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TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing

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TRIPS AFTER FIFTEEN YEARS: SUCCESS OR FAILURE, AS MEASURED BY COMPULSORY LICENSING

Donald Harris*

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I. INTRODUCTION

Has it been successful? Or, has it been a failure, ready to be put out to pasture? These are the questions that surround the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS was a landmark event. It has been hailed as “the most far reaching and comprehensive legal regime ever concluded at the multinational level in the area of intellectual property rights . . .” and “unquestionably the most important development in international intellectual property law [in the last century].” Yet, only fifteen years since its adoption, some are questioning its vitality. In some quarters, TRIPS was outdated the moment it was signed. While addressing—for the first time under one international IP scheme—seven different areas of intellectual property, it did not include provisions related to digital technology. This was left for other international intellectual property treaties. Moreover, even regarding the areas TRIPS covers, the purported major gains achieved by its adoption have been questioned. For some, TRIPS’ time has come and gone. For others, the picture is not clear, and it may require more time to accurately assess its impact on international intellectual property policymaking.

Nevertheless, after fifteen years, it is appropriate to evaluate whether TRIPS has been successful and to evaluate its impact on the development of global intellectual property standards. This Article attempts to do so. The Article proceeds as follows. Part II will ask whether TRIPS is relevant. This is an important question. If TRIPS has lost its relevance in international intellectual property after only fifteen years, its demise is likely assured. After having moved to the top of the hierarchical structure in international intellectual property lawmaking, its rapid descent and the strategic behavior of states seeking to change IP norms in alternative fora to undermine TRIPS suggest that TRIPS will not be able to recapture its lost glory (if indeed it had any). Part III

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evaluates whether TRIPS has been successful. This is not an easy task. Most importantly, how should one define success? In this Part, a number of different measures to judge success are identified and critiqued. Ultimately, the definition of success turns on how much of an impact the treaty has had in changing the global intellectual property lawmaking regime. Under that standard, the most salient provision to assess and evaluate TRIPS might be TRIPS' compulsory licensing provision. Part IV does this. Using compulsory licensing as a window to TRIPS' success yields mixed results. In some ways, the compulsory licensing story has been remarkable. WTO Members came together to amend TRIPS—no small feat. Yet, the provision rarely has been used. How should one view this? The final part analyzes the results from the compulsory licensing question and makes some concluding remarks for future consideration.

II. IS TRIPS RELEVANT?

Before addressing whether TRIPS has been successful, a necessary threshold inquiry is whether TRIPS is still relevant. While TRIPS' relevance is tangentially related to its past success, it is directly related to TRIPS' future success. In particular, whether TRIPS is relevant will impact whether the international community should further concern itself with TRIPS so that TRIPS can accomplish those goals it set out to accomplish.

A number of recent developments demonstrate that states are strategically seeking "to propose norms in alternative fora specifically to undermine, if not upend, TRIPS obligations." That major IP battles are being fought in other fora—intentionally outside of the WTO—raises serious concerns for TRIPS, and for IP development in general. Graeme Dinwoodie and Rochelle Dreyfuss make this point: "In recent years, it has become clear that the TRIPS regime is in trouble. Although lawmaking in the World Trade Organization (WTO) has essentially stalled, there is a continuing need to recalibrate the rules applicable to knowledge production."

For Dinwoodie and Dreyfuss, TRIPS' significance in international intellectual property lawmaking is decreasing, in part because TRIPS has not been amenable to changes necessary to address newly emerging technology or trends. These scholars are not alone in their view. There are a number of

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indicators that support these scholars' view that TRIPS' influence and importance may be waning. These include: (1) the various newly-negotiated intellectual property agreements covering areas excluded from or outside of TRIPS; (2) the numerous free trade agreements (FTAs) concluded by the United States and the European Union with other countries (which FTAs frequently require TRIPS-plus standards); (3) the United States' threats of unilateral trade retaliation, which TRIPS was thought to supersede; and (4) the perceived limited use and impact of the WTO dispute settlement system to resolve TRIPS-related disputes.

A. INDICATIONS OF IRRELEVANCE

1. Emerging Technologies, Special Subject Matter, and Regime Shifting.
   a. WIPO Copyright Treaties. Before the ink was dry on the TRIPS Agreement, it was outdated. TRIPS did not deal with the “digital agenda”—the problems raised by digital technology and particularly the Internet. As such, only two years after TRIPS was adopted, the World Intellectual Property Organization (WIPO), rather than the WTO, adopted the WIPO Copyright Treaty (WCT) to clarify existing norms related to digital technology and, where necessary, to create new norms to respond to the challenges created by this new technology. At precisely the same time (at the same Diplomatic Conference), WIPO adopted the WIPO Performances and Phonograms Treaty (WPPT) as with the WCT, the WPPT addressed issues in the digital environment with particular concern for performances and phonograms. The WPPT provided for rights for the storage and transmission of works in digital form. As seen then, TRIPS—heralded as the most important development in intellectual property in the last century—was certainly not the last word in international intellectual property matters, and was barely two years old before it was superseded in matters relating to the new digital environment.
   b. Traditional Knowledge, Folklore, and Genetic Resources. TRIPS also excluded from its coverage other forms of intellectual property that fell outside of the traditional Western-style forms of intellectual property (e.g., patents, copyrights, trademarks, trade secrets, etc.). Such lesser regarded knowledge products, such as traditional knowledge, folklore, and genetic resources, represented intellectual property important and indigenous to developing countries. As a result, protection for these IP goods has been pursued outside of TRIPS.

The Convention on Biological Diversity (CBD) is one example. Under the umbrella of WIPO, the CBD covers the preservation of the diversity of generic resources found in nature, including those resources found in animals and plants. The CBD provides rules recognizing state ownership and control over genetic resources located within the state’s territorial boundaries. Importantly, the relationship between the CBD and TRIPS has been the subject of considerable controversy since TRIPS was adopted. The TRIPS Council was instructed “to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members . . . .” In the last decade, it has become increasingly clear that TRIPS’ relationship to the CBD is attenuated, at best. Once again, it is WIPO that has made significant progress in efforts to develop an international legal instrument for the protection of traditional knowledge, traditional cultural expression, and genetic resources—all outside of TRIPS.

2. Special 301. Special 301 of the United States trade legislation is another area that arguably demonstrates that TRIPS has been ineffective or has had limited relevance. That section provides a mechanism that allows for a possible retaliatory trade action against countries providing inadequate protection for United States’ intellectual property rights. The provision requires the Office of the United States Trade Representative (USTR) to prepare a report concerning foreign countries’ intellectual property-related practices. The “Special 301” Report is an annual review of the state of global intellectual property rights protection and enforcement.
Countries that have been identified as being the most egregious violators of United States' intellectual property rights are placed on a “Priority Watch List.” Annex I to the 2010 report describes this priority status: “Countries that have the most onerous or egregious acts, policies, or practices and whose acts, policies, or practices have the greatest adverse impact (actual or potential) on the relevant United States’ products must be designated as ‘Priority Foreign Countries.’”12 Countries on the Priority Watch List become the focus of unilateral attention by the United States.13

Special 301 is germane to this discussion because, in the build up to TRIPS, countries which were the subjects of retaliation under Special 301 believed that adopting TRIPS would shield them from further United States unilateral action, and that the United States instead would commit to the WTO multilateral process for redress of alleged IP rights violations.14 Despite this, the United States has continued to use the Special 301 procedure.15 Some have argued that this is due to certain setbacks in the international expansion of intellectual property, such as through TRIPS.16 In any event, United States enforcement efforts have shifted away from WTO dispute settlement and towards a return to unilateral action via Special 301, possibly signaling TRIPS’ declining importance.17

12 Special 301 Report, supra note 10.
13 The 2010 Priority Watch List, for example, includes: Algeria, Argentina, Canada, Chile, China, India, Indonesia, Pakistan, Russia, Thailand, and Venezuela. A secondary list, the “watch list,” includes countries who are developing their intellectual property policies, countries with whom the U.S. is working to protect specific U.S. industries (example: pharmaceutical protection in Finland in 2010), countries who are trying but not complying with previous agreements, and whose impact on U.S. industries is less than the impact of the “priority” list countries (for example, in 2009, the U.S. lists many of the same issues with Lebanon as with China).
14 See, e.g., Joost Pauwelyn, The Dog that Barked but Didn’t Bite: 15 Years of Intellectual Property Disputes at the WTO, 1(2) J. INT’L Disp. SETTLEMENT 389, 389 (2010) (“[TRIPS] embodied a trade-off between the United States and other WTO members (especially developing countries) whereby the United States agreed to stop unilaterally enforcing United States IP rights backed-up by unilateral trade sanctions under what is known as ‘Special 301’, in exchange for multilaterally controlled and enforced IP standards made binding on all WTO members.... [T]his has not meant the end of ’Special 301’. It is still used as a preliminary procedure that may result in triggering a TRIPS case before the WTO as well as to address IP issues not regulated in TRIPS (and therefore not subject to Article 23 of the DSU).”).
15 Id.
16 Id. at 392.
17 Id. at 429 (“[T]he political victory of IP skeptics at Doha led many IP proponents to shift attention, tail-between-legs, away from the WTO and toward unilateral enforcement (in the United States, under ’Special 301’) and, especially, preferential trade agreements where so-called TRIPS-plus commitments were sought and obtained.”).
3. Bilateral Treaties. In tandem with its renewed reliance on Special 301, the United States (and the European Union) has sought to include TRIPS-plus commitments in its recent free trade agreements (FTAs), which it could not have achieved within the WTO. In many ways, this represents a stronger signal that TRIPS has been supplanted with respect to current intellectual property matters. The intellectual property provisions negotiated in bilateral agreements between developed countries, such as the United States and the European Union, and developing countries, including least-developed countries, restrict TRIPS’ flexibilities and, moreover, demand more stringent TRIPS-plus commitments, such as increased data protection and restricted use of compulsory licensing.

The United States and European Union free trade agreements are considered in greater detail below in regard to compulsory licensing. Here, however, the main point is that, by taking advantage of the asymmetry in economic power, both the United States and the European Union have increased the pace of such agreements being concluded in the post-TRIPS period, and, by leveraging such agreements, they have undermined TRIPS, ultimately “ratcheting up” IP protection beyond what TRIPS requires.

4. ACTA. The most recent shift of intellectual property matters away from TRIPS concerns increased enforcement efforts, as addressed by the Anti-Counterfeiting Trade Agreement (ACTA). ACTA provides detailed provisions for enforcing intellectual property rights. It contains four substantive sections related to introducing global standards for (1) civil enforcement (making clear that injunctions are available for infringing conduct); (2) border measures (providing for “effective border enforcement of intellectual property rights”); (3) criminal enforcement (applying criminal procedures and penalties for at least cases of willful trademark counterfeiting or copyright infringement, and providing for seizure, forfeiture, and destruction of counterfeit goods); and (4) enforcement of intellectual property rights in the

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19 Id.
20 Id.
23 Morin, supra note 18.
There are many criticisms leveled against ACTA.\textsuperscript{25} Most pertinent here is the concern that ACTA is an attempt to bypass TRIPS to “create not an agreement between several countries, but a global standard on copyright infringement, without going through any true multilateral process.”\textsuperscript{26} Indeed, Victoria A. Espinel, the U.S. Intellectual Property Enforcement Coordinator (the U.S. Intellectual Property Czar) has claimed that TRIPS is “outdated,” thus requiring the new intellectual property enforcement treaty.\textsuperscript{27}

To be sure, the above evidence could, as Dinwoodie and Dreyfuss claim, demonstrate that “[c]ountries are showing signs of giving up on the WTO.”\textsuperscript{28} The above examples support such a conclusion. Nonetheless, there are contrary indicators signaling that TRIPS remains relevant.\textsuperscript{29} Most notable of these are (1) Members’ continued implementation of TRIPS obligations, (2) the continued use of the WTO dispute settlement system to resolve TRIPS-related disputes, and (3) compliance with recent adverse TRIPS’ decisions.

B. INDICATIONS OF RELEVANCE

1. Countries Still Implementing TRIPS Provisions. There is no doubt that countries are continuing to enact implementing legislation to comply with their TRIPS obligations. Within the last \textit{few months} alone, numerous countries have passed such legislation. The following is a representative list.


\textsuperscript{26} Margot Kaminski, \textit{The Origins and Potential Impact of the Anti-Counterfeiting Trade Agreement (ACTA)}, 34 YALE J. INT’L L. 247 (2009); see also Laurence R. Helfer, \textit{Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking}, 29 YALE J. INT’L L. 1, 55–61 (2004) (stating the criticism that ACTA is an attempt to apply IP maximalism from the top down); McManis, \textsuperscript{25} supra note 25, at 1237 (stating that regime-shifting is not a new phenomenon; rather the move to the WTO from WIPO was considered a regime shift for developed countries that no longer believed that WIPO was in their best interests).
\textsuperscript{28} Dinwoodie & Dreyfuss, \textsuperscript{24} supra note 4, at 1192.
\textsuperscript{29} Id. at 1223.
with Montenegro’s TRIPS obligations. The law was published in the Official Gazette of Montenegro No. 72/2010 on December 8, 2010 and entered into force on December 16, 2010. It should be noted that implementing TRIPS-compliant legislation is crucial for Montenegro’s accession to the WTO.

b. Macedonia Passes New Copyright Law Criminalizing IP Infringement. On September 8, 2010, Macedonia passed a new copyright law. The Law on Copyright and Related Rights harmonized Macedonia’s copyright law with TRIPS and with the European Union acquis as part of its Strategy for Intellectual Property (2009–2012). A significant change is that the new law, in accordance with the EU Enforcement Directive [and consistent with TRIPS Article 61], treats copyright infringement as a criminal offence and not as a misdemeanor. For copyright infringement, the law provides for a prison sentence of 6 months to 5 years for natural persons, and a fine for legal entities.

c. Sweden Proposes New Trademark Act. Sweden has also passed recent legislation consistent with its TRIPS obligations. The legislation, which is to take effect on July 1, 2011, introduces significant new changes to “modernize” the Trademark Law, which had not been substantially revised since the 1960s.

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293-XIII, which entered into force on November 23, 1994. Significantly, the law was drafted by the State Agency for Intellectual Property (AGEPI), in cooperation with European experts, as part of the program Assistance in Implementing the Partnership and Cooperation Agreement (PCA) “and the World Trade Organization (WTO)” to harmonize Moldova’s legislation with international provisions, including TRIPS.

2. Continued Use of the WTO Dispute Settlement System for TRIPS-Related Disputes. In addition to these indications of relevance, the fact that major WTO Members—such as the United States and China—are continuing to use the WTO Dispute Settlement process, and, moreover, continue to comply with adverse rulings by WTO Panels, is further evidence of the continued vitality of TRIPS. In 2007, for example, the United States filed two TRIPS-related complaints against China. In both, China was required to amend its laws. China has done so regarding one complaint and is in the process of doing so regarding the other. This is significant, as it signals that the two largest trading countries in the world respect TRIPS and the dispute settlement process.

Without question, there are signs that TRIPS’ importance may be on the decline. Cries of its death, however, are premature. Accordingly, this Article proceeds on the assumption that TRIPS is relevant and asks the next question—has TRIPS been successful? If so, will it continue to be so? If not, will it eventually be so? The next two sections take up these questions. First, Part III identifies and responds to various metrics of success. Following that, Part IV argues that the compulsory licensing provision—though only one provision in a complex treaty covering multiple intellectual property areas and related issues—can be used as a window to view TRIPS’ success. We then look at the compulsory licensing provision and its impact to evaluate TRIPS’ success.

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37 Id.
38 Id.
III. DEFINING SUCCESS

A. THE VIEW FROM INTERESTED PARTIES' PRE-TRIPS EXPECTATIONS

Measuring success by comparing TRIPS’ impact with interested parties’ pre-TRIPS expectations appears, at first blush, to be the most straightforward manner of measuring success. At the outset of the TRIPS negotiations, member states expected that TRIPS could result in a global IP system that would meet the demands of all member states.\(^2\) For advocates of high levels of intellectual property protection, the expectations were high.\(^3\) TRIPS promised that patentability would extend to nearly all technology fields recognized in developed patent systems.\(^4\) TRIPS would increase the level of international intellectual property protection, and give more bite to the economic obligations under the Paris and Berne Conventions.\(^5\) The procedures under TRIPS entitled private parties to expedient dispute settlement, and provided for criminal penalties—including fines and imprisonment—to deter counterfeiting and commercial piracy.\(^6\) Moreover, the Dispute Settlement Understanding (DSU) provided many levels and stages of processes, better ensuring the successful resolution of disputes.\(^7\) With an Appellate Body serving as a review board for a TRIPS dispute panel, the Agreement at its signing provided an increased chance that nations would comply with adverse WTO rulings and could rise above domestic pressures to violate international law.\(^8\) The framework of the DSU also provided a means for establishing a legal framework through jurisprudence, which in turn was considered to provide clearer standards and expectations for intellectual property protection than existed prior to TRIPS.\(^9\)

\(^2\) Id. at 22.


\(^4\) TRIPS art. 27(1).


\(^6\) Oman, supra note 1, at 27. TRIPS border control provisions also were viewed as a legitimate and promising result of the Agreement. Reichman, supra note 43, at 105–06.

\(^7\) Geller, supra note 45, at 114.

\(^8\) Id. (explaining how this addresses the concern with the dispute settlement process that nations are vulnerable to pressures to violate international law to serve their best interests).

\(^9\) Id. Yet, there is also a concern that TRIPS panels may never be able adequately to address larger issues that accompany global intellectual property disputes in the areas of privacy, freedom of expression, and access to information. Id. at 114–15.
For less-industrialized countries, TRIPS promised a global IP system that promoted technological, social, and cultural progress. The WTO also provided for tradeoffs (linkages) in areas other than intellectual property, namely access to developed-country markets for textiles and agricultural products. There were, certainly, concerns about the consequences of increased intellectual property protection. Would the increased standards result in less discretion or policy space to advance crucial domestic undertakings? Would the built-in TRIPS flexibilities have bite? Would they provide the means to access knowledge, technology, and goods to modernize and industrialize developing-country economies?

In light of these, at times, competing expectations, one could rationally compare the post-TRIPS developments and conclude whether TRIPS has or has not been successful. This will implicate an analysis of WTO/TRIPS complaints, developments in various countries’ domestic intellectual property laws, and international and domestic intellectual property enforcement efforts.

B. THE VIEW FROM TRIPS OBJECTIVES AND PRINCIPLES

Perhaps a better benchmark for success is the view from TRIPS’ objectives and principles, embodied in Articles 7 and 8. Certainly, if these objectives have been achieved, we can claim success. The purpose of the TRIPS Agreement, according to its preamble, was to solve “the need for new rules and disciplines” by providing, among other things, clearer intellectual property standards in trade and means for enforcing those standards.50

TRIPS’ foremost objective is to liberalize the international trading system and the “protection and enforcement of intellectual property rights.”51 Another of TRIPS’ principal objectives is to eliminate “free-riding” distortions resulting from the fact that some countries did not protect intellectual property rights.52 TRIPS’ aim is also to “reduce distortions and impediments to international trade, and to take into account the need to promote effective and adequate protection of intellectual property rights . . . .”53

50 TRIPS at pmbl. Other purposes included providing clearer standards for how GATT principles would apply international intellectual property rights, providing procedures to prevent and resolve international intellectual property disputes, and providing arrangements to allow for countries to transition their intellectual property regimes to enable implementation of the TRIPS agreement.
51 Id. art. 7 & pmbl.
52 Id. at pmbl.
53 Id. The overarching theme of the TRIPS Agreement was to reduce barriers to trade by protecting intellectual property rights. TRIPS’ title, “Agreement on Trade-Related Aspects of Intellectual Property Rights,” and the very first line of its Preamble “to reduce distortions and
Additionally, the objectives seek to promote the transfer and dissemination of technology "to the mutual advantage of producers and users of technological knowledge" and attempt to do so "in a manner conducive to social and economic welfare . . . ."\textsuperscript{54}

TRIPS' "Principles found in Article 8," purport to balance the rights holders' private rights against the public need to prevent abuses, protect public health and nutrition, and promote sectors important to a country's socio-economic and technological development.\textsuperscript{55} While the attainment of these objectives and principles would indicate that TRIPS has been successful, it is no simple matter to determine whether these goals have in fact been met.

C. THE VIEW FROM USE OF THE DISPUTE SETTLEMENT SYSTEM

Yet another way to evaluate whether TRIPS has been successful is to look to WTO complaints filed by WTO members under the WTO Dispute Settlement Procedure. Joost Pauwelyn takes up this challenge.\textsuperscript{56} From this vantage point, Pauwelyn describes TRIPS as "the dog that barked but did not bite."\textsuperscript{57} Pauwelyn reviews "(i) the number and type of TRIPS disputes actually filed and decided, (ii) institutional and substantive decisions and interpretations reached by WTO panels and the Appellate Body in their application of the TRIPS agreement and, finally, (iii) the status of implementation of adverse WTO rulings under TRIPS,"\textsuperscript{58} and compares these factors with pre-TRIPS expectations.

Pauwelyn argues that both the hopes and the fears of the pre-TRIPS environment were "largely exaggerated."\textsuperscript{59} His conclusion that TRIPS was more "bark than bite" rests primarily on the observation that only three WTO/TRIPS disputes decided during the entire duration of TRIPS "centered

impediments to international trade . . . ." reflects its commitment to trade. One of its objectives as set forth in the Preamble to the WTO Agreement is "the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international trade relations." \textit{Id.} \textsuperscript{54}

TRIPS art. 7 states in full:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

\textit{Id.} art. 8(1)-(2).

\textit{Pauwelyn, supra} note 14.

\textit{Id. at 2}.

\textit{Id. at 1}.

\textit{Id. at 2}.

\textit{Id. at 2}.

\textit{Id. at 2}.

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on traditional, substantive IP questions (rather than trade discrimination) which
could not have been decided without TRIPS."60 And, as to all of these, none
reached the Appellate Body.61 Thus, TRIPS did not result in the "major boost
in the depth and width of worldwide protection of IP rights," leaving "little or
no room[] for national policy space or social objectives" for developing
countries.62 While his observations and conclusions are noteworthy, Pauwelyn
acknowledges that they say "something about the role and impact of formal
dispute settlement under TRIPS, [and] less about the broader changes brought
about by the TRIPS agreement."63 As such, it is difficult to rely on this alone to
appraise TRIPS' success.

D. THE VIEW FROM COUNTRIES' COMPLIANCE WITH TRIPS RULINGS

Even if, as Pauwelyn suggests, use of the WTO dispute settlement system
could be used to appraise TRIPS' success, such use would ring hollow if
countries did not abide by WTO rulings. Thus, perhaps the true measure of
success is compliance. Of the twenty-seven WTO cases filed involving TRIPS,
nine were actually decided by a WTO panel and violations were found in
eight.64 Of these, five rulings have been implemented.65 Pauwelyn notes that
this seventy percent implementation rate is only slightly lower than the eighty
percent overall WTO dispute settlement implementation rate.66 Many TRIPS
violations require legislative changes, and such changes often are difficult.
"This makes implementation longer and more difficult," and could indicate that
the relatively high implementation rate renders TRIPS successful.67

While all of these—and other—criteria could potentially measure TRIPS
success,68 none of them are immune from attack. Relying on the interested
parties' expectations, for example, has limitations. As it has played out, TRIPS
has provided something for everyone. What TRIPS offered in increased

60 Id. at 11.
61 See id.
62 Id. at 4.
63 Id. at 2. These changes include "sweeping (and often costly) legislative amendments in many
developing countries, monitoring through the TRIPS Council and bargaining 'in the shadow' of
TRIPS both to weaken and strengthen global IP protection . . . ." Id.
64 See id. at 6.
65 Id. China recently agreed to implement one ruling not previously included as implemented.
Current Status, supra note 41.
66 Pauwelyn, supra note 14, at 41.
67 Id. at 46.
68 Yet another example of how to judge success would be to look to whether countries have
implemented their TRIPS obligations and, in turn, whether they have then enforced those
obligations.
protection was arguably diluted through the many concessions made to developing countries. WTO dispute settlement panels issued nuanced and balanced decisions that, in part, satisfied both sets of expectations. Perhaps the fact that both sides’ expectations were met—even in part—qualifies TRIPS as successful. For many, however, this criterion for determining success may leave a lot to be desired.

Relying on TRIPS complaints merely reflects the fact that parties have used the dispute settlement system. How many complaints must be filed in order for the system to be considered a success is unclear. Is a high number good—suggesting that the WTO provides a robust enforcement system? Is a low number good—suggesting widespread compliance, obviating the need for enforcement complaints? Neither how WTO panels nor the Appellate Body ruled signifies success. In other words, the question whether the decisions strengthened or weakened intellectual property protection is itself contested, and it is not clear whether strengthening or weakening protection (serving rights holders’ interests or demonstrating the flexibilities in the treaty) would qualify as successful.

Relying on TRIPS’ objectives and principles is similarly fraught with ambiguity. While Articles 7 and 8 set forth fairly clearly TRIPS objectives and principles, no WTO panel has yet interpreted these provisions. As such, it is difficult to ascertain whether post-TRIPS developments are consistent with these provisions, or whether the TRIPS objectives have been achieved. No doubt, as Peter Yu concisely states, these two provisions “deserve greater attention from both the DSB and members participating in the WTO dispute settlement process,” as the two provisions might “provide the key basis for a pro-development interpretation of the TRIPS Agreement.” Whether a pro-development interpretation is within everyone’s definition of success also is debatable.

This Article adds to the mix by offering still another metric for evaluating TRIPS’ success. The Article links success to TRIPS’ impact and to the broader changes TRIPS has brought to international intellectual property. More specifically, it is argued here that, if TRIPS’ success is to be measured by looking at its impact, an appropriate metric is the TRIPS provision that has had (or could have) the most significant impact on the international community and

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69 Doris E. Long, Copyright and the Uruguay Round Agreements: A New Era of Protection or an Illusory Promise, 22 AIPLA Q.J. 531, 577 (1994).
the international intellectual property regime: TRIPS' compulsory licensing provision.\textsuperscript{71}

IV. ANOTHER WINDOW TO VIEW SUCCESS: COMPULSORY LICENSING

A. NEGOTIATING ARTICLE 31

Compulsory licensing was an area of intense negotiations leading up to TRIPS.\textsuperscript{72} Developed countries generally sought stronger protection of patented technologies.\textsuperscript{73} Developing countries wanted TRIPS to provide easier access to patented technology, primarily through compulsory licenses.\textsuperscript{74} Brazil and Korea, for example, argued for allowing compulsory licensing, while Austria and Hong Kong requested more restrictive measures.\textsuperscript{75} Even after GATT Director General Dunkel endorsed a draft TRIPS agreement, which served as the basis for the agreement ultimately adopted, concerns remained regarding compulsory licenses.\textsuperscript{76} The United States was concerned with how TRIPS would affect the pharmaceutical industry, whereas India had general reservations about restrictions on compulsory licenses for patents.\textsuperscript{77}

The compromise resulting from the negotiations was Article 31. That section, titled "Other Use Without Authorization of the Right Holder," gives countries broad discretion on, \textit{inter alia}, government use of compulsory

\textsuperscript{71} While the thrust of this Article suggests that the compulsory licensing provision has been expansively interpreted or amended expansively, allowing countries—primarily developing countries—greater flexibility and discretion in using the provision to address public health concerns, concededly "it is notoriously difficult to assess whether a treaty has been expansively or restrictively interpreted." Pauwelyn, \textit{supra} note 14, at 15. Moreover, relying on one provision in a treaty to define success also has its limitations, as will be discussed later.

\textsuperscript{72} A compulsory license is a state-granted license issued to a third party to manufacture and produce a patented invention without the patent owner's consent. Paul Gorecki, \textit{Regulating the Price of Prescription Drugs in Canada: Compulsory Licensing, Product Selection, and Government Reimbursement Programmes}, TECHNICAL REP. SER. (1981) (defining a compulsory license as "an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state").

\textsuperscript{73} DANIEL GERVAS, \textit{THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS} 15 (1st ed. 1998).

\textsuperscript{74} \textit{Id.} at 16.

\textsuperscript{75} \textit{Id.} Specifically, Austria and Hong Kong proposed means for judicial review, a limitation of licensed products to domestic markets, non-exclusivity of licenses, and appropriate compensation to rights owners.

\textsuperscript{76} \textit{See id.} at 26–27 (describing the continuing disagreements among member states in the negotiating rounds regarding compulsory licenses).

\textsuperscript{77} \textit{Id.} at 27.
licensing. However, the grounds are not unlimited; TRIPS contains numerous
conditions that must be met before the government can authorize licenses.
Three of the main conditions are that, as a general rule: (1) an effort should be
made to negotiate a voluntary license on reasonable commercial terms; (2) the
government must provide for “adequate remuneration” to the right holder; and (3) the license use must be “predominantly for the supply of the domestic
market.”

B. THE DOHA DECLARATION

While negotiations surrounding the TRIPS compulsory licensing provision
were contentious, compulsory licensing in action took center stage in 2001, when
South Africa attempted to reduce drug costs and address its overwhelming
AIDS pandemic by enacting the South African Medicines and Related
Substances Control Amendment Act of 1997 (the Act). The Act allowed local
manufacturers to make AIDS drugs (compulsory licensing) or import them
from neighboring countries that produced them less expensively than the patent
owners (parallel importation). The Act sought to ensure the supply of drugs at
affordable prices, thus allowing victims to get the drugs much less expensively
than they would be able to otherwise.

In response to the Act, the patent owners of the HIV/AIDS drugs—
primarily European and United States pharmaceutical companies—objected,
arguing that the Act violated international patent laws, including TRIPS.
According to these parties, the Act violated TRIPS because it allowed the South

78 TRIPS art. 31. Arguably, countries also might justify compulsory licenses based on a public-
interest exception (Article 8(1)), or as a means to prevent abuses by intellectual property rights
holders (Article 8(2)). Compulsory licenses based on these principles still must be consistent with
Article 31.

79 This requirement may be waived in case of “national emergency,” “other circumstances of
extreme urgency,” or “in cases of public non-commercial use.” Id. This exception allows a
government to bypass the step of negotiating compensation with the patent holder in the
interests of expediency. In 2002, Zimbabwe invoked this exception to override patents on
antiretroviral drugs in response to the AIDS crisis gripping the country. Press Release, Doctors

80 TRIPS art. 31.

81 As mentioned throughout, there are many exceptions to the general rules, including non-
commercial use. Other conditions include: (1) the scope and duration of the license must be
limited to the purpose of the authorization; (2) the license is non-exclusive and is generally non-
transferable; (3) the license is terminated when “the circumstances which led to it cease to exist
and are unlikely to recur;” and (4) the government’s decision is subject to independent judicial
review. Id. art. 31(c), (f), (k), (l).
African health minister to act unilaterally without first having to prove a drug manufacturer abused its patent, and allowed local manufacturers to make the drugs without first seeking the patent owner’s permission—both of which TRIPS requires.82

Although the pharmaceutical companies eventually dismissed the suit, the suit did highlight the likelihood that patents and monopoly pricing would keep essential medicines out of the reach of millions of HIV/AIDS victims.83 This “growing crisis” led WTO members to meet in Doha, Qatar to engage in more negotiations to address the issue.84

In an effort to improve access to essential medicines, the WTO Ministerial Conference adopted the Doha Declaration on the TRIPS Agreement and Public Health in November 2001.85

82 The Act also makes no provision for compensating the patent-holder. In all, thirty-nine drug companies sued South Africa. Despite South Africa’s assurances that it only planned to use the Act in the spirit of the World Trade Organization’s (WTO) patent rules, which allow intellectual property rights to be overridden in exceptional circumstances, the companies argued that the Act allowed South Africa to override patents at will. Pharmaceuticals Drop Lawsuit to Stop South Africa From Importing Generic AIDS Drugs, BULLETIN’S FRONTRUNNER, Apr. 20, 2001 [hereinafter BULLETIN’S FRONTRUNNER]. Concurrent with the lawsuit, the United States placed South Africa on its “Section 301 Watch List.” Section 301 retaliatory actions include withdrawing benefits the foreign country enjoys because of a trade agreement with the United States, entering into new agreements to eliminate the offending action, or imposing duties or other import restrictions against goods or an economic sector of the foreign country. These actions may be taken irrespective of any breach of an international agreement, such as TRIPS. McDorman, supra note 76, at 90. The United States then imposed sanctions against South African goods, and, further, went to the WTO to try to enforce U.S. patent rights. Marcus Mabry, Give Us This Day Our Daily Meds, NEWSWEEK, July 5, 1999, available at http://www.newsweek.com/1999/07/04/give-us-this-day-our-daily-meds.html. The pharmaceutical industry also closed factories in South Africa and canceled numerous investments. BULLETIN’S FRONTRUNNER, supra note 82.

83 In April 2001, the pharmaceutical companies acquiesced and dismissed the suit. They agreed that the Act could be enforced as written, and said that they would pay the government’s legal costs. BULLETIN’S FRONTRUNNER, supra note 82. Pharmaceutical companies agreed to reduce the price of the AIDS drugs. For example, Bristol-Meyers Squibb said it would supply the drugs at below cost to Africa. It also pledged “not to let patents to [sic] stand in the way of access.” Nigeria: Development News: Global Companies in Price War Over Aids Drugs for Africa, AFRICA NEWS, Mar. 18, 2001. BMS Executive Vice President John McGoldrick was quoted as saying: “We seek no profits on AIDS drugs in Africa, and we will not let our patents be an obstacle.” Id.


85 Doha Declaration, supra note 8, at 756 (acknowledging the issue faced by developing countries in Paragraph 6: “WTO Members with insufficient or no manufacturing capacities [of pharmaceuticals] could face difficulties in effective[ly] us[ing] compulsory licensing under the
The Doha Declaration confirmed that patents would not prohibit countries' ability to use compulsory licensing to address public health needs. It also granted countries wide discretion and great flexibility in issuing compulsory licenses, including the grounds upon which such licenses could be issued and the amount of remuneration given to the patentee. The Declaration also identified a glaring weakness of TRIPS' compulsory licensing provision—the inability of countries that lacked sufficient manufacturing capacity to take advantage of compulsory licenses to locally manufacture generic medicines. This was remedied a few years later with the August 30, 2003 Decision, which led to an Amendment of Article 31: Article 31bis.86

C. THE AMENDMENT—ARTICLE 31 BIS

On December 6, 2005, the WTO Members adopted the Amendment to Article 31.87 The Amendment enabled countries without the capacity to manufacture generic substitutes for patented pharmaceuticals under domestic compulsory licenses to import those substitutes from other countries that had the capacity to do so, without risk of interference from patent holders.88 Article 31bis was intended to address the "public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics."89

D. USE OF COMPULSORY LICENSING THROUGH ARTICLE 31 OR ARTICLE 31BIS

Now armed with relatively broad powers and wide discretion to use compulsory licenses to gain better access to essential medicines to treat public health diseases, expectations were high for significant use of compulsory

TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."); Abbott & Reichman, supra note 8, at 929.

86 Gervais, supra note 73, at 395 (quoting the Doha Declaration).
87 Abbott & Reichman, supra note 8, at 932.
88 TRIPS art. 31bis; Abbott & Reichman, supra note 8, at 932. In particular, Article 31(f) of the TRIPS Agreement provided that compulsory licensing was only available in the domestic market. TRIPS art. 31(f). Article 31bis allows for a waiver of Article 31(f)’s limitation to the domestic market. Id. art. 31bis.
licenses. The reality was far different. Relatively few countries have issued compulsory licenses under Article 31, and only one country has issued a license under Article 31bis.

1. Thailand’s Use of Compulsory Licensing. In 2006 and 2007, Thailand issued compulsory licenses to produce antiretroviral drugs (ARVs), which included Merck’s efavirenz and Abbott’s lopinavir/ritonavir combination, Kaletra. Again, in August 2010, Thailand extended compulsory licensing for the Merck and Abbott ARVs until the expiration of their patents.

Thailand’s action precipitated immediate retaliation. Abbott halted the introduction of new drugs into Thailand. According to Abbott, “Thailand has chosen to break patents on numerous medicines, ignoring the patent system. As such, [Abbott] elected not to introduce new medicines there.” Abbott was not alone in its retaliation. The United States responded by placing Thailand on the Special 301 watch list of countries that fail to “provide an adequate level of intellectual property rights protection or enforcement.”

Both Abbott’s conduct and the United States’ action have influenced other developing countries to refrain from taking advantage of the compulsory licenses for fear of retaliation by Big Pharma companies.

2. Brazil’s Use of Compulsory Licensing. In 2007, Brazil also issued compulsory licenses to produce Merck’s efavirenz. Until then, Brazil had only threatened the use of compulsory licenses for ARVs in an effort to drive down prices. Merck had offered to lower the price, but the generic versions were significantly cheaper. Thus, Brazil issued compulsory licenses. However, Brazil has also...

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90 See AVERT, AIDS, Drug Prices, and Generic Drugs, AVERT.org, http://www.avert.org/generic.htm (describing the expectations of compulsory licensing in offering more access to patented medicines to fight HIV/AIDS in developing countries).
91 Id.
92 Id.
93 Id.
95 Id.
96 Ed Silverman, US Trade Rep: Thailand on Watch List, PHARMALOT, Apr. 30, 2007, http://www.pharmalot.com/2007/04/us_trade_rep_thailand_on-watch. The U.S. cited the “lack of transparency and due process” as the primary concern. Id. What sort of transparency is necessary or should be required beyond the requirements of Article 31? And, what kind of “due process” is expected in a compulsory licensing system? Note that neither Abbott nor the U.S. Trade Office accused Thailand of not following the requirements of Article 31. Also, note the efforts to retaliate against Thailand from domestic lobbying groups within the U.S.
97 AVERT, supra note 90.
98 Abbott & Reichman, supra note 8, at 951.
99 Id. at 952.
been very successful in using compulsory licenses as leverage in price reduction negotiations with other Pharma companies. The agreement Brazil reached with Gilead, which cut the price of drugs in half, is such an example.100

More recently, Brazil threatened to use cross-retaliation methods against the United States. In March of 2010, Brazil published a list of goods and services subject to import tariffs and other measures.101 This list includes intellectual property rights for pharmaceutical products;102 at least one analyst surmised that the cross-retaliation would allow Brazil to issue compulsory licenses without compensation.103 To date, Brazil and the U.S. have reached an agreement on cotton,104 but the importance of pharmaceutical patents and compulsory licenses cannot be underestimated. Not only has Brazil used pharmaceuticals to negotiate down drug prices, it has also used pharmaceuticals as leverage for more favorable trade practices across the board.105

3. Other Examples of Compulsory Licensing Use. Since the Doha Declaration, compulsory licenses have been issued in at least ten countries. In addition to Brazil and Thailand, South Africa, Zimbabwe, Malaysia, Indonesia, Mozambique, Zambia, Eritrea, Ghana, Kenya, and Ecuador have also issued licenses, taking advantage of Article 31.106 More particularly, South Africa issued compulsory licenses in 2001 for ARVs owned by Boehringer Ingelheim


104 Joint Communication from Brazil and the United States, United States—Subsidies on Upland Cotton, WT/DS267/45 (Aug. 25, 2010).

105 See Current Status, United States—Subsidies on Upland Cotton, WT/267 (Sept. 21, 2010).

and GlaxoSmithKline. Shortly thereafter, in 2002, Zimbabwe issued a government use compulsory license; generics company Varichem Pharmaceuticals produced ARVs for the country’s domestic use. In 2004, Malaysia and Indonesia also issued government use compulsory licenses. That same year, Mozambique issued a compulsory license for the production of ARVs by Pharco Mozambique Lda. A few months later, Zambia followed suit by issuing a compulsory license for the ARVs lamivudine, stavudine, and nevirapine. Finally, in 2005, Eritrea and Ghana issued government use compulsory licenses.

4. Canada-Rwanda’s Use of Compulsory Licensing under Article 31bis Waiver. Scholars and public interest organizations had hoped that Thailand and Brazil’s issuance of compulsory licenses under Article 31 would make the political climate more favorable for the use of Article 31bis. Thus far, this has not been the case; Canada has been the only country to use an Article 31bis compulsory license to provide generic AIDS medicine to Rwanda. This first use of Article 31bis was enabled by Doctors Without Borders, which signaled

107 ALEC VAN GELDER & PHILLIP STEVENS, INT’L POLICY NETWORK, THE COMPULSORY LICENSE RED HERRING 5 (2010), http://www.minimalgovernment.net/media/compulsory-2010 11.pdf (arguing that changes to the compulsory license system through the WTO would be futile). The authors argue that access to drugs has improved under the system and that resources would be better spent in improving access to health-care generally in poor countries. Id.
109 VAN GELDER & STEVENS, supra note 107, at 5.
110 Id. at 6.
111 Id.
112 Id. Kenya was an early advocate for changes to Article 31 that ultimately resulted in Article 31bis. Ben Shinya, Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya, WORLD TRADE ORG., http://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm (last modified Feb. 10, 2009). In 2004, Kenya considered issuing a compulsory license; this ultimately resulted in a voluntary license being negotiated with the brand name manufacturer. In 2010, Ecuador issued a compulsory license to produce Abbott’s Ritonavir. The license was issued to a local distributor for Cipla, the Indian generics manufacturer. Catherine Saes, Ecuador Grants First Compulsory License, for HIV/AIDS Drug, INTELL. PROP. WATCH, Apr. 22, 2010, http://www.ip-watch.org/weblog/2010/04/22/ecuador-grants-first-compulsory-licence-for-hivaid-s-drug/. Ecuador might issue another compulsory license in the near future as another Indian company has requested a license for Ritonavir. Id. Since the Doha Declaration, about fifty-two countries have issued compulsory license including the countries just mentioned. INDIA DEP’T OF INDUS. POLICY AND PROMOTION, supra note 106, at 3.
113 See, e.g., Abbott & Reichman, supra note 8, at 957.
that it wanted to test the Amendment. In July 2007, Rwanda submitted to the WTO its intent to seek a foreign-produced TriAvir. Canada issued a compulsory license to Apotex two months after Rwanda’s announcement. By October, Canada informed the TRIPS Council of its issuance of the compulsory license. As detailed below, Canada and Rwanda’s use of this Article 31bis compulsory license did not come without significant problems.

5. India-Nepal’s Proposed Use of Compulsory Licensing under Article 31bis Waiver. Incidentally, in 2008, Nepal also applied for a license under Article 31bis. The Indian pharmaceutical company Natco applied for an exporter license to export the manufactured medicines to Nepal. One of the patent holders, Roche, lobbied for the right to attend the hearing to approve the compulsory license. When the Indian court permitted Roche to attend the hearing, Natco postponed the hearing. Roche then sued Natco for patent infringement. Two years later, the compulsory license application is still pending.

6. Difficulties of Using Article 31bis and Compulsory Licensing.
   a. A Complicated Process. Since Canada and Rwanda became the first countries to use the TRIPS Article 31 waiver, as exporting country and importing country respectively, no other countries have used the waiver. The paltry use of a mechanism initially hailed as a potential means of saving many lives in the developing world is disconcerting. But, a number of factors explain this lack of use. First, the test case of Rwanda and Canada demonstrated the difficulties in using Article 31bis. The process was viewed as too cumbersome for both eligible exporting and importing countries. From the

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116 Id.
117 Id.
118 Id.
122 Hestermeyer, supra note 115.
perspective of Apotex, the manufacturer, the process was too complicated, with few incentives.\footnote{123}{Id. (citing Press Release, Apotex, \textit{Life Saving AIDS Drug for Africa Gets Final Clearance} (Sept. 21, 2007)).} Apotex complained that it would not use the system again:

Although Apotex announced the shipping to Rwanda, on September 24 [2008], of seven million doses of its agent, the CAMR's operation, criticized as cumbersome by some commentators, seems unlikely to be copied. Elie Betito, the generic firm's director of public affairs, said: “it took us more than four years just to get to this point. It's a huge process, with huge costs involved.\footnote{124}{Apotex, http://www.apotex.com/global/about/press/20090514.asp.}

Apotex confirmed that, unless the legislation is amended, it will not agree to take part in another such deal.\footnote{125}{TRIPs Mechanism Set to Fail as Apotex Ships ARV, PHARMA LETTER, Sept. 29, 2008, http://www.thepharmaletter.com/file/80641/trips-mechanism-set-to-fail-as-apotex-ships-arv.html.} Part of the lengthy delay was the two years of negotiations between Apotex and the patent holders.\footnote{126}{Id.; see also Press Release, Apotex, \textit{Life Saving AIDS Drug for Africa Gets Final Clearance} (Sept. 20, 2007), available at http://www.apotex.com/global/about/press/20070920.asp.} Apotex was also concerned, as were other generic manufactures, that the compulsory license issued could be limited to too short of a term, making it challenging to recover costs for investing in the manufacture of the medicines.\footnote{127}{TRIPs Mechanism Set to Fail, supra note 125.}

The TRIPS Council was similarly concerned about the lack of use of the system.\footnote{128}{Members Ask: Is the "Par.6" System on Intellectual Property and Health Working?, WORLD TRADE ORG. (Mar. 2, 2010), http://www.wto.org/english/news_e/newse10_e/trip_02mar10_e.htm.} In a March 2010 Council meeting, developing countries asserted that the limited use of the mechanism may be a sign that the Doha Declaration has been ineffective.\footnote{129}{Id.} Developed countries disagreed.\footnote{130}{Id.} The developed countries reasoned that other means are available to provide affordable medicines to the impoverished in developing countries.\footnote{131}{Id.} These means include the use of charitable funds to purchase needed medicines and the reduction of prices by patent holders because of the threat of the compulsory licensing.\footnote{132}{Id.}

The NGO sector has also been critical of the lack of use of the Amendment. Doctors Without Borders said during the TRIPS Council's October 2010
meeting that the system has become so complicated that it will remain virtually
unused until the WTO reforms the system to make it less cumbersome and
more streamlined.133

The United Nations is also concerned. Its concern is that developing and
lesser developed countries are entering into free trade agreements with more
developed countries, and are negotiating away their flexibility under the waiver
to issue compulsory licenses, particularly to produce life-saving medications for
their citizens.134

b. Fear of Retaliation. Another explanation for the lack of use is, as
mentioned earlier, that some countries fear retaliation both from other
countries and from pharmaceutical companies. In 2007, when Thailand issued
its compulsory license under Article 31, both the United States and European
Union responded by censoring the country;135 the United States also placed
Thailand on its “Priority Watch List.”136 Pharmaceutical maker Abbott
announced it would not apply for licenses for seven of its new products in the
Thai market, including a heat-resistant form of the ARV.137 Brazil’s use of
compulsory licensing was criticized by pharmaceutical companies, which
claimed that compulsory licensing would negatively affect research for new
medicines.138 The predictable negative reaction by pharmaceutical companies
poses obvious worries for countries. Large pharmaceutical companies bring
jobs and investments to developing countries; developing countries are thus leery

136 U.S. Trade Representative Places Thailand on Priority Watch List in Annual Report, MEDICAL NEWS TODAY (May 3, 2007), http://medicalnewstoday.com/articles/69507.php (“The Office of the U.S. Trade Representative in its annual report released on Monday placed Thailand on its Priority Watch List in part because the country recently issued compulsory licenses for several medicines, including two antiretroviral drugs. . .
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137 Id. See Keith Alcorn, Abbott to Withhold New Drugs from Thailand in Retaliation for Kaletra Compulsory License, NAM AIDS MAP (Mar. 15, 2007), http://www.aidsmap.com/page/1426590/ (describing Abbott’s response to Thailand’s compulsory licensing of the ARV). For further detail on the retaliations faced by Thailand as a result of its use of compulsory licensing, see Abbott & Reichman, supra note 8, at 953–56.
138 Abbott & Reichman, supra note 8, at 953.
of making enemies out of these companies by using the compulsory licensing system.\footnote{139}{See Anderson, supra note 119, at 107–08.}

In what might be characterized as yet another form of retaliation, developed countries have started to increase border measures aimed at seizing pharmaceutical products. Xavier Sueba, who recently analyzed this issue,\footnote{140}{Xavier Sueba, Border Measures Concerning Goods Allegedly Infringing Intellectual Property Rights: The Seizures of Generic Medicines in Transit (2009) (unpublished manuscript), available at http://www.iprs online.org/New\%202009/Seuba_Border\%20Measures.pdf.} confirmed the seizure of significant quantities of various drugs while in transit in the European Community.\footnote{141}{Id. at 1.} Almost all of these shipments originated in India; all of the shipments were bound for developing countries such as Brazil and Ecuador.\footnote{142}{Id.} The generics manufacturers were told that their drugs were seized because the drugs infringed both patents and “supplementary protection certificates granted in [European Union] Member states.”\footnote{143}{Id.} The European Union has come under fire by NGOs for its use of customs regulations and detention of drugs.\footnote{144}{Europe! HANDS OFF Our Medicine, DOCTORS WITHOUT BORDERS, http://www.doctorswithout borders.org/publications/article.cfm?id=4790&cat=briefing-documents (discussing the tactics by the EU).} As Doctors Without Borders points out, European governments justify their actions as a way to combat the trade in life-threatening fake drugs.\footnote{145}{See infra note 149.} Motivations aside, it is certain that increased border measures are seen as retaliatory actions against developing countries seeking access to generic drugs. Doctors Without Borders points to such border measures as simply another form of “attack” by the European Union.\footnote{146}{See infra note 149 (noting that FTA and ACTA are other “attack” measures by the EU).}

c. Restrictions In Bilateral Agreements. Furthermore, commitments obtained in bilateral agreements have restricted or limited the use of compulsory licensing. The United States has entered into fourteen free trade agreements (three FTAs with Colombia, Panama, and South Korea are awaiting approval by Congress).\footnote{147}{Office of the United States Trade Representative, Bilateral Trade Agreements, http://ustrad erep.gov/Trade_Agreements/Bilateral/Section_Index.html (last visited Jan. 2, 2011).} The types of provisions contained in these bilateral agreements limiting countries’ ability to obtain generic medication under compulsory licensees include: (1) requirements that the data generated by the patent holder be exclusive to the patent holder; (2) prior notification to the patent owner that its patent is the subject of the compulsory license, or prior consent by the
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Among the agreements that could curtail the development of generic drugs under the TRIPS waiver because of data exclusivity provisions are the Central American Free Trade Agreement (CAFTA), the Singapore FTA, the Australia FTA, the Korea FTA, and the Oman FTA. And, among the agreements that also could curtail the development of generic drugs under the TRIPS waiver because patent owners either must consent to such licensing or be notified of such licensing are CAFTA, the FTA with Jordan, the FTA with Chile, the FTA with Morocco, the FTA with Bahrain, and the FTA with Oman.

The FTA with Jordan has been criticized as violating the spirit of the Doha Agreement—which gives liberty to countries to determine the grounds on which compulsory licenses can be granted—by limiting compulsory licenses only to those necessary to remedy anti-competitive practices, to cases of public noncommercial use, to cases of national urgency or other situations of extreme urgency, and for failure to meet working requirements. There are similar provisions in the FTAs with Singapore and Australia.

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152 United States–Korea Free Trade Agreement Art. 18.9(1)(a), June 30, 2007.
154 DR-CAFTA FTA, supra note 149, ch. 15.
156 United States–Chile Free Trade Agreement Art. 17.10(b), June 6, 2003, 42 I.L.M. 1026.
159 U.S.–Oman FTA, supra note 153, art. 15.9(4).
161 See Gaelle P. Krikorian & Dorota M. Szynamkowiak, Intellectual Property Rights in the Making: The Evolution of Intellectual Property Provisions in US Free Trade Agreements and Access to Medicine, 10 J. WORLD INTELL. PROP. 388, 405 (2007). In contrast, the TPA with Peru seems more in alignment with the TRIPS waiver; the Peru TPA and the Panama TPA say that data is protected “except where necessary to protect the public” and the agreement explicitly says both parties “may take measures to protect public health” in accordance with the Doha Declaration.
V. SUCCESS OR FAILURE?

A. INITIAL REACTIONS

In view of the limited use of compulsory licensing under both Article 31 and Article 31bis, evaluating TRIPS' success based on compulsory licensing might signify that TRIPS has in fact not been successful. Or, as Pauwelyn argues, it might indicate that TRIPS is "more bark than bite." But, it would be a mistake to dismiss the compulsory licensing story or TRIPS as a failure.

As others have noted, even though the TRIPS waiver has been rarely used, it has been used as a negotiating tool for developing countries. This in itself is useful. Brazil is the prime example of using the threat of compulsory licenses to secure price reductions for ARV medications. In 2010, the online organization WikiLeaks released, among others, a cable that revealed that the U.S. Embassy to Brazil served as a channel to relay messages to drug companies such as Gilead Sciences, (Merck & Co. subsidiary) Merck, Sharp and Dohme, and Abbott Laboratories that Brazil would issue compulsory licenses for HIV/AIDS drugs unless the companies lowered their prices.

WTO Director General Pascal Lamy has noted this use of Article 31bis. He has asserted that the very availability of Article 31bis, coupled with "the changing climate among the health community and drug companies," could be used by developing countries and NGOs to exert leverage in procuring drugs at reduced prices. He further reminds us that "[i]he objective was never to issue lots of compulsory licenses as an end in itself. The objective was and remains

Panama Trade Promotion Agreement Art. 15.10, June 28, 2007; United States–Peru Trade Promotion Agreement Art. 16.10(2), Apr. 12, 2006. As well, the North American Free Trade Agreement has a provision that could curtail the effectiveness of the TRIPS waiver: requiring that compulsory licenses should be used primarily for a country's domestic market. North American Free Trade Agreement Art. 1709(10)(f), United States–Canada–Mexico, Dec. 17, 1992, 32 I.L.M. 289 (1993).

162 Pauwelyn, supra note 14.
164 But cf Gabriela Costa Chaves, Marcela Fogaça Vieira & Renata Reis, Access to Medicines and Intellectual Property in Brazil: Reflections and Strategies of Civil Society, 8 SUR–INT’L J. ON HUM. RTS. 163, 170 (2008). It may be the case that the negotiating technique can become less satisfactory because Brazil saw an increase in the price of two HIV drugs despite its negotiating stance. Id.
cheaper medicines for the poor." On this front, the mechanism has been successful, as drug prices in the developing world have fallen and more drugs have been delivered to the poor.

There has been resistance to the FTA restrictions. A number of countries have balked at United States trade negotiators’ desire to include restrictive provisions in their FTAs. The issues of compulsory licensing and data exclusivity of pharmaceutical patents have been at the center of disagreements between Thailand and the United States over an FTA that has stagnated for years. New Zealand proposed last fall—during the fourth negotiating round of the Trans Pacific Partnership between the United States and eight Asia-Pacific nations—that the agreement should not be “TRIPS-plus” but rather “TRIPS-aligned,” including a ban on data exclusivity provisions. And, unlike free trade negotiations with Middle East countries and other parts of the world, Latin American countries’ FTAs with the United States involve intellectual property standards that are less restrictive.

A final noteworthy point: encouragingly, a number of other countries have revised their patent laws to implement Article 31bis. These include China, Belgium, France, India, Norway, and Switzerland. Notably, none of these countries’ implementing legislation contains the noted obstacles contained in Canada’s Article 31bis legislation.

B. UPON FURTHER REFLECTION

However, there is more that can be gleaned from the compulsory licensing controversy. The international response to the controversy was remarkable. It was so not only for what the international community achieved but also for how the result was achieved. In other words, both the process and the substance were significant. As to the process, the WTO members reached a consensus; it was only through their coordinated efforts that they were able eventually to produce the Declaration and then the Amendment. This is

166 Id.
169 Krikorian & Szymkowiak, supra note 161, at 409.
170 Frederick M. Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 AM. J. INT’L L. 317, 327. This is not to suggest that the process was without
TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing

...nothing short of a miracle, given the challenges involved in getting the WTO Members to agree to what that amendment would entail. Compulsory licensing became politically salient only shortly after TRIPS took effect and at a time when it seemed unlikely that the parties would consider renegotiating an agreement that took over eight years to conclude (the Uruguay Round lasted from 1986–1994). Yet, the WTO members responded and reached a consensus on a contentious issue.

Moreover, the fact that they were able to use the system in the manner they did demonstrates that the system is flexible enough to permit a political process to generate a result that was better than the status quo. The significance of amending a WTO Agreement cannot be overstated. To date, only one WTO Agreement has ever been amended—TRIPS Article 31. In view of the hard fought gains made during the Uruguay Round, and the contentious nature of much of the negotiations, such an achievement demonstrates that TRIPS is responsive to change and that WTO members can indeed “recalibrate the rules.” To some extent, this responds to and refutes the criticism that TRIPS’ legislative process is too cumbersome or inflexible, leading to forum shifting.

Controversy. Three issues dominated the negotiations: the scope of applicable diseases, which countries would be eligible for the “solution,” and which provisions of TRIPS would be addressed. Id. at 327–28. Developing countries wanted the scope of diseases to remain broad, while developed nations wanted the scope to be limited to identified diseases. Paragraph 1 of the Doha Declaration identified “HIV/AIDS, tuberculosis, malaria, and other epidemics,” while other paragraphs referred to protecting “public health.” In the end, the Amendment did not restrict the diseases for which a compulsory license could issue. Id. at 327 (citing the Doha Declaration, supra note 8) (quotations omitted). Regarding eligibility, the Amendment provided special treatment to the least-developed countries, and applied more complicated treatment depending on a country’s level of development. See id. at 335–38 (describing the various situations for different stages of development). Finally, the Amendment required that Article 31, not Article 30, be amended. Id. at 340. The Amendment applied to Article 31(f), allowing for a waiver of the domestic requirement for compulsory licensing, and Article 31(h), limiting the obligation of remuneration to the patent holder to when the remuneration is paid in the exporting country. TRIPS art. 31bis.

See Abbott, supra note 170, at 326–45 (describing the negotiations following the Doha Declaration, supra note 8). Some experts believe that the Doha Declaration and the subsequent Amendment to Article 31 may demonstrate that health care and public health concerns outweigh standards of intellectual property protection. See, e.g., Ellen ’t Hoen, TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha, 3 CHI. J. INT’L L. 27, 45 (“The very fact that public health and access to medicines have been singled out...in TRIPS implementation indicates that health care and health care products need to be treated differently from other products.”).

General Council, Amendment of the TRIPS Agreement, WORLD TRADE ORG. (2005), http://www.wto.org/English/tratop_e/trips_e/wt641_e.htm.

Cf. Dinwoodie & Dreyfuss, supra note 4, at 188.
The substance of the response is self-evident. The Declaration and the Amendment made clear that compulsory licensing could be used to enhance the supply of essential medicines to countries with limited manufacturing capacity, and that TRIPS could address a global health crisis, while also protecting intellectual property. Governments can use this mechanism and TRIPS’ flexibilities to lower worldwide prices for medicines, especially first-line ARVs. This is of no small moment. As D.G. Lamy declared: “[T]he Doha Declaration has... helped to shape the framework for multilateral cooperation on IP and public health through the course of this decade.”

There are other considerations that counsel against characterizing TRIPS a failure as viewed from the perspective of compulsory licensing. The compulsory licensing issue is not over. According to the World Health Organization (WHO), the Article 31bis mechanism will take on greater importance once a new generation of HIV/AIDS drugs and other essential medicines hit the market. These second line treatments will likely be protected by patents, unlike many of the current first line treatments, and compulsory licensing will be necessary to ensure the availability of second-line drugs in developing countries.

Also, Article 31bis will take on increasing importance because India—currently supplying the developing world with generic medicines—is obligated to adhere to TRIPS and, as such, is now granting patents on medicines. Thus, India will no longer be able to supply medicines worldwide unless it is able to grant compulsory licenses. It will not be able to export more than half its production without invoking Article 31bis. In light of these conditions, India is currently formulating a policy on the issuance of compulsory licensing. India’s Department of Industrial Policy & Promotion (DIPP) sought comment in 2010 on compulsory licenses in the pharmaceutical sector. According to the DIPP, the TRIPS flexibilities have been incorporated into India’s 2005

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174 Lamy, supra note 165.
reform of its Patents Act, and the department is exploring such questions as: (1) whether the government should formulate guidelines for the issuance of compulsory licenses; (2) whether compulsory licenses should be confined to public health emergencies or if licenses could be issued for drugs used in the treatment of cancer or diabetes; (3) what the basis of royalty payments under compulsory licenses should be; and (4) whether compulsory licenses can be used to remedy anti-competitive practices.

India has another concern that implicates compulsory licensing. In the past few years, foreign companies have been purchasing Indian pharmaceutical companies. In the past four years alone, foreign firms have acquired six Indian drug firms. This has India alarmed, due to the possibility of restricted or limited access to medicines in the future. The concern is that the newly foreign-owned companies will be reluctant to issue compulsory licenses and that these companies will use current Indian marketing channels to sell more expensive patented drugs, rather than the generic drugs currently being sold through such channels.

India has considered a number of responses, including immediately issuing compulsory licenses. Additionally, the Indian health minister has stated that publicly-funded Indian research organizations must stipulate—while

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180 India Dep’t of Industrial Policy & Promotion, supra note 178.
181 The six companies are: Matrix Lab, Dabur Pharma, Ranbaxy Labs, Shanta Biotech, Orchid Chemicals, and Piramal Healthcare. The total cost of the takeover is estimated at $1.58 billion. Ranbaxy was purchased by Japan-based Daiichi Sankyo Co in June 2008; Piramal Healthcare was bought by U.S. based Abbott Laboratories; and Dabur Pharma was acquired by German Fresenius Kabl. See Madhur Singh, India May Issue Compulsory Licenses to Control Drug Prices, 27 BNA INT’L TRADE REP. 1349 (2010).
182 Id.
183 The health ministry instructed the commerce minister that it should consider seeking stricter foreign direct investment (FDI) policy for the sector. Health minister Ghulam Nabi Azad said in a letter to Commerce minister Anand Sharma.

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The issue of takeover of Indian pharma companies by MNCs, is of serious concern and needs to be tackled effectively in terms of FDI Policy for the sector. Therefore, FDI needs to be revisited immediately and such investments shifted from automatic to FIPB route to ensure healthy growth of pharmaceutical industry and availability and access of our people to quality and affordable medicines, which is so critical from the requirement of public health, Aditi Tandon, Health Min Wants to Revisit FDI Norms in Pharma, TRIB. INDIA, Nov. 1, 2010, http://www.tribuneindia.com/2010/20101102/biz.htm#3. The government is also considering restricting FDI in pharmaceutical companies; currently, 100% FDI is allowed in the sector. Another proposal will allow for patents to revert to domestic publicly funded research companies when these companies sell or transfer such patents to Indian private companies, which then pass into foreign hands. Singh, supra note 181.
selling or transferring patents to private sector companies—that ownership of patents would revert to the research organizations if the companies are taken over by foreign firms. Some of the recent takeovers have involved Indian companies whose patents have either been supported by the Government or have obtained patents from Indian research organizations.184

As a final point, it is worth noting that TRIPS has been in existence for only fifteen years, a relatively short time as far as international treaties are concerned. The Berne Convention for the Protection of Literary and Artistic Works and the Paris Convention for the Protection of Industrial Property, the other two major international intellectual property treaties, have existed for over a century (since the 1880s). They have been subject to numerous revisions, occurring approximately every twenty years. While there are no immediate signs that TRIPS will be further revised, it is reasonable to assume—in light of previous experience with international intellectual property treaties—that it is too early to give up on TRIPS. Give it more time.

VI. CONCLUSION

Whether TRIPS thus far has been a success or failure is not clear. In its fifteen years, its message has been mixed. While there have been many positive developments, negotiations for further advancement have stalled. In looking at the issue that arguably has garnered the most attention and has generated the most controversy—compulsory licensing—we also come away with mixed feelings. Significant progress has been made. Much more can be made. Nonetheless, the WTO has made remarkable strides in advancing compulsory licensing so that it is poised truly to address the needs for which it was created. The opportunity is there. Whether we will seize it and continue a positive TRIPS legacy remains to be seen. Let us revisit TRIPS and compulsory licensing in another fifteen years.

184 On compulsory licensing (CL) under the Indian Patents Act, 2005, the Health Ministry has clarified that the Controller of Patents, whenever he considers an application for CL, particularly for public health emergencies under Section 92A of the Act, should dispose of the application on a fast-track basis. Tandon, supra note 183.