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Private Enforcement of TRIPS by Applying the EU Law Principles of Direct Effect and State Liability

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PRIVATE ENFORCEMENT OF TRIPS BY APPLYING THE EU LAW PRINCIPLES OF DIRECT EFFECT AND STATE LIABILITY

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INTRODUCTION

The Word Trade Organization ("WTO") Marrakesh agreements[1] are treaties negotiated between Member States to help trade flow as freely as possible by lowering interstate trade barriers.[2] Consequently, the organization regulates in areas that are inevitably a product of globalization that generates new problems and disputes requiring international cooperation.[3] The WTO accommodates for the resolution of such disputes by the creation of the Dispute Settlement

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[1] Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S 3 [hereinafter Marrakesh Agreement].

[2] *Understanding the WTO: Who We Are*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/who_we_are_e.htm (last visited Mar. 3, 2014).

[3] AMRITA NARLIKAR, THE WORLD TRADE ORGANIZATION A VERY SHOT INTRODUCTION 59 (2005).

Understanding ("DSU")[4]. The utilization of the DSU, however, is limited to disputes between Member States and does not provide a venue for private litigants to address their concerns.[5] Indeed, private litigants will not be able to utilize the DSU mechanism anytime soon.[6] Though the WTO obligations are, at least theoretically, supposed to help producers of goods and services conduct their business, the obligations only bind Member States and do not confer rights on private individuals.[7]

Yet, as the WTO evolves, so does the legalism of the organization.[8] This comment proposes a mechanism of private enforcement of the WTO obligations against Member States. The mechanism is derived from the laws of the European Union ("EU"). The theory, however, is only applied to the Trade Related Agreement on Intellectual Property Rights ("TRIPS")[9] agreement section of the Marrakesh Agreement.[10] TRIPS is part of the Marrakesh Agreement package and it requires Member States to provide a minimum standard of protection for intellectual property rights.[11] It also requires WTO Members to incorporate the agreement's obligations into their national laws.[12] For this reason, the requirement of national implementation of international obligation may render the TRIPS agreement more fixable to private enforcement.[13] With such an arrangement, the private litigant, for instance, could challenge the constitutionality of national law

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[4] Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.C 401 [hereinafter DSU].

[5] *Dispute Settlement*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm (last visited Jan. 14, 2014) ("The authors of these agreements are the member governments themselves — the agreements are the outcome of negotiations among members. Ultimate responsibility for settling disputes also lies with member governments, through the Dispute Settlement Body.").

[6] *The WTO in Brief*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr00_e.htm (last visited Jan. 13, 2014) (stating that WTO negotiation "bind governments to keep their trade policies within agreed limits to everybody's benefit.").

[7] *Id.* (stating that WTO negotiations' purpose is to help producers but they are negotiated by governments and only bind governments).

[8] NARLIKAR, *supra* note 3, at 86.

[9] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.C 299 [hereinafter TRIPS].

[10] *See* Marrakesh Agreement, *supra* note 1.

[11] TRIPS, *supra* note 9, art. 3, 4.

[12] *Id.* art. 1.

[13] *See infra* Part III.B.

implementing the TRIPS as opposed to the terms of the international agreement itself.[14]

This nature also facilitates the analysis in light of EU law. The requirement to implement TRIPS obligation under the national legal order makes the agreement very similar to EU directives,[15] which are binding in their result yet give Member States of the EU the freedom in their implementation.[16]

The EU principles that are relevant to the proposal in this comment are the Principle of Direct Effect[17] and the Principle of State Liability.[18] Under EU law, and in the event that an EU Member State fails to honor its obligation under the EU treaties, the two principles enable private litigants to enforce their rights which EU law has conferred on them.[19]

The theoretical exercise in this article applies EU Principles of Direct Effect and State Liability to the recent *Novartis AG v. Union of India*[20] ("*Novartis v. UOI*") case. In *Novartis v. UOI*, the claimant alleged that India, a WTO member, failed to honor its TRIPS obligations. In 2005, India amended its intellectual property ("IP") laws to bring them in conformity with its obligations under TRIPS. However, *Novartis* alleged that the current amendments are contrary to India's obligations under the TRIPS agreement. Although the outcome would probably not be any different, *Novartis* provides a useful factual pattern to apply the proposed mechanism.

It is worthwhile to keep in mind that the EU legal order may sound different, yet theoretically, it is the same as the WTO agreements: an international agreement, signed by members of different sovereign, in the wake of the Second World War, for the purpose of trade liberalization, and ultimately benefiting the nations and citizens of the members to agreement.[21] What was then farfetched, like relin-

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[14] *See e.g.* Novartis AG v. Union of India, (2007) 4 MADRAS L.J. 1153 [hereinafter Novartis v. UOI (Mardas H.C.)], *available at* http://www.scribd.com/doc/456550/High-Court-order-Novartis-Union-of-India, *aff'd*, Novartis AG v. Union of India, Civil Appeal Nos. 2706-2716 of 2013 (India Apr. 1, 2013) [hereinafter Novarits v. UOI (Ind.)], *available at* http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212.

[15] *See infra* Part III.C.2.b.iii.

[16] The European Parliament, SOURCES AND SCOPE OF EUROPEAN UNION LAW 3 (2014), *available at* http://www.europarl.europa.eu/ftu/pdf/en/FTU_1.2.1.pdf.

[17] *See infra* Part III.

[18] *See infra* Part III.

[19] *See Infra* Part II.C.

[20] Norvartis v. UOI (Ind.), *supra* note 14, at X.

[21] *Compare* PASCAL FONTAINE, EUROPE IN 12 LESSONS at 6 (2010), *available at* http://bookshop.europa.eu/en/europe-in-12-lessons-pbNA3110652 ("To ensure that

quishing state autonomy and control on issues of trade to a higher body, is now the current reality.

This comment is divided into three sections. Part I introduces the WTO generally and analyzes the TRIPS agreement specifically. Part II discusses the proposed theory and its basis. It then introduces *Novartis*. The comment then explores the relevant EU laws and analyzes the jurisprudence of Direct Effect and State Liability. Part III applies EU law to *Novartis*.

PART I: THE WTO AND TRIPS: A BIT OF BACKGROUND

A. WTO-Generally

The Marrakesh Agreement[22] is composed of four Annexes. It covers mainly three areas of international trade: goods, services, and intellectual property.[23] The purpose of the WTO is to provide a forum that facilitates multilateral trade liberalization.[24] The expected benefits of membership are market access, protection against the powerful developed countries, and enforceable dispute-settlement mechanism.[25] Those benefits, however, are certainly debatable. Yet regardless of the debate on the politicized "questionable decision-making process," and the willingness to give up a lot, Member States still believe that the benefits of belonging to the WTO outweigh the downsides.[26] This is apparent from the membership increase since the creation of the WTO.[27] The organization started with 123 members in 1995 and the membership increased to 159 members by March 2013.[28]

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as many people as possible benefit from this Europe-wide market of 500 million consumers, the EU is endeavouring to remove obstacles to trade and is working to free businesses from unnecessary red tape."), *with The WTO in Brief*, *supra* note 6 (stating that WTO negotiations' purpose is to help producers but they are negotiated by governments and only bind governments).

[22] Marrakesh Agreement, *supra* note 1.

[23] NARLIKAR, *supra* note 3, at 60.

[24] *Id.* at 51.

[25] *Id.* at 58.

[26] *Id.*

[27] *Id.* at 51.

[28] *Compare The Uruguay Round*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm (last visited Mar. 19, 2014), *with Members and Observers*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Mar. 19, 2014).

B. The TRIPS Agreement

1. Generally

Annex 1C of the Marrakesh Agreement contains the TRIPS agreement.[29] TRIPS establishes minimum standards that countries must abide by in seven areas[30] of intellectual property rights. The agreement is based on the principles of transparency and non-discrimination between Member States.[31]

2. Reasons for Inclusion

There are several reasons[32] for the inclusion of TRIPS under the WTO package.[33] First, developed countries were pushing for the expansion of the WTO mandates in the directions of new issues.[34] In fact, the agreement was a product of U.S. and EU concerns that their competitive advantage as exporters of intellectual property was being undermined by counterfeits.[35] Second, by the 1980s and concurrent with the WTO negotiations, the United States started imposing unilateral sanctions on developing countries that are in breach of the U.S. patent laws.[36] Fearing such threats; developing countries began to reconsider their opposition to TRIPS. Third, developing countries underestimated the technical nature of TRIPS and, at the time of signing the agreement, believed that TRIPS was limited to counterfeit goods when the agreement was far more complex that what the developing countries perceived.[37]

3. Two Sides of the Debate

TRIPS is an exceptional agreement and perhaps the most important development in international intellectual property law since

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[29] TRIPS, *supra* note 9.

[30] The areas of intellectual property that TRIPs covers are: copyright and related rights, trademarks, geographical indications, industrial designs, patents; the layout-designs of integrated circuits, and undisclosed information including trade secrets and test data. *Overview: the TRIPS Agreement*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Jan. 17, 2014).

[31] TRIPS, *supra* note 9, art. 3, 4.

[32] Those reasons are not exclusive.

[33] NARLIKAR, *supra* note 3, at 82.

[34] *Id.* at 82.

[35] *Id.* at 81.

[36] Special 301 section of the Omnibus Trade and Competitiveness Act of 1988 empowered the U.S. Trade Representative to threaten countries with objectionable IPR regime. *Id.* at 82.

[37] *Id.*

the 1880s.[38] However, the agreement has been criticized severely on several grounds. First, the treaty may be far reaching and affects vital sectors in a country, including health services, human rights, and economic and technological development.[39] Second, it raises clear issues of economic coercion and reveals the adverse effects of intellectual property on economic development, access to food, medicines, public goods, and ultimately sustainable development.[40] Third, it also has been labeled as a treaty of adhesion that is unfair to developing countries.[41]

On the other side, the WTO defends the agreement on the basis that it strikes a balance between the long term benefits and possible short term costs to society.[42] Society benefits in the long term when intellectual property protection encourages creation and invention, especially when the period of protection expires and the creations and inventions enter the public domain.[43] For better or for worse, TRIPS was included as part of WTO package.[44]

C. The Dispute Settlement Understanding

1. Generally

Annex 2 of the Marrakesh Agreement concerns the Dispute Settlement Understanding ("DSU").[45] The DSU and the WTO enforcement mechanism are unique in the history of interstate dispute resolutions.[46] The "jewel in the crown" of the WTO achievement is the powerful DSU and through this DSU, it has been said, the WTO has acquired teeth.[47] For better or worse, the mechanism embodies an unprecedented level of legalization in the WTO.[48] The developments are significant with major system-wide consequences.[49]

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[38] Donald P. Harris, *Carrying a Good Joke Too Far: Trips and Treaties of Adhesion*, 27 U. Pa. J. Int'l Econ. L. 681, 724 (2006).

[39] *Id.* at 749.

[40] *Id.* at 683-84.

[41] *Id.* at 685.

[42] *Intellectual Property: Protection and Enforcement*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Jan. 11, 2014).

[43] *Id.*

[44] NARLIKAR, supra note 3, at 82.

[45] DSU, *supra* note 4.

[46] Harris, *supra* note 38, at 749.

[47] NARLIKAR, *supra* note 3, at 85.

[48] *Id.* at 85.

[49] *Id.*

2. Characteristics

There are several significant characteristics to the DSU. First, the use of the DSU is the exclusive responsibility of the Member States[50] and private parties have no access to the WTO venues. A dispute arises when one country adopts a trade policy measure that other WTO members consider to be breaking the WTO agreements, or when a country fails to live up to its obligations.[51] The DSU allows for the creation of the Dispute Settlement Body ("DSB") that could issue decisions that compel a Member States to abide by the rules of the WTO or face retaliation by another Member States.[52] Second, contrary to its predecessor in the GAAT, the establishment of the DSB and the adoption of a panel report can no longer be blocked by one of the parties of a dispute.[53] Finally, the parties can also appeal a panel ruling to the Appellate Body ("AB") on points of law, creating a two-tiered dispute settlement system.

3. Two Sides of the Debate

The WTO praises the system as being time efficient[54] characterized by structured procedural process.[55] The mechanism also deprives developed countries from resorting to unilateral and bilateral measures and imports certainty and predictability in the system.[56] By contrast, some view the dispute settlement system as structurally imbalanced and claim it favors powerful members.[57] Developing countries find it difficult to use the mechanism in their advantage.[58]

D. Private Enforcement of TRIPS against Member States

Currently, the WTO treaty does not provide for private enforcement of the WTO obligations nor does it grant individual access to the DSB.[59] This is understandable. Currently the Appellate Body is facing

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[50] *Id.* at 89.

[51] *Understanding the WTO: Settling Disputes*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm (last visited Jan. 11, 2014).

[52] *Id.*

[53] *Id.*

[54] According to the WTO, disputes should not take longer than 15 months, including the appeal process. *See id.*

[55] *Id.*

[56] *Id.*

[57] Harris, *supra* note 38, at 687.

[58] NARLIKAR, *supra* note 3, at 86.

[59] *See id.* at 89.

significant growth in the volume of disputes.[60] The system is already operating at its maximum with only 153 possible litigants. It would be impossible to contain the workload if private parties had access to the DSB and the DSB opened its gate "to the world."[61]

This comment, however, provides a theoretical procedure that may enable the private enforcement of one of the WTO agreements against Member States. The procedure is limited to TRIPS but it may be a partial solution to such limited access to the "fortress of the DSB." Before exploring the procedure, it may be beneficial to examine the pros and cons of it. The argument for and against private enforcement of TRIPS against a Member State may shed light on its utility.

1. Argument for Private Enforcement of TRIPS

There are several arguments that may support the need for private enforcement of TRIPS agreement. First, the need for private enforcement may stem from defects in the WTO system generally and the dispute settlement system specifically. The WTO negotiation process can sometimes skew the outcomes in favor of the already powerful in the WTO.[62] Additionally, recent remarks by a former WTO judge convey a sentiment of frustration on the current situation, and warning on the future of the dispute settlement system.[63] The judge criticizes the stagnation in the development WTO negotiations.[64] He stresses on the need for "legislative complement" and development in the WTO project as a whole, otherwise the "the institution will wither, and with it, the system of dispute settlement."[65] The judge also advocates the reform of the dispute settlement system to make it more efficient and capable of handing the increase in the number and complexity of cases. Such views only support the need for an alternative to the current disputes settlement procedure if the system were to survive. Second, the WTO Appellate Body stated that treaties are "the international equivalent of contracts."[66] Hence, it could be argued that

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[60] *WTO Appellate Body Chairman Reiterates Concerns Over Increased Workload, Delays*, Int'l Trade Daily Online (BNA) No. 51 (Mar. 17, 2014) ("The 'overall trend since 1995 has been a significant increase in the workload of the Appellate Body,' Ramirez-Hernandez said. 'The year 2013 has been an exceptionally busy year for WTO panels and it is to be expected that this will translate into a heavy workload for the Appellate Body in 2014 and beyond.'").

[61] *Cf. id.*

[62] NARLIKAR, *supra* note 3, at 51.

[63] *Former WTO Judge Says Failure to Advance Trade Agenda Threatens to Fragment System.* 31 Int'l Trade Rep. (BNA) No.6, at 264-65 (Feb. 6, 2014).

[64] *Id.*

[65] *Id.*

[66] Appellate Body Report, *Japan - Taxes on Alcoholic Beverages*, 15, WT/DS8/AB/R (Oct. 4, 1996).

if a country fails to honor its commitment under TRIPS, a private citizen should not be the victim when the failure is attributed to the Member State. Third, addressing social, economic, and political concerns can rescue the international system from structural imbalances in the WTO dispute settlement system that favors powerful members.[67] It is not surprising then when a former WTO judge says that the Appellate Body "does not represent the membership, but it must reflect the diversity that makes up the membership" and that "it has always been a strength of the Appellate Body that its Members come from very different legal traditions, and very different societies." Thus, private enforcement in national courts may be a mechanism to address the concerns of the judge.[68] This is because national courts may be better equipped in addressing such concerns than the WTO bodies.[69] Third, broadening the WTO jurisdiction may stretch the limited WTO resources and may result in inconsistency in international law.[70] Consequently, WTO panels and Appellate Bodies should be reserved as a last resource. Fourth, TRIPS allows Member States to take public interest into consideration when implementing the TRIPS obligations.[71] Hence, a national court may be at a better position in interpreting the special interest of a Member State and may be an effective means to retain the cultural diversity of the WTO and limit the global Americanization of intellectual property rights ("IPR") enforcement.[72] Fifth, a helpful analogy could be drawn from the EU legal order. Just like an EU directive, TRIPS is an instructive agreement. TRIPS and EU directives are binding in their result, yet leave Member States free in their implementation.[73] The Court of Justice of the European Union (the "ECJ") noted that freedom in implementing directives preserves the cultural diversity of the Union which must be respected. It also opined

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[67] Harris, *supra* note 38, at 687.

[68] *See, e.g., id.* (advocating applying the doctrine of adhesion in contracts to interpret TRIPS as a method to remedy the unfairness of TRIPS and accommodate for the national needs of individual Member States).

[69] *See id.* at 737-38 ("TRIPS . . . affects critical aspects of society . . . and global governance-related issues (e.g., the ability of states to determine for themselves which issues take precedence and where to allocate scarce resources).")

[70] *Id.* at 717.

[71] TRIPS, *supra* note 9, art. 8 ("Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.")

[72] *See* Harris, *supra* note 38, at 725 ("[T]he United States began efforts to move intellectual property from WIPO to GATT . . . [GAAT] included the relatively strong and effective enforcement mechanisms . . . Those mechanisms were one of the prizes sought by the developed countries in TRIPS.").

[73] *Compare supra* Part I.B, *with infra* Part III C.2.b.iv.

that the ability to enforce directives against the state is necessary for the effectiveness of the EU system.[74] Fifth, the enforcement would provide an avenue of relief for citizens of the Member State who may not be able to enforce their rights against their own nation since the DSU is reserved for disputes between Member States.[75]

2. *Argument Against Private Enforcement of TRIPS*

Certainly this comment is not blind to the possible adverse effect of private enforcement of TRIPS or even its impossibility. First, giving Member States the power to interpret TRIPS may amount to judicial activism that rewrites TRIPS provisions and alters members' rights and obligations.[76] Second, the power may also lead developing countries to avoid the democratic framework of the WTO.[77] Third, the mechanism may be futile as the United States and other developed countries would probably strive to circumvent any adverse interpretation of TRIPS by resorting to unilateral pressures outside the scope of TRIPS.[78] Such may lead developed countries to obtain the same or greater obligations from developing countries.[79]

PART II: THE PATH TO PRIVATE ENFORCEMENT OF TRIPS AGAINST MEMBER STATES

After providing the abovementioned background information about the WTO, it is helpful to reiterate the main theoretical exercise of this comment. The discussion below will provide the structure of the proposal, its components, and its conclusion.

A. *A Proposal for Private Enforcement of TRIPS against Member States*

1. *The Proposal*

In simple terms, the proposal provides a procedure: (i) by which private litigants can enforce the TRIPS agreement; (ii) against a Mem-

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[74] *See* Case 41/74, Van Duyn v. Home Office., 1974 E.C.R. 1337, para 12. ("[T]he useful effect of such an act would be weakened if individuals were prevented from relying on it before their national courts and if the latter were prevented from taking it into consideration as an element of Community law.").

[75] *See supra* Part I.C.

[76] *See e.g.* Harris, *supra* note 38, at 746 (stating that applying the contract's doctrine of adhesion as part of DSB interpretation of TRIPS may amount to judicial activism and may allow WTO panels and Appellate Body to rewrite TRIPS provisions and alter member's rights and obligations.).

[77] *Id.* at 746.

[78] *Id.* at 752.

[79] *Id.*

ber State; (iii) in circumstances where the Member State fails to afford private parties their rights that TRIPS confer on them.

2. *Its Feasibility*

The objective of the proposal is feasible because of two reasons: (1) the special nature of TRIPS implementation which makes it more fixable for private enforcement; and (2) the EU Principles of Direct Effect[80] and State Liability provide,[81] a well-developed framework existing in very similar circumstances.

B. The Special Nature of TRIPS

What makes this exercise less futile and more plausible is the special nature of the TRIPS agreement. There are several characteristics of TRIPS that make the agreement more malleable to private enforcement against a Member State than its sister agreements, the GATT and GATS.

First, unlike GATT and GATS, the agreement requires Member States to implement domestic laws that translate the TRIPS protections within the legal order of the Member State.[82] This step removes the protection from the realm of international law and makes the protection afforded by the agreement a part of the domestic law. Generally, in the context of international law, the relationship between a private claim and an international public treaty is rarely sufficiently direct so that it may be said to "arise under" the treaty.[83] By contrast, the domestic laws implementing TRIPS become "the carrier of the protection." Consequently, private individuals could challenge such law within the domestic system based on grounds such as: constitutionality, due process, equal protection of citizen, public interest, morals, etc.[84]

Second, taking the United States as an example, an international treaty becomes part of the legal order if it is self-executing or if Congress ratifies it.[85] Consequently "[b]ecause a treaty ratified by the

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[80] *See infra* Part III.C.2.b.

[81] *See infra* Part III.C.2.c.

[82] TRIPS, *supra* note 9, art. 1.1 ("Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.").

[83] 44B AM. JUR. 2D International Law § 178.

[84] *See, e.g.*, Novartis v. UOI (Madras H.C.), *supra* note 14, para. 5 (answering the question of whether Indian national law that implementing the TRIPS agreement on the basis that it is against the Constitution of India).

[85] Medellin v. Texas, 552 U.S. 491, 505 (2008) ("[T]reaties 'may comprise international commitments . . . they are not domestic law unless Congress has either en-

United States is not only the law of [the United States] . . . but also an agreement among sovereign powers," the U.S. Supreme Court "traditionally considered as aids to its interpretation the negotiating and drafting history . . . and the postratification understanding of the contracting parties."[86] Similarly, and in the context of WTO, interpretation of domestic laws could be performed in light of TRIPS.[87]

Third, in implementing TRIPS into their legal order, Member States usually have discretion over the implementation that may be abused or erroneously exercised. This discretion isderived from Article 27 of TRIPS which provides that "[m]embers may exclude from patentability inventions . . . to protect [public order] or morality, including to protect human, animal or plant life or health."[88] A Member State however, may err in its implementation.[89] Such error would be a breach of the Member State's treaty obligations[90] and damages should be reserved to compensate the injured party. This becomes more relevant if the error caused an injury to a citizen of the State itself. In this case, the DSU would not be hear the claim because it would be paradoxical for a nation to sue itself.[91]

1. *A Case Exactly on Point:* Novartis v. UOI.

The special characteristics of TRIPS make it the "path of least resistance" for private litigants to enforce their WTO rights within, and particularly against, a Member State. Indeed, private litigants discovered such a path rather quickly. In 2005, the claimants in *Novartis v. UOI*,[92] challenged India's Patent Act implementing the TRIPS agreement within a year from its complete adoption into the

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acted implementing statutes or the treaty itself conveys an intention that it be 'self-executing' and is ratified on these terms.'").

[86] Zicherman v. Korean Air Lines Co., Ltd., 516 U.S. 217, 226 (1996).

[87] *Cf.* TRIPS, *supra* note 9, art. 41.5 ("It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general.").

[88] TRIPS, *supra* note 9, art. 27, para. 2.

[89] *See, e.g.*, C-393/93, The Queen v. H. M. Treasury *ex parte* British Telecomm. Plc, 1993 E.C.R. I-1656, paras. 39, 40. (holding that EU directives, which require national implementation, give rise to state liability when incorrectly implemented in the national legal order of a Member State).

[90] TRIPS, *supra* note 9, art. 1.1 ("Members shall give effect to the provisions of [the TRIPS] Agreement.").

[91] *See* DSU, *supra* note 4, art. 1.1 ("The rules and procedures of the DSU shall . . . apply to . . . the settlement of disputes between Members concerning their rights and obligations under the provisions of the [WTO] Agreement . . . .").

[92] *See* Novartis v. UOI (Madras H.C.), *supra* note 14.

Indian legal order in 2005.[93] The case sheds lights on the special nature of TRIPS and the agreement's similarity to the EU directives. I examine the relevant facts and the procedural posture of the case to highlight these points.

a. The General Facts

Novartis International AG ("Novartis") is a public pharmaceutical corporation headquartered in Basel, Switzerland.[94] In 1998, Novartis filed a product-improvement patent in India for a drug used for the treatment of blood cancer.[95] Prior to its accession to the WTO, India's patent law only allowed for process, but not product, patents for pharmaceutical inventions.[96] After implementing the latest amendment to the Patent Act 1970, India removed the restriction on product patent for pharmaceutical compounds in 2005. However, the amendment added section 3(d) which prevents trivial modification to existing pharmaceutical inventions.[97]

The patent application was for the Beta Crystalline ("Beta") form of an already patented product, Imatinib Mesylate salt,[98] and marketed in India under the name "Gleevec."[99] Novartis claimed that Beta has more beneficial flow properties, better thermodynamic stability, and lower hygroscopicity than Gleevec.[100] The company alleged that these properties make Beta a new and superior product.[101]

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[93] The Patents Act, No. 39 of 1970 *amended by* The Patents (Amendment) Act, No. 17 of 1999, The Patents (Amendment) Act, No. 38 of 2002, and The Patents (Amendment) Act, No. 15 of 2005 [hearinafter The Patent Act 1970], *available at* http://www.ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf

[94] *About Navartis,* NOVARTIS US, http://www.us.novartis.com/about-novartis/index.shtml (last visited Mar. 25, 2014).

[95] Novartis v. UOI (Ind.), *supra* note 14, paras. 2, 8.

[96] The Patent Act 1970, *supra* note 93, §5 ("[N]o patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable."); *see also* Linda L. Lee, Note, *Trials and TRIPS-Ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281, 284 (2008).

[97] *See* Patent Act 1970, *supra* note 93, §3(d) ("[T]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.").

[98] *Id.* para. 8.

[99] *Id.* para. 2.

[100] *Id.* para. 8.

[101] *Id.*

In 2006, The Office of Controller General of Patents, Designs and Trademarks ("Controller")[102] rejected the application primarily on the basis that section 3(d) of the Patents Act 1970 disallowed the patentability of Beta.[103] Novartis petitioned the Indian government to reverse the Controller's decision and due to subject matter jurisdiction reasons, the case was bifurcated.[104] Novartis appealed the decision of the Controller General to the Intellectual Property Appellate Board ("IPAB") which dismissed the Novartis appeal.[105] Novartis then petitioned the Supreme Court to grant the patent and review the case on the merits.[106] The Supreme Court reviewed the case *de novo* and stayed the IPAB decision by dismissing the case.

In addition to the IPAB appeal, Novartis challenged section 3(d) in another proceeding, on constitutionality grounds and compliance with TRIPS by petition to the Madras High Court. Novartis alleged that section 3(d) was not compliant with TRIPS and that section 3(d) was vague, unambiguous and in violation of Article 14 of the Constitution.[107] The Madras High Court also dismissed the petition.

b. The Madras Court Arguments

Novartis challenges section 3(d) on two grounds, mainly that "(a) it is not compatible to [TRIPS] and (b) it is arbitrary, illogical, vague and offends Article 14 of the Constitution of India."[108] The Court then entertained three questions: (i) whether the Court has jurisdiction to review the compatibility of Section 3(d) with TRIPS, and alternatively whether the Court can grant declaratory relief that section 3(d) is not compliant with TRIPS; (ii) assuming that the Court has jurisdiction, whether Section 3(d) is compliant with TRIPS; and (iii)

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[102] INDIA CONTROLLER GENERAL OF PATENTS, DESIGNS AND TRADEMARKS, http://www.ipindia.nic.in/ (last visited Mar. 20, 2014). The Patent Act vest most powers to the Controller, and the Controller may delegate some powers to subordinate offices. Lee, *supra* note 99, 287. Filing of a patent is done through one of the multiple offices of Controller. *See Patents*, CONTROLLER GENERAL OF PATENTS DESIGNS AND TRADEMARKS, http://ipindia.nic.in/ipr/patent/patents.htm (last visited Mar. 13, 2014).

[103] Novartis v. UOI (Ind.), *supra* note 14, para. 14.

[104] *See* Lee, *supra* note 96, 299-300.

[105] In 2007, The Intellectual Property Appellate Board commenced to hear appeals from the decisions of the Controller of Patents. *See* INTELLECTUAL PROPERTY APPELLATE BROAD, http://www.ipab.tn.nic.in/ (last visited Mar. 2014); *See also* Lee, *supra* note 96, at 288 n.50.

[106] Novartis v. UOI (Ind.), *supra* note 14, para. 16.

[107] Novartis v. UOI (Madra H.C.), *supra* note 14, para. 2.

[108] *Id.*

whether Section 3(d) violates Article 14[109] of the Constitution of India.[110]

i. Jurisdiction

Although the Court rejected the argument, it is not surprising that Novartis relied on a case from the United Kingdom addressing the direct applicability of EU law within the United Kingdom. In *Equal Opportunities Commission v. Secretary of State for Employment*,[111] the British courts answered the question of whether claimants have standing to challenge United Kingdom laws that are incompatible with EU directives in a British court. The court answered the question in the affirmative by relying on Section 2 of the European Communities Act, 1972 which recognizes that EU treaties' rights are "without further enactment to be given legal effect or used in the United Kingdom shall be recognized and available in law, and be enforced, allowed and followed accordingly." The Madras Court held that the European Community Act "domesticated" EU laws as the domestic laws of England. By contrast, India did not domesticate TRIPS.[112] Additionally, the Court rejected jurisdiction because TRIPS is a contractual agreement between Member States and opined that the contracting parties decided that disputes shall be resolved by the DSB.[113]

Regarding the alternative argument, the Could held that declaratory relief should not be given where it would serve no useful purpose to Novartis because Novartis could not compel the Indian legislators to amend or enact a law even if the Court declares that section 3(d) is unconstitutional.[114]

ii. Compliance with TRIPS

After rejecting jurisdiction, the Madras Court did not examine section 3(d) compliance with TRIPS. However, the court recognized the flexibility of TRIPS to accommodate individual needs of the Member States.[115]

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[109] INDIA CONST. art. 14. ("The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India.").

[110] Novartis v. UOI (Madras H.C.), *supra* note 14, paras. 5, 6.

[111] R v. Sec'y of State for Emp't, [1994] UKHL 2, [1995] A.C. 1 (H.L.) (appeal taken from Eng.) *available at* http://www.bailii.org/uk/cases/UKHL/1994/2.html.

[112] Novartis AG v. UOI (Madra H.C.), *supra* note 14, para. 6.

[113] *Id.* para. 8.

[114] *Id.* para 9.

[115] *Id.* para. 15.

iii. Constitutionality

The Madras Court also held that section 3(d) did not violate Article 14 of the Constitution of India and was not vague or arbitrary.[116] The court acknowledged that section 3(d) contains undefined terms that were not defined in the Patent Act.[117] However, it held that legislators use general language and leave discretion to administrative agencies to interpret the language based on the facts of each case.[118]

c. The Supreme Court Arguments

The India Supreme Court reviewed the appeal from the IPAB on the rejection of the Gleevec patent by the Patent Office.[119] As mentioned above, prior to the signing of TRIPS, India did not allow for product patents.[120] The Court acknowledged India's obligation under TRIPS[121] and heavily discussed some of the articles of the TRIPS Agreement.[122]

The three relevant sections affected by the amendment are: section 2(1)(j), 2(1)(ja), and section 3(d) of the Patent Act, 1970.[123] Section 2(1)(j) requires a product to satisfy three conditions to qualify as invention.[124] The product must be: i) new, ii) involve an inventive step, and iii) capable of an industrial application.[125] Inventive step is defined in section 2(1)(ja) as a feature of an invention that involves technical advance and makes the invention *not obvious* to a person skilled in the art.[126]

The Court held that Beta did not qualify as an invention. It held that patent was for a known substance and hence did not qualify as an "invention" in terms of Section 2(1)(j)[127] and Section 2(1)(ja)[128] of

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[116] *Id.* para. 19.
[117] *Id.* para. 14.
[118] *Id.*
[119] Novartis v. UOI (Ind.), *supra* note 14.
[120] Novartis v. UOI (Madra H.C.), *supra* note 14, para. 24 ("[T]he Patent Act, 1970, had a provision in section 5 . . . that barred grant of patent to substance intended for use . . . as food or medicine or drug . . . .").
[121] Novartis v. UOI (Ind.), *supra* note 14, para. 59.
[122] *Id.*
[123] *Id.* para. 3.
[124] *Id.* para. 88.
[125] *Id.*
[126] *Id.* para. 89.
[127] Patent Act, 1970, *supra* note 93, § 2(1)(j) ("'invention' means a new product or process involving an inventive step and capable of industrial application.").
[128] Patent Act, 1970, *supra* note 93, § 2(1)(ja) ("'inventive step' means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.").

the Act.[129] The Court also held that section3(d) bars the patentability of Beta.[130] It held that Beta is a new form of a known substance and thus fully implicates section 3(d).[131] Further, it held the mere change of form with properties inherent to that form would not qualify as "enhancement of efficacy" of a known substance.[132]

The Court also analyzed the amendments' compliance with TRIPS. The appellees, Union of India, asserted that the Act is fully compliant with TRIPS.[133] They took the stand that TRIPS has sufficient flexibility in a manner to avoid an adverse impact on public-health.[134] The Court agreed. It held that TRIPS allows Member States to take "public order"—such preventing the deprivation of affordable drugs to the poor—considerations in implementing its commitments.[135] It also held that in amending its legislation, India strove to balance its international treaty commitment and the promotion of public health.[136]

d. Conclusion

All the arguments advanced in the *Novartis v. UOI* decisions show the special nature of TRIPS and its similarity to EU directives. The case shed light on the availability of private enforcement vehicles that individual could potentially raise against a signatory Member States. The enforcement mechanisms include constitutional challenges, declaratory judgments, and interpretation of domestic laws in light of an international treaty. Such mechanisms are what make TRIPS a flexible treaty for private enforcement.

C. Relying on the Principles of Direct Effect and State Liability to Establish a Mechanism of Enforcement

The Section below discusses the relevance of EU law to the proposal of this comment. It then provides background on the relevant EU jurisprudence and the Principles of Direct Effect and State Liability.

1. Why EU laws May Be Relevant to the Proposal

The abovementioned mechanisms do not provide full protection to private litigants in enforcing their TRIPS rights. All the challenges discussed above are related to existing laws in the national legal order.

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[129] Novartis v. UOI (Ind.), *supra* note 14, paras. 133, 162.
[130] *Id.* para. 191.
[131] *Id.* para. 161.
[132] *Id.* para. 181.
[133] *Id.* para. 65.
[134] Novartis v. UOI (Ind.), *supra* note 14, para. 65.
[135] *Id.* para. 66.
[136] *Id.*

However, there exist situations where such mechanisms cannot help the private litigants. A gap in the protection would be apparent in two hypothetical circumstances. First, where the Member State fails to implement TRIPS as there would be no national law to challenge. Second, a national law implementing TRIPS could be constitutional on its face but contrary to TRIPS obligations. In these situations, the only recourse to the private litigants, apart from the normal DSU path, is perhaps the direct applicability of TRIPS. Consequently, the EU Principles of Direct Effect and State Liability become relevant to the proposal of this comment.

Direct applicability, however, is an extreme measure. In order to provide a safeguard to Member States against uncontrolled direct applicability, this option should be conditioned to circumstances where the Member State fails to honor its obligation or if the Member State is in clear breach of its TRIPS obligation. In order to achieve this objective, this comment learns from the EU Principles of Direct Effect and State Liability to provide private individual with recovery recourse while reserving direct applicability for cases of breach.

2. *The Relevant EU Jurisprudence and Laws*

After establishing the special nature of TRIPS, this comment proposes utilizing the principles of Direct Effect and State Liability to establish the mechanism of enforcement. Thus, before drawing analogies and exploring the WTO in light of the EU legal order, it is necessary to lay a foundational background on the relevant EU laws. The following section briefly details some relevant EU concepts necessary to the understanding of the Principle of Direct Effect and State Liability.

a. *Types of EU Legislations*

Prior to exploring the principles of Direct Effect and State Liability, it is necessary to examine the scope and types of EU legislations. The ability to invoke the right in a court of law depends on the type of the legislations. There are two types of legislations: (i) Primary and (ii) Secondary.

Primary Legislations are the founding EU Treaties: The Treaty on European Union[137] ("TEU"), Treaty on the Functioning of the Euro-

[137] Consolidated Version of the Treaty on European Union, Oct. 2012, 2012 O.J. (C 326) [hereinafter TEU].

pean Union[138] ("TEFU"), and the Charter of Fundamental Rights of the European Union.[139]

Secondary Legislations are legislative acts by Union institutions and are listed in Article 288 TFEU.[140] They included regulations, directives, decisions, and recommendations. *Regulations* are generally applicable, binding in their entirely, and directly applicable in all Member States as soon as they enter into force, they must be complied with fully by those to whom they apply (private persons, Member States, Union Institutions), and they do not require implementing acts to be transported into national law.[141] *Decisions* are binding in their entirety on those they are addressed to (Member States, natural or legal person).[142] *Recommendations and Opinions* do not confer rights or obligation on those to whom they are addressed to.[143]

Directives are binding as to the result to be achieved upon any Member States to whom they are addressed.[144] Just like TRIPS, national legislators must adopt a transporting act or implementing measure to transport directives and bring national law in line with the directives' objectives.[145] Directives are the most relevant type of secondary legislations for the purpose of this comment and for the discussion of the Principle of Direct Effect discussed below.

b. The Principle of Direct Effect

i. Generally

The European law not only engenders obligations for Member States, but also rights for individuals.[146] Consequently, the Principle of Direct Effect was enshrined by the ECJ and it enables individuals to invoke EU law before national and EU courts, independent of whether national law exists.[147] Individuals may therefore take advantage of these rights and *directly invoke European acts* before national and European courts. Under the Principle of Direct Effect, an EU law will

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[138] Consolidated Version of the Treaty on the Functioning of the European Union, Oct. 10, 2012, 2012 O.J. (C 236) [hereinafter TFEU].
[139] Charter of Fundamental Human Rights of the European Union, Oct. 10, 2012, 2012 O.J. (C 326).
[140] TFEU, *supra* note 138, art. 288.
[141] The European Parliament, *supra* note 16, at 2.
[142] *Id.* at 3.
[143] *Id.*
[144] *Id.*
[145] *Id.*
[146] European Union, *The Direct Effect of EU law*, EUROPA, http://europa.eu/legislation_summaries/institutional_affairs/decisionmaking_process/l14547_en.htm (last updated Sept. 22, 2010).
[147] *Id.*

prevails over national legislation.[148] For example, an EU law provision creates a directly applicable right which a nationals of a Member State could invoke in a national court.[149]

ii. Aspects of Direct Effect

There are two aspects to the principle: a vertical aspect and horizontal aspect.[150] Vertical direct effect ("VDE") concerns relationship between individuals and the State.[151] It means that an individual could invoke an EU provision *against the State*.[152] Horizontal direct effect ("HDE") concerns relationships between private parties. It means that an individual could invoke an EU provision *against another individual*.[153]

Depending on the type of EU act or legislation, the ECJ adopted either "full direct effect" that include horizontal direct effect and a vertical direct effect or "partial direct effect" which is confined to VDE.[154] However, this comment only analyzes VDE because it concerns enforcement of private rights against a State.

iii. The Direct Effect of EU Legislations

Primary legislations are directly effective[155] (vertical and horizontal) on the condition that they are precise, clear, unconditional and they require no additional measures.[156] *Regulations* always have direct effect.[157] *Decisions* may have direct effect when they are addressed to a Member State.[158]

Directives differ from primary legislations and regulation in their direct effect. Because directives are addressed to Member States—as opposed to creating private rights—in principle, they are not directly applicable.[159] The ECJ, however, recognizes in case law

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[148] *Id.*

[149] Van en Loose, C-26/62 Case 26/62, Van Gend en Loos v. Administratie der Belastingen, 1963 E.C.R. 3, ¶8. .

[150] European Union, *supra* note 146.

[151] *Id.*

[152] *Id.*

[153] *Id.*

[154] *Id.*

[155] *See* Case 26/62, Van Gend en Loos v. Administratie der Belastingen, 1963 E.C.R. 3, 13.

[156] *See* Joined Case C-46 & 48/93, Brasserie du Pêcheur v. Bundesrepublik Deutschland, The Queen v. Sec'y of State for Transp. ex *parte* Factortame Ltd., 1996 E.C.R. I-1029, ¶ X [hereinafter *Factortame*].

[157] TFEU, *supra* note 138, art. 288.

[158] European Union, *supra* note 146.

[159] *Id.* By contrast, directives do not impose horizontal direct effects. The ECJ recognized some exceptions for the HDE of directive in limited number of cases. This

the partial or vertical direct effect of directives in order to protect the rights of individuals against a Member State in the national courts of the Member State.

Van Duyn[160] is the case that primarily established the Principle of Direct Effect in the EU legal order. In *Van Duyn*, the plaintiff was a Dutch national who was offered a position as a secretary with the Church of Scientology in England.[161] The English government refused the plaintiff's entry into the United Kingdom because England did not agree with the ideology of the Church.[162] The plaintiff relied on a directive on the free movement of workers and claimed that her refusal of entry was unlawful. England has implemented the directive but did not adopt its exact wording.[163] The ECJ held that the directive confers on individuals rights which are enforceable by them in the national courts of a Member State and which national courts must protect.[164]

iv. Conditions for the VDE of Directives

An individual can rely on a directive against any national provision which is incompatible with the directive or if the provisions of the directive define rights which individuals are able to assert against the Member State.[165] The conditions for the application of the Principle of Direct Effect are laid down in the *Marshall* decision.[166] The principle is applicable when: (1) The Member State failed to implement the directive or incorrectly implemented the directive,[167] (2) the deadline

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means that a directive may not of itself impose obligations on an individual and that a provision of a directive may not be relied upon against another private party. Case 152/84, Marshall v. Southampton & South-West Hampshire Area Health Auth., 1986 E.C.R. 723, para. 48. The jurisprudence of HDE will not be discussed in this comment. *See generally* C-106/89, Marleasing v. La Comercial Internacional de Alimentacion, 1990 E.C.R. I 4135.

[160] Case 41/74, Van Duyn v. Home Office., 1974 E.C.R. 1337.

[161] *Id.* at 1343.

[162] *Id.* at 1340.

[163] *See id.*

[164] *Id.* at 1352.

[165] Case C-6/90, Francovich v. Italy, 1991 E.C.R. I-5357, ¶11.

[166] Case 152/84, Marshall v. Southampton & South-West Hampshire Area Health Auth., 1986 E.C.R. 723.

[167] *Marshall*, 1986 E.C.R. 723, para. 46. In *Marshall*, the appellant worked as dietitian for a public health institute was dismissed at the age of sixty-two. *Id.* paras. 3, 4. England legislations provide that state pension is to be granted to men from the age of 65 and for women at the age of 60. *Id.* para. 7. The appellant contended that her dismissal was based on sex discrimination, *Id.* para. 9., and infringed on principle of quality of treatment laid down by an EU directive. *Id.* para. 10. The Court held that an individual may rely on a directive where the State fails to implement the directive or incorrectly implement the directive, pro-

to implement the directive has expired,[168] or (3) the obligation in question is unconditional and sufficiently precise.[169] On the precision of the directive, factors to consider are the identity of the person entitled to the guarantee, the content of the minimum guarantee, and the identity of the person liable to provide the guarantee,[170] and (4) the State or an organ of the state is a party against which enforcement is claimed.[171]

c. The Principle of State Liability

i. Generally

The principle of State Liability takes the principle of direct effect a step further by compensating the plaintiff for damages in connection with a Member State's failure to honor its EU obligations. In

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vided that the directive in unconditional, sufficiently precise, and the State is a party against which the enforcement is claimed. *Id.* para. 46. The Court also held that England law conflicted with the directive and the appellant may rely on the EU directive to set aside the national law. *Id.* Summary of Judgment para. 1.

[168] Case 148/78, Ratti., 1979 E.C.R. 1629, para. 43. In *Ratti*, the ECJ held that "it is only at the end of the prescribed period and in the event of the Member State's default. *Id.* at 1629.

[169] *Id.* para. 23.

[170] Joint Cases C-6 & 9/90, Francovich & Bonifaci v. Italy 1991 E.C.R. I-5357, para. 12. In *Francovich*, employees of companies that declared insolvencies sued their employer to recover compensation guaranteed by EU directive intended to guarantee employees a minimum level or protection under EU law in the event of the insolvency of their employer. *Id.* para. 3. The Member State, Italy, failed to implement the directive. *Id.* para. 4. The Member State, Italy, failed to implement the directive. The Court examined from the terms of the directives that the persons entitled to the guarantee were employees. *Id.* para. 13. The Court also examined the content of the directive and held that the directive provides that measures must be taken to ensure the payment of outstanding claims resulting from contract of employment. *Id.* para. 15. Finally with regards to the identity of the person liable to provide the guarantee, the ECJ quoted the directive and held that from its terms, the entity responsible of the guarantee is the Member State. *Id.* para. 25. With regard to the unconditional nature of the directive, the Court also held that even when the state has discretion in its options to provide compensation that the possibility of limiting the guarantee under the directive does not make it impossible to determine the minimum guarantee. *Id.* para. 20.

[171] C-80/86, Kolpinghuis Nijmegen, 1987 E.C.R. 3969, ¶ 10 ("A national authority may not rely, as against an individual, upon a provision of a directive whose necessary implementation in national law has not yet taken place."). In *Marshall*, the plaintiff claimed that her rights were violated by a public health institute as opposed to the state itself. Case 152/84, Marshall v. Southampton and South-West Hampshire Area Health Auth., 1986 E.C.R. 723, para. 2. The ECJ held that directives do not impose obligation on private individuals but a person may rely on the directive against a State employer or public authority. *Id.* paras. 48, 51.

Marshall, the plaintiff was able to use the principle of direct effect to set national legislations that contradicted an EU directive.[172] By contrast, in *Francovich*, the case that sets the jurisprudence to State Liability, the plaintiffs relied on the principle of state liability for damages compensation caused by state failure to comply with EU law.[173]
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ii. State Liability Conditions Dependent on Type of Breach

The conditions under which liability gives the right to reparation depends on the nature of the breach of EU law.[174] There are four types of breaches recognized by the ECJ that gives the right of damages by the Member State.

1. Failure to Implement a Directive.

In *Francovich*,[175] the ECJ sets down the state liability jurisprudence for failure to implement a directive or the *Francovich* Principle. The ECJ held that "[a] national court must, in accordance with the national rules on liability, uphold the right of [individual] to obtain reparation of loss and damage caused to them as a result of failure to transport the directive."[176] Technically, the failure to implement a directive is a breach of primary legislation, Article 189 of the Treaty, which requires a Member States to take all the necessary measures to achieve the result intended by the directive.[177]

For failure to implement a directive, the ECJ established the condition for State Liability: (i) the directive must confer rights on individual,[178] (ii) "it should be possible identify the content of those rights on the basis of the provisions of the directive",[179] and (iii) there must exist a causal link between the breach of the State's obligation and damages suffered.[180]

In *Francovich*, the ECJ upheld the liability of Italy to Italian employees where Italy failed to implement a directive intended to protect employees in case of employer insolvency. The Court held that the directive confers a right on employees because the directive "entails the grant to employees of a right to a guarantee of payment of their

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[172] *Marshall*, 1986 E.C.R. 723, ¶ 56
[173] Case C-6/90. Francovich v. Italy,1991 E.C.R. I-5357, para. 28.
[174] *Id.* para 38.
[175] *Id.* para. 1.
[176] *Id.* para. 45.
[177] *Id.* para. 39.
[178] *Id.* para. 40.
[179] *Francovich*, 1991 E.C.R. I-5357, para. 40.
[180] *Id.*

unpaid wages claims."[181] The Court used its analysis in determining the direct effect of the directive to establish that the content of the rights could be determined on the basis for the provision of the directive.[182] Finally, on causation, the Court held that it is in accordance with the national rules on liability and that national courts determine damages and causation.[183]

2. National Legislation in Breach of a Treaty Provision.

In *Factortame*, the ECJ set down the state liability jurisprudence for national measures that are contrary to the fundamental EU treaty provisions.[184] The ECJ held in *Factortame* that primary EU provisions "have direct effect in the sense that they confer on individuals rights upon which they are entitled to rely directly before the national courts. Breach of such provisions may give rise to reparation."[185]

For national measures that are contrary to the EU, the ECJ established the condition for State Liability. First, the rule infringed must confer a right on the individual. Second, the breach must be sufficiently serious established by whether the MS manifestly and gravely disregarded the limits on its discretion.[186] The Court laid down the factors that must be assessed by the national courts,[187] in determining the seriousness of the breach.[188] The factors include: (i) the clarity and precision of the rule breached, (ii) the measure of discretion available to MS in complying with the primary legislation provision, (iii) whether the infringement was intentional and voluntarily, and (iv) whether the error of law was excusable or inexcusable.[189] Third, there must be a direct causal link between the breach of the EU law and the damages suffered.[190]

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[181] *Id.* para. 43.
[182] *Id.* para. 44.
[183] *Id.* para. 45.
[184] *Factortame*, *supra* note 156.
[185] *Id.* para. 23.
[186] *Id.* para. 55.
[187] *Id.* para. 58.
[188] *Id.* para. 56.
[189] *Id.*
[190] *Factortame*, *supra* note 156, para. 51. In Factortame, French beer manufacturers brought action against Germany for losses suffered when Germany imposed marketing restrictions on French beer. The manufacturer alleged that the restriction was incompatible with Article 30 TFEU, which prohibits marketing restriction on lawfully manufactured products by different MS state. *Id.* para. 4. The Court opined that in the absence of harmonization, i.e no directives or regulations, the national legislature has wide discretion in lying down rules that achieve the objective of the primary EU law, i.e. the EU treaty provisions. *Id.* para. 23. On the

3. Incorrect Implementation of EU Directive.

The case of *Ex Parte British Telecom* involved the incorrect implementation of a directive. The court applied the State liability principle subject to *Factortame*[191] conditions.[192]

4. Decision of an Administrative Authority.

In *Hedley-Lomas*, the ECJ held that the decision of an administrative authority that is not compliant with a directive constituted a breach of a primary legislation.[193] Because the infringement is a breach of a primary legislation, the court applied the condition of state liability under *Factortame*.[194] The Court held that the Member State has an obligation to compensate the claimant for damages caused by a refuel to issue an export license.[195]

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first element, the Court held that the marketing restriction was prohibited by Article 30. *Id.* para. 54. Additionally, it held that the provision not only imposed restriction on MS, it also confers rights on individuals. *Id.* On the second element, the Court left the determination to national courts; however, it commented that it would be difficult to consider the marketing prohibition on beer as excusable error. *Id.* para. 59. On the third, element the Court left it for national courts to determine causation and damages under national law. *Id.* para. 65.

[191] See supra note 184 and accompanying text.

[192] C-393/93, The Queen v. H. M. Treasury *ex parte* British Telecomm. Plc, 1993 E.C.R. I-1656, paras. 39, 40. In Ex Parte British Telecom British company initiated a proceeding against the government of the United Kingdom for annulling a national legislation implementing an EU directive. *Id.* para. 2. The Court held that the U.K. national legislations went beyond the scope of the directive and implemented the directive incorrectly. *Id.* para. 29. The Court, however, held that the breach in this case is not sufficiently serious, and hence the Member State was not required to compensate the claimant. *Id.* para. 45.

[193] Case C-5/94, The Queen v Ministry of Agriculture, Fisheries and Food *ex parte* Hedley Lomas (Ireland) Ltd., 1996 E.C.R. I-2553, para. 17.

[194] *Id.* para. 26.

[195] *Id.* para. 27. In Hedley, the claimant, an Irish company, initiated a proceeding when the Ministry of Agriculture, Fisheries and Good for England and Wales refused to issue the plaintiff a license for export of live sheep to Spain. *Id.* para. 17. The administrative authority refused the license on the ground that Spain's slaughterhouses treatment of animals was contrary to an EU directive. *Id.* paras. 2, 3. Spain has implemented the directive into its national law and after complaints from the U.K and negotiation with the EU Commission; Spain strengthened its compliance with the directive. *Id.* paras. 6, 8. The Court held that the decision of an administrative authority was is non-compliant with the directive constitute a quantitative restriction on expert, contrary to the primary legislation, Article 34 of the Treaty. *Id.* para. 17.

5. *Post* Factortame *Cases*

Several modern cases expanded the Principle of State Liability including liability of public bodies. In *Haim*, the Court held that "[c]ommunity law does not preclude a public-law body, in addition to the Member State itself, from being liable to make reparation for loss and damage caused to individuals as a result of measures which it took in breach of Community law."[196] The Court opined that where conditions for state liability are met, the Member State must compensate private individuals for breach of Community law by a public-law body.[197]

PART III: APPLY EU LAW PRINCIPLES TO *NOVARTIS v. UOI*

The *Novartis v. UOI* case provides an excellent fact pattern to apply the Principles of Direct Effect and State Liability to enforce the rights of private individuals against a Member State in breach of its WTO obligations.

A. *Options Available for Novartis*

In applying the principle of EU law, *Novartis* would have two options.

First, Novartis could rely on the Principle of Direct Effect to set aside section 3(d) of the Patent Act 1970 that bars its patent application. Second, Novartis could also rely on the Principle of State Liability and require compensation for damages resulting from the Patent Office decision that rejected the Beta patent. In relying on the principle of State Liability, Novartis would assert that the breach is due to either (i) failure of the state to implement TRIPS correctly or (ii) the Patent Office, which is a public office, infringed its rights granted by the Patent (Amendment) Act, 2005, implementing the TRIPS agreement into the Indian legal order.

For the sake of brevity, this comment only considers the *Novartis v. UOI* case in light of the Principle of Direct Effect.

B. *Applying the Principle of Direct Effect to the Novartis v. UOI* Fact Pattern

In paralleling the EU procedure and applying the principle of Direct Effect discussed above to the *Novartis v. UOI* case, the Member State would be India, the directive-like law is the TRIPS agreement,

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[196] C-429/97, Haim v. Kassenzahnärztliche Vereinigung Nordrhein, 2000 E.C.R. I-5168.

[197] *Id.* paras. 31-33. The claimant in Haim was a dental practitioner who raised a proceeding against Member State public body in order to obtain compensation for financial losses by breach of EU law by the public body. *Id.* para. 2

the national law is the India's Patent Act, 1970 as amended by Patent Amendment of 2005, and the private litigant would Novartis. Novartis would also claim the direct effect of TRIPS to set aside national Indian law that is contrary to TRIPS. The requirements of EU Direct Effect in light of the TRIPS agreements are as follow:

1. *The Member State, India, failed to implement TRIPS or incorrectly implemented TRIPS.*[198] India did not fail to implement the TRIPS agreement[199] but Novartis could claim that India failed to implement the directive correctly. Just like *Marshall*,[200] Novartis could claim that Indian national law conflicted with TRIPS and the appellant may rely on TRIPS directly to set aside the national law.
2. *The deadline to implement TRIPS has expired.*[201] This element is satisfied because in *Novartis v. UOI* the patent was rejected in 2006 after the implementation of TRIPS into the Indian legal order in 2005.
3. *The obligation in question is unconditional and sufficiently precise.*[202] Certainly this would probably be the most contested element. On the precision of the directive, the ECJ in *Francovich* considered the terms of the agreement and considered factors such as the identity of the person entitled to the guarantee, the content of the minimum guarantee, and the identity of the person liable to provide the guarantee.[203] With regard to the person entitled to the guarantee in TRIPS, the agreement states that "[m]embers shall make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement."[204] The terms of the agreement specifically state that the people entitled to the guarantee are the holders of the rights.[205] Additionally, the content of the minimum guarantee is all intellectual property *covered by the agreement*. Finally, the party responsible to provide the guarantee are the Member State. By

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[198] Case 152/84, Marshall v. Southampton & South-West Hampshire Area Health Auth., 1986 E.C.R. 723, para. 46.

[199] Novartis v. UOI (Ind.), *supra* note 14, para. 59.

[200] *See supra* note 167 and accompanying text.

[201] Case 148/78, Criminal Proceeding Against Tullio Ratti., 1979 E.C.R. 1629, para. 43.

[202] *Id.* para 23.

[203] S Joint Cases C-6 & 9/90, Francovich & Bonifaci v. Italy 1991 E.C.R. I-5357, para. 12

[204] TRIPS, *supra* note 9, art. 40.

[205] *See, e.g.*, *Id* art. 3 ("Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals . . . .").

contrast this element is undermined by provisions in TRIPS that give the Member State discretion in implementing the TRIPS obligation to take into consideration measures that "promote the public interest in sectors of vital importance to their socio-economic."[206]

4. *The State or an organ of the state is a party against which enforcement is claimed.*[207]

Novartis would initiate the action against the Controller of Patents.[208] Just like *Marshall* where the plaintiff relied on the directive against a public health employer, Novartis may rely on TRIPS against India's Patent Office.

CONCLUSION

This comment proposes a mechanism for private enforcement of TRIPS against signatory Member States of the WTO. The proposal is feasible because of the special nature of the TRIPS agreement. The agreement requires Member States to promulgate national laws that provide minimum protection for intellectual property rights. Unlike its sister agreements, GAAT and GATS, the TRIPS requirement of national implementation renders it more flexible for private enforcement. This is because a private individual could challenge the national laws implementing TRIPS as opposed to relying directly on TRIPS. Nevertheless, even if the Member State does not promulgate national laws, the proposal suggests that private enforcement is still possible. This is because the requirement of national implementation of an international agreement makes TRIPS very similar in nature to EU directives (and, in certain cases, treaties). EU directives are binding on their result but give Member States freedom in their local implementation. Hence, it is possible to rely on the EU jurisprudence to provide complete protection for individuals under the TRIPS agreement.

Under EU laws, a private citizen can enforce a directive or an EU treaty against a Member State that fails to honor its EU obligation. Private enforcement procedures are based on the Principles of Direct Effect and State Liability under the EU jurisprudence. The proposal in this comment parallels these procedures to propose a potential mechanism where private citizens can enforce TRIPS against Member States of the WTO.

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[206] *Id.* art. 8.1.; *see, e.g.*, Novartis v. UOI, *supra* note 14, para. 65.

[207] Criminal Proceeding Against Kolpinghuis Nijmegen BV, C-80/86, 1987 E.C.R. 3982, ¶10 ("A national authority may not rely, as against an individual, upon a provision of a directive whose necessary implementation in national law has not yet taken place.").

[208] *See supra* note 105 and accompanying text.

An emerging trend towards private enforcement of TRIPS is noticeable internationally. The *Novartis* case shows the shift towards the direct effect of WTO laws within a Member State's national order. In this case, the claimant challenged India's national laws that implemented TRIPS on a constitutional basis. Additionally, they challenged India's compliance with its international obligations. In renderings it decision, the courts of India relied directly on TRIPS to analyze the adopted national legislation. The Madras High Court decided that India's Patent Act, 1970 was constitutional. The Supreme Court of India decided that the act was fully compliant with TRIPS. This significance of the *Novartis* case is actually how the claim gained access to the courts of India in the first place. The outcome of the case is probably a secondary issue to the proposal of this comment. Nevertheless, the outcome of the case could be significant if India's national law clearly infringes the Member State's obligation under TRIPS or if the DSU panels encounter a similar case and decides that product improvement patents are protected under TRIPS.