In 2002, combined profits for the ten largest United States drug manufacturers’ combined profits totaled $35.9 billion, more than five-and-one-half times the mean profit grossed by all other industries represented in the Fortune 500.1 Drug companies’ profits continue to escalate exponentially, in part due to an increase in the purchase price of pharmaceuticals.2 Critics of the industry contend that higher purchase prices bar indigent individuals’ access to affordable pharmaceuticals, including live-saving medicines. In response, drug companies emphasize that expensive research and development costs are driving the high prices.3 Pharmaceutical companies profess the need to gross more profit in order to offset these costs; accordingly, the pharmaceutical industry supports strong intellectual property rights to protect against the unauthorized production of generic medicines (“generics”) that might detract from their profits.

In most nations, prior to the World Trade Organization’s (WTO) ratification of Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994, domestic pharmaceutical companies manufactured generics without restraint and sold them at reduced retail prices.4 Although TRIPS imposed some restraints on these manufacturers, many WTO members recognized the importance of public health considerations. Accordingly, to circumvent these restraints, TRIPS includes provisions which allow WTO members to manufacture generics in certain situations.

In contrast, U.S. multilateral trade agreements, such as the Central American Free Trade Agreement – Dominican Republic (CAFTA-DR), prohibit smaller pharmaceutical companies from manufacturing generics, even in situations that are permissible under TRIPS. CAFTA-DR reinforces the status quo by shielding large pharmaceutical companies from lost profits and preventing poor consumers from accessing affordable medications by (1) extending the length of patent terms; (2) failing to explicitly permit compulsory licenses; and (3) requiring a five-year data exclusivity period.

A. The TRIPS Agreement

Developed nations generally advocate for strong international intellectual property rights because businesses, such as pharmaceutical companies, that design innovative products are located within their borders. TRIPS evolved in response to intense lobbying from the U.S., European Union, and Japan for the WTO to expand intellectual property rights to an international scope.7 TRIPS permits a WTO nation to access international trade markets from a more advantageous standpoint, provided that the nation accessing the markets conforms to the stringent intellectual property laws outlined in TRIPS’ provisions.

At the time of TRIPS enactment, many WTO members believed that it was inappropriate for a state to issue pharmaceutical patents, or had never before issued such patents within their borders.8 Thus, members purposefully incorporated exceptions into TRIPS that allow a state to circumvent intellectual property patent requirements with respect to pharmaceuticals.9 For instance, compulsory licenses allow a state to compel a pharmaceutical manufacturer to relinquish its patent rights to a particular drug. In this situation, the WTO member nation grants a compulsory license to an alternate pharmaceutical company to manufacture an equivalent medicine.10 Normally, a patent would have prevented the alternate pharmaceutical company from manufacturing the drug.11 Under this exception, a state can grant a compulsory license to a pharmaceutical company at any time as long as the state requests permission and compensates the patent-holding pharmaceutical company. A state need not request permission from the patent holder, however, before issuing a compulsory license during a national emergency or circumstance, an extreme urgency, or for public non-commercial consumption.12

For many years, developing nations were unsure of how these flexible provisions would be interpreted. They consequently feared using them without first receiving further clarification as to how the compulsory license provisions would function. The request for further clarification led member nations to convene at a conference in Doha, Qatar, to enact the Declaration on the TRIPS Agreement and Public Health (Doha Declaration).13

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B. The Doha Declaration and Paragraph 6

During the Doha convention in 2001, each government entity reiterated that TRIPS contains flexible provisions to circumvent pharmaceutical patents in order to ensure that governments can protect public health.14 The Doha Declaration not only affirmed that states should implement and interpret TRIPS to support public health by promoting access to medicines, it also emphasized that states are entitled to issue compulsory licenses and permit parallel imports.15 Essentially, the Doha Declaration forced WTO members to acknowledge that a balance must exist between strict intellectual property rights and public health. WTO Director-General Mike Moore stated that TRIPS “...strikes a carefully-negotiated balance between providing intellectual property protection...and allowing nations the flexibility to ensure that treatments reach the world’s poorest and most vulnerable people. Countries must feel secure that they can use this flexibility.”16

Even more significantly, the Doha Declaration ordered WTO members to further negotiate and formulate a solution whereby nations lacking domestic manufacturing capabilities would still have the opportunity to import generics.17 Two years later, in 2003, WTO members enacted Paragraph 6 of the Doha Declaration, explicitly permitting WTO nations to issue compulsory licenses to export generic drugs to other nations which had not previously issued a patent for a certain pharmaceutical.18 Prior to the adoption of Paragraph 6, a WTO member could only issue compulsory licenses for drugs which would be primarily consumed within the country’s own borders.19

II. CAFTA-DR

In spite of lobbying efforts, the United States failed to obtain the level of intellectual property protection that it had originally sought during the TRIPS negotiations. Specifically, the U.S. feared the overuse of compulsory licensing and had desired lengthier patents and data exclusivity to prevent “unfair commercial use.” Instead, the U.S. adopted bilateral and multilateral trade agreements to incorporate these measures.20 These aggressive agreements impose strict intellectual property rights standards on all countries that are a party to them and, in turn, help soothe investors’ worries about losing profit to generic drug manufacturers.21 CAFTA-DR stretches patent protection to an extreme level which effectively bars domestic manufacturers from producing generics during the patent term. Consequently, many citizens in Central America are denied access to essential medicines due to the lack of affordable generics.

CAFTA-DR is a multilateral trade agreement enacted between the United States and Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras, and Nicaragua that restricts these Latin American countries’ ability to manufacture generic drugs.22 In addition to this central treaty, each state has signed multiple side letters with the United States. A side letter provides an additional understanding between the parties that goes beyond the main text of a multilateral trade agreement. Understanding Regarding Certain Public Health Measures is a side letter which has been adopted by all parties to CAFTA-DR.23 This agreement, however, does not expand the state’s ability to issue patents to a domestic pharmaceutical company to manufacture generics.

A. CAFTA-DR Extends the Length of a Patent

CAFTA-DR impedes the ability of domestic drug companies to manufacture generic medicines by extending patent lengths. First, CAFTA-DR Article 15.9 § 6(a) obligates states to adjust the length of a patent to compensate for unreasonable delays.24 An “unreasonable delay” occurs when it takes a state longer than five years to issue a patent.25 In these situations, if requested by the pharmaceutical company, the patent-issuing state must adjust the length of the patent term to compensate for the delay.26 In TRIPS, however, the patent term is limited to twenty years.27 Although WTO members raised the prospect of extending patent terms to compensate for regulatory delays, the WTO failed to enact this provision in TRIPS; thus, TRIPS does not obligate states in the same manner as CAFTA-DR in this regard.28

Moreover, CAFTA-DR Article 15.9 § 6(b) further extends patent lengths by demanding that nations automatically toll the original patent term if an “unreasonable curtailment” occurs during the marketing process.29 Although CAFTA-DR Article 15.9 § 6(a) provides examples of an “unreasonable delay,” the meaning of the term “unreasonable curtailment” is left ambiguous. Thus, it is unclear how a WTO member should interpret an “unreasonable curtailment.” In layman’s terms, the definition of “curtailment” is “to make less by or in some way cut off some part.”30 Read narrowly in CAFTA-DR, the term “unreasonable” would modify curtailment; hence, only a drastic impediment or situation arising during the marketing process would force a state to reinstate the full patent term. Yet, read broadly, an “unreasonable curtailment” could apply to any delay during the marketing process.
Due to the lack of clarity, a manufacturer could conceivably argue that any and all delays during the marketing process are unreasonable up until the time the drug enters the market. In effect, unlike TRIPS, where the twenty-year patent term begins on the date of application, under CAFTA-DR, the twenty-year patent length can begin many years later. By way of this provision, CAFTA-DR provides U.S. pharmaceutical companies far greater protections in foreign countries than they would receive under a patent filed in the United States.

In sum, CAFTA-DR automatically extends the length of a patent term and thus prevents domestic manufacturers from developing generics without a compulsory license. In turn, the pharmaceutical company will hold a lengthier monopoly over the patent, making it more difficult for indigent persons to obtain reasonably priced drugs.

B. CAFTA-DR Does Not Protect Compulsory Licensing

CAFTA-DR fails to include the most integral public health provision in TRIPS – the provision pertaining to compulsory licensing. TRIPS Article 31 states that, if permitted by local laws, a nation can authorize a third party to disregard a pharmaceutical company’s patent and produce generics if the state had previously requested permission from the patent holder and the request had been unfulfilled after a reasonable period of time. Therefore, a state does not need to obtain actual authorization; rather, the state only needs to make efforts to obtain an authorization. Further, in cases of “a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use,” TRIPS allows states even greater flexibility by eliminating the requirement to request permission from the patent holder altogether. By explicitly permitting a state to waive a patent when necessary TRIPS gives a WTO member more extensive rights than the Central American countries are provided under CAFTA-DR.

The United States and the Central American nations have endorsed a side letter on public health, titled Understanding Regarding Certain Public Health Measures. This side letter attempts to reaffirm that CAFTA-DR does not encroach upon a state’s ability to take necessary measures to protect public health. Although this letter appears to offer assurances that Central American nations can grant compulsory licenses, it is unlikely that these assurances supersede CAFTA-DR Article 11 in Chapter Fifteen that states must adhere to patent obligations “except as [CAFTA-DR] provides otherwise.” Moreover, the explicit text of CAFTA-DR neither recognizes nor incorporates this side letter.

Further, these letters are only “commitments” and will not take the effect of law until the House and Senate pass legislation to implement the modifications. If the United States violates this side letter, its reputation with regard to both trade agreements and side letters will sour tremendously, a risk the U.S. may not wish to take. Nevertheless, a belief that the U.S. will not violate a side letter for fear of ruining its reputation is not as compelling of a deterrent as a legal prohibition.

Even if this side letter ripens into an enforceable agreement, it still would not afford sufficient protection to Central American states to permit domestic manufacturers to produce generics without authorization. For example, the CAFTA-DR side letter is not as flexible as TRIPS because it requires that measures to protect health be “necessary,” and only permits “access to medicines” with regards to epidemics, or circumstances of extreme emergencies such as HIV/AIDS, tuberculosis, malaria, and other epidemics.

A “necessary” measure is a high standard that is narrowly defined to balance the dual goals of maintaining the freedom of members to set and achieve their own regulatory objectives and discouraging the adoption of measures which unduly restrict trade. Necessity tests typically require that measures which restrict trade not exceed what is “necessary” to achieve a member’s policy objective. Under this framework, the implementing nation must prove that a regulation is necessary and effective, and that no less restrictive trade measures are available to achieve the same purpose. In addition, the regulation should not be a “disguised use.”
restriction on international trade” or amount to “arbitrary or unjustifiable
discrimination.”40 Thus, if the public health measure is discriminatory to
trade, the measure may be found to be in violation of trade rules, even if the
state did not intend to discriminate. By incorporating the word “necessary”
into the side letter of CAFTA-DR, the U.S. has dictated a burdensome
standard that Central American nations must meet before they can possibly
begin the production of generics.

Conversely, TRIPS does not require a member state to prove a legitimate
reason for issuing a compulsory license with regard to national emergencies
or extreme urgencies. Instead, under TRIPS, nations are afforded complete
autonomy to define their own national emergencies and extreme urgencies.
Unlike CAFTA-DR, TRIPS does not require member states to prove that
the regulation is necessary or that there are less restrictive alternatives.

The CAFTA-DR side letter overly restricts public health by only permitting
“access to medicines” during times of epidemics, national emergencies,
or extreme circumstances. By listing specific diseases and epidemics, the
side letter suggests that other public health concerns not explicitly
mentioned may not be covered as a public health exception. As support
that CAFTA-DR allows nations similar, if not identical, flexible provisions
as provided in TRIPS, the United States contends that it supported both
the 2001 Doha Declaration by stating that it would produce drugs needed
to fight epidemics,41 and also supported the 2003 consensus by allowing
nations to import generic drugs to combat infectious epidemics.42 This
language remains inadequate because it restricts the rights of nations to
manufacture generic drugs during epidemics. In contrast, TRIPS supports
broader member rights than merely “producing drugs to fight epidemics”
or “importing drugs needed for infectious epidemics” because it permits
nations to produce generic drugs to protect the health of all persons beyond
times of epidemic outbreaks.

C. CAFTA-DR Protects Data Exclusivity

Most nations require that safety and efficacy tests are performed before a
pharmaceutical company is allowed to launch a new drug into the market.
When generic manufacturers want to introduce a generic equivalent of
the original drug, they typically draw on the safety and efficacy tests completed
by the original patent holder and are only required to prove that the generic
drug is therapeutically equivalent to the original.43 Data exclusivity
refers to a time period in which the original manufacturer possesses a
monopoly over the safety and efficacy tests – a period during which a
generic manufacture can not utilize these test results.44 In theory, small
generic manufacturers can introduce generics if they complete their own
independent safety and efficacy tests; in practice, data exclusivity creates
a monopoly for the original patent holder because it is unlikely that small
generic manufacturers will have the financial means to conduct these tests.

CAFTA-DR imposes a mandatory five-year data exclusivity period on a
drug once the original pharmaceutical company submits undisclosed data
to the state. Article 15.10(a) states: “If a Party requires, as a condition
of approving the marketing of a new pharmaceutical . . . product, the
submission of undisclosed data concerning safety or efficacy, the Party shall
not permit third persons, without the consent of the person who provided the
information, to market a product on the basis of (1) the information, or (2) the
approval granted to the person who submitted the information for at least five
years for pharmaceutical products . . . .”45 In essence, when a state
necessitates safety and efficacy testing, the state cannot permit a third
party to manufacture a generic equivalent of the drug unless the third
party performs its own safety and efficacy tests or receives approval
from the original manufacturer.

Unlike CAFTA-DR, TRIPS provides WTO members with extensive flexibility with regard to test data, only asserting
that WTO members should protect “undisclosed test or other data” against
unfair commercial use and disclosure.46 During the TRIPS negotiations,
developed nations zealously lobbied for the inclusion of a data exclusivity
provision; however, this provision is noticeably absent. In fact, TRIPS
provides that to protect the public, member nations can allow a generic
manufacturer to utilize the patent holder’s safety and efficacy results when
necessary.

Finally, CAFTA-DR mandates protection of test data that has been
submitted in a nation that is not a party to CAFTA-DR. Article 15.10(1)(b)
forbids generic manufacturers from using safety and efficacy test results
from a patent application filed in a separate state.47 For example, the
United States applies for a patent for Drug A in the Dominican Republic
and submits results from the safety and efficacy tests. Thanks to CAFTA-
DR, the U.S. now holds a virtual monopoly over the drug for a period of
five years. Immediately before the five-year data exclusivity period ends,
the U.S. applies for a patent for Drug A in Ecuador, beginning a new five-
year data exclusivity period. Under the restrictions of CAFTA-DR, generic
manufacturers in Ecuador were already unable to use safety and efficacy
results submitted by the U.S. in the Dominican Republic. Once the U.S.
submits safety and efficacy results for the Ecuadorian patent, a new five-
year data exclusivity period begins in that country. In effect, Ecuador will
be unable to access test results to produce generics of Drug A for a total
of ten years – five years during the data exclusivity hold in the Dominican
Republic and five years once the data was subsequently submitted in
Ecuador.

Data exclusivity is a mechanism designed to delay the introduction of
generic competition. By mandating five years in which third parties can
not produce generics, CAFTA-DR, unlike TRIPS, even further prevents
access to affordable generics by failing to include many of the flexibilities
inherent in TRIPS.

III. Conclusion

WTO members purposefully incorporated flexibilities into TRIPS to
protect public health, especially access to medicines by individuals,
if needed. The U.S., on the other hand, was disappointed with the
incorporation of these accommodating provisions and, in response,
promoted the adoption of more stringent intellectual property protections through bilateral and multilateral trade agreements. CAFTA-DR may economically benefit the Latin American countries that are parties to the treaty, but at the same time, it impinges on the ability of small pharmaceutical companies to manufacture generics. Consequently, intellectual property protections of this nature ultimately harm the impoverished individuals in foreign countries by limiting their access to affordable medicines.

2 See id. at 4.
6 See Bass, supra note 3, at 191.
8 See Bass, supra note 3, at 201.
9 See id. at 198.
10 See id.
11 See id.
12 See TRIPS, supra note 5, art. 31.
17 See Declaration on TRIPS, supra note 15, para. 6. (“We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council . . . to find an expeditious solution . . .”)
18 See Abbott, supra note 13, at 318-19.
19 See id. at 319.
25 See id.
26 See id.
27 See TRIPS, supra note 5, art. 33.
29 See CAFTA-DR, supra note 22, art. 15.9(b). (“With respect to any pharmaceutical product that is covered by a patent, each Party shall make available a restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product in that Party.”)
31 See TRIPS, supra note 5, art. 31.
32 See id.
33 See Office of the United States Trade Representative, supra note 23.
34 See CAFTA-DR, supra note 22, art. 15.1 11.
36 See Office of the United States Trade Representative, supra note 23.
38 See id.
39 See id.
40 See id.
that global trade rules allow nations to decide what constitutes a health emergency and to issue compulsory licenses to produce drugs needed to fight epidemics.”

42 See id. (“In August of 2003, the U.S. led to work towards an WTO consensus that allows poor nations without domestic drug production capacity to issue compulsory licenses to import drugs needed to combat diseases such as HIV/AIDS, malaria, tuberculosis and other infectious epidemics.”)

43 See id.


45 See CAFTA-DR, supra note 22, art. 15.10(a)

46 See TRIPS, supra note 5, art. 9.3.

47 See CAFTA-DR, supra note 22, art. 15.10(1)(b).