations any less difficult. A special session of negotiations has been scheduled in connection with the TRIPs Council meeting that is going on this week. It is likely that this first meeting will be primarily procedural, so stay tuned.

Other issues that were covered in the Doha Ministerial Declarations and Decisions will be addressed in the TRIPs Council on a priority basis and a report on each issue must be submitted to the WTO's Trade Negotiation Committee in

\textsuperscript{18} See Robert M. Tobiassen, On Common Ground, 13 TRANSNAT'L LAW. 75, 79 (2000) (noting the purpose of such a system is to administer and enforce protective measures).


\textsuperscript{20} See John Fraser, WTO Divided Over Branding Dispute, BUSINESS DAY (South Africa), Mar. 18, 2002, at 4 (noting multinational support for the creation of a database).
December of this year. In fact, all of these issues were already being addressed in the Council as part of the Council's so-called built-in agenda, that is, those items which the TRIPs Agreement requires be reviewed by the Council. For example, under Article 71:1, the TRIPs Council is to review the Agreement with regard to the experience gained in its implementation and in light of any relevant new developments that might warrant modification or amendment of the Agreement.21

The United States and other developed countries view the latter as an opportunity to incorporate the obligations of the WIPO Copyright Treaty,22 which recently came into force, and the WIPO Performers and Phonograms Treaty,23 which will come into force shortly. Some developing countries regard the review as an opportunity to amend the Agreement in ways that, in our opinion, would weaken the protection provided, particularly with respect to patents.

Among the issues that the Ministers expressly directed the Council to address is the possible extension of the additional protection currently provided geographical indications for wines and spirits to geographical indications for foodstuffs and other products. Essentially, a geographical indication for wines and spirits cannot be used on any wines or spirits that do not actually come from the place indicated, even if consumers would not be mislead by such use.24 Such indications cannot be used even with expressions such as "like", "type", "style" or "imitation".

A number of WTO Members, lead by Switzerland, have been advocating such extension over the last year or two. Argentina, Australia, Canada, Chile, Japan, Mexico, New Zealand, and the United States have strongly opposed such an extension, partly

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24 See Patrick Wadula, From Grappa to Hake?, BUSINESS DAY (South Africa), Feb. 29, 2000, at 15 (noting the TRIPs geographic provision limits geographic indications for wines even if there is no misleading identification).
because no evidence has been provided showing that the protection currently available with respect to geographical indications for products other than wines and spirits is inadequate. The other reason for objection is that the cost of extension would be considerable and no benefits were traded in the Uruguay Round that resulted in creation of the WTO in exchange for assuming the obligations extension would entail.

Perhaps we should pause to make that point clearer. The WTO is absolutely unique among multilateral organizations in that agreements are reached on the basis of a real exchange of benefits. It all began with an exchange of tariff reductions, with each then GATT Member agreeing to lower its tariffs on products of interest to other Members in exchange for reductions on products of interest to it. After eight rounds of negotiations, tariffs of most developed countries are very low and exchanges of benefits in other areas, such as with respect to intellectual property have been the basis on which additional benefits are negotiated.

The United States was willing to agree to additional protection for geographical indications for wines and spirits primarily because the approval authority of the Bureau of Alcohol, Tobacco, and Firearms enabled us to implement those obligations without changing our law. That would not be true were the additional protection extended to other products. Switzerland, and many of the other demandeurs, however have formal systems for recognizing and enforcing geographical indications for products such as cheese and other dairy products, meats, even watches. The issue will be included on the regular TRIPs Council agenda for each of the four meetings this year and a report of the results of the discussions will have to be submitted to the Trade Negotiating Committee in December. As we said before, stay tuned.

Another issue that the Ministers have directed the TRIPs Council to consider is the relationship between the TRIPS


Agreement and the Convention on Biological Diversity (CBD).27 The CBD is intended to encourage its Contracting Parties to conserve biological diversity, promote the sustainable use of its components and provide for the fair and equitable sharing of the benefits arising from the use of genetic resources.28 In the view of the United States, which, by the way, is not a Party to the CBD, the TRIPs Agreement and the CBD are mutually supportive, to the degree there is any relationship at all. We have already introduced in the TRIPS Council a detailed description of the use of contracts to ensure that those being given access to genetic resources of a country and will follow up at future meetings with examples of contracts used by, for example, the National Institutes of Health when they collect genetic materials from other countries, and by Yellowstone National Park, when people collect genetic material from the Park. These contracts contain specific provisions for benefit sharing in relation to any commercialization of product, including patented products, resulting from use of the genetic materials.29 We also are taking steps to ensure that the TRIPS Council takes note of, and does not duplicate, work being done in, for example, the World Intellectual Property Organization and other multilateral fora.

One of the demands being made by a number of countries with regard to the CBD is that patent laws be amended world wide to require, as a condition of patentability, that applicants identify in their patent applications the source of any genetic materials, indicating whether those materials were obtained with the informed consent of their owners.30 The United States opposes such amendments. We have suggested that a contract system, which we have described in considerable detail in a paper submitted to the TRIPS Council, would permit a country, or an entity in a country to control access to its genetic resources.31 First, it would allow the country or entity to specify where

27 See Vandana Shiva, India: Imposition of a New WTO Round, THE HINDU, Oct. 9, 2001 (noting conflicts between the WTO and the CBD have caused significant concern).
30 See id. at 374 (noting such a requirement is a direct importation of CBD art. 15).
31 See id. at 393 (noting European support for such a plan).
collections could be made and prohibit collection of particular material of significance to the country or entity. Contracts also would enable the country or entity to require the party being given access to genetic resources, *inter alia*, to provide an inventory of materials collected, to provide regular reports of research being done regarding those materials, to notify any inventions made or products developed from those materials and to notify any patent applications filed claiming those inventions. A contract could also expressly require that the contract be identified in any patent application filed claiming the inventions and that the benefits resulting from such patented invention be shared in a particular manner. Finally, a contract could oblige the party that collected genetic materials to impose the same obligations on any party that might be involved in research or to which access to the materials was given.

Such a system would benefit both parties by ensuring that all rights and obligations were spelled out before any genetic materials were collected. In addition, contracts are generally easily enforced if they are clearly drafted and judgments in contract cases are generally enforceable across national borders. We hope that the examples of contracts from NIH and Yellowstone will provide useful examples on which other countries that currently lack any system for regulating access to their genetic resources can build.

Similarly, we believe that the use of contracts would be the most effective way to ensure protection of another item Ministers directed be addressed by the TRIPs Council — "traditional knowledge" and "folklore." These terms are like the term "intellectual property," they refer to a disparate group of concepts. The difference is that "intellectual property" experts can identify for you the various forms of intellectual property, describe the subject matter each covers, the manner in which each is acquired, the rights attached to each and the limitations on those rights, and the period the rights last because law and multilateral agreements, in fact, already exist establishing all of those things. Those advocating protection of "traditional knowledge" and folklore can point to very few laws and no

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multilateral agreements defining those terms. Indeed, they often cannot even agree amongst themselves on an explicit definition of what they mean by those terms.

While some countries have suggested the creation of a *sui generis* system for such protection, we do not believe that is either necessary or prudent. First of all, some protection is already available to some subject matter that would fall within those terms. To the degree that knowledge of the medicinal benefits of a particular leaf, for example, is not generally known, the indigenous community in control of that knowledge could begin to take steps to ensure that trade secret law would apply to their knowledge if they wanted to ensure that it was not made public. They would benefit, in this regard, from the fact that the TRIPs Agreement has established uniform standards for trade secrets and their enforcement. As with genetic resources, a contract with anyone seeking disclosure of the knowledge could both ensure the secret status of the information and provide for benefit sharing of any commercial use of inventions or products developed using the knowledge. A contract could also require that the benefits in any copyrighted works related to traditional knowledge or folklore be shared and that the source of the knowledge or folklore be acknowledged.

Some Members have expressed concern in the TRIPs Council about what they refer to as “biopiracy,” by which they seem to mean getting a patent on the genetic resources or traditional knowledge obtained without the authorization of the owner of the particular resources or knowledge. We would again like to emphasize that in the case of both genetic resources and traditional knowledge, the resources themselves or the knowledge itself would not be patentable. Patents are available only for inventions that are new, useful, and non-obvious, so material that exists in nature or knowledge that is disclosed in writing would not be patentable. Patents are not issued to

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34 See Dutfield, *supra* note 32, at 259 (2001) (noting under TRIPs trade secrecy used to protect traditional knowledge rights).

35 Uruguay Round vol. 31 (1994) 33 I.L.M. 81 (1994). Known as the TRIPs Agreement, provides in Article 27 that the “patents shall be available for any inventions . . . provided that they are new, involve an inventive step and are capable of industrial application.”
naturally occurring biogenetic resources.\textsuperscript{36} Patents also are not granted on material in the public domain.\textsuperscript{37} If a patent were granted on public domain material or genetic material, as it exists in nature, it could be invalidated on a showing of those facts.

Discussions in the TRIPs Council have also dealt with the morality of granting patents on life forms. Because of the fact that a patent does not give its' owner a right to do anything with its invention—merely the right to prevent others from taking certain actions with respect to the invention—it is our view that the appropriate approach for controlling research and development regarding living beings would be to address the issue directly, not including exceptions to patentability in their patent laws. We would point out by way of analogy that no country would think of addressing the issue of arms control by discussing whether weapons should be patentable.

Whether the U.S. view of the appropriate way to implement the provisions of the CBD having to do with genetic resources and traditional knowledge will prevail remains to be seen. Work is going forward in the WIPO collecting contract terms that could be used as examples by countries trying to devise a contract system for protection of their traditional knowledge. Stay tuned.

The TRIPs Agreement contained a five-year moratorium on non-violation claims.\textsuperscript{38} A non-violation claim is based on an action of another Member that, while not inconsistent with the provisions of the agreement, nonetheless nullified or impaired a benefit that the complaining party could reasonably have expected to flow as a result of the Agreement.\textsuperscript{39} The moratorium resulted from Members' concern that the TRIPs Agreement was somehow different from other WTO Agreements and that the "scope and modalities" of such complaints had to be considered.

\begin{itemize}
  \item \textsuperscript{36} See generally Diamond v. Chakrabarty, 447 U.S. 303, 309-10 (1980) (suggesting that patentable items could be "anything that is made by a man," but stating that "the laws of nature, physical phenomena, and abstract ideas [are] not patentable").
  \item \textsuperscript{37} Richard S. Gruner, \textit{Intangible Inventions: Patentable Subject Matter for an Information Age}, 35 LOY. L.A. L. REV. 355, 371-72 (2002) (stating a "patent that would withdraw access to information already in the public domain" would not be authorized by Congress).
  \item \textsuperscript{38} TRIPs Agreement, \textit{supra} note 35, at art. 64 (providing for a five-year moratorium).
  \item \textsuperscript{39} Peter M. Gerhart, \textit{Slow Transformations: The WTO as a Distributive Organization}, 17 AM. U. INT'L L. REV. 1045, 1076 (2002) (explaining that "under TRIPs, the moratorium on bringing non-violation violations was to last five years during which time the Council for TRIPs was to make recommendations concerning non-violation violations").
\end{itemize}
carefully before such complaints should be allowed. By the time of the Doha Ministerial, the TRIPs Council had not reached any conclusions regarding how non-violation complaints would work, so the Ministers directed the Council to continue its work and to make recommendations to the Fifth Ministerial Conference in 2003.

In the view of the United States, concern regarding non-violation cases is unnecessary. The ability to raise non-violation disputes has been part of the multilateral trading system since its inception. Precluding use of dispute settlement in connection with the TRIPs Agreement would only encourage creative legislation by Members that seek to avoid their obligations. In the more than 50 year history of the GATT/WTO, there have been fewer than a dozen non-violation complaints raised and only two of those have been successful. This is not surprising since to prevail, a complaining party must be able to demonstrate that it could reasonably have expected a benefit to result from the rights and obligations of an agreement, that because of a particular action of another Member that reasonable expectation was not forthcoming, and that the action taken by the other Member was not reasonably foreseeable at the time negotiations on the Agreement took place. To give an example, some U.S. parties have suggested that price controls would be subject to a non-violation complaint. It should be clear that such a complaint would be unsuccessful because the use of price controls was reasonably foreseeable when the TRIPs Agreement was negotiated.

In addition, Article 8 of the TRIPs Agreement expressly states that Members may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided the measures are consistent with the provisions of the Agreement. It would be a poor

40 See generally James P. Durling & Simon N. Lester, Original Meanings and the Film Dispute: The Drafting History, Textual Evolution, and Application of the Non-Violation Nullification or Impairment Remedy, 32 GEO. WASH. J. INT'L L. & ECON. 211, 245 (1999) (discussing the general nature of the complaints).

41 See Adrian T. L. Chua, Reasonable Expectation and Non-Violation Complaints in GATT/WTO Jurisprudence, J. WORLD TRADE, Apr. 1998 (applying "the reasonable expectations" principle in the World Trade Organization and General Agreement on Tariffs and Trade).

42 TRIPs Agreement, supra note 35, at art. 8. TRIPs Agreement, art. 8 provides:
lawyer indeed or a particularly malevolent government that could not devise a TRIPs consistent way to accomplish its objectives related to any of those policy areas. In any non-violation case, therefore, the party accused could, in addition to the precedents provided by prior GATT/WTO cases, raise Article 8 as authorizing the action it had taken. During the period the Council is considering the matter, Members are prevented from raising non-violation complaints. This actually is not a problem since it will be years before all the violation cases can be addressed. As with other issues, stay tuned.

A final directive from the Ministers concerns a provision that requires developed countries to provide incentives to enterprises and institutions within their territories to encourage them to transfer technology to least developed countries in order to enable those countries to create a sound and viable technological base. The Ministers have directed the Council to establish a mechanism to monitor implementation of the obligations. The United States has no objection to this provision but questions its usefulness.

In 2000, the United States and other developed country Members submitted information on the incentives they provided. The notification of laws and description of programs submitted by the United States was so voluminous that the WTO Secretariat asked us to provide a brief summary of each item so that interested Members could request the whole package, although to date, no other Member has requested the information. In addition, the United States did, at the last

Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this agreement.


44 Markus Nolff, Compulsory Patent Licensing in View of the WTO Ministerial Conference Declaration on the TRIPs Agreement and Public Health, 84 J. PAT. & TRADEMARK OFF. SOC'Y 133, 147 (2002) (quoting the Declaration on the TRIPS Agreement and Public Health section 7 providing that "[w]e reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members").

45 See generally, Ruth Okediji, TRIPs Dispute Settlement and the Sources of (International) Copyright Law, 49 J. COPYRIGHT SOC'Y U.S.A. 585, 615 (2001) (explaining
TRIPs Council meeting in 2001, describe in some detail the programs of the African Development Foundation, an independent government agency that funds specific projects in sub-Saharan Africa. Only the representative of Zambia asked for the address of the local office of the Foundation in its region and no other Member asked for copies of the written material.

The United States will continue to provide information on the functioning of various of the incentive programs, many of which apply to developing countries as well, so that we will have complied with the Ministers' direction to provide such information by the end of the year. Of value to the U.S. government is the opportunity to compile a more comprehensive account of our capacity building activities, something that has not previously been highlighted in for a such as the WTO. A few Members have requested that an indicative list of the best kinds of incentives be provided. This does not seem to us to be a useful exercise since the forms of incentives provided by developed countries are similar but the particulars vary depending on the countries' legal systems, their culture, their size, and their proximity to least developed countries. Stay tuned.

While hardly "cliff-hangers," the status of each of these issues indicates that there will be further action ahead. Given the nature of the WTO, what happens will depend to some extent on the negotiations going on in agriculture, services, government procurement, etc. The Ministers have called for completion of all these negotiations by the Sixth Ministerial Conference in 2006. As government employees, we are not really supposed to make wagers on government time, but were we to do so, we would put our money on the work not being complete by that time. It is far more likely that, as was the case with the 1970's Tokyo Round and the 1980's Uruguay Round, this round will take more like six to eight years to complete.

Further, because of the possibility for the TRIPs Council to make additional recommendations for modification or

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46 See generally, 2346th Council Meeting - Brussels, 14/15 May 2001, RAPID, May 14, 2001 (announcing the discussions that took place at the meeting).
47 See generally, First Intl Summit for Access to Generic HIV Drugs May 3 - 7 2001, AFRICA NEWS, Apr. 9, 2001 (providing that "every country must comply with the TRIPs Agreement by 2006").
amendment of the Agreement as part of the review of new developments under Article 71.1, it is quite possible, indeed inevitable, that before the round is over, more amendments could and undoubtedly will be proposed. Whether those will reflect the current wish list of the United States, or the wish lists of other Members, remains to be seen. As with much involving the WTO and TRIPs, it is probably a safe thing to say at this juncture, we will have to simply stay tuned.