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University of Wollongong Department of Economics Working Paper Series 2002

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WP 02-01

Legitimacy and the TRIPS Agreement

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Introduction

It has been a matter of serious discussion among the international legal scholars that without the regulatory power of the state in domestic law, so many rules of international law are so frequently followed by so many states.¹

Franck's perception of legitimacy is a "perception on the part of those to whom it is addressed that it has come into being in accordance with right process. Right process includes the notion of valid sources but also encompasses literary, socio-anthropological and philosophical insights." ²

Dworkin identified three characteristics, which are conducive to the rule of law: fairness, justice and integrity or consistency. ³ Koh⁴, Keohane⁵, Weisburd⁶, Setear⁷ and Murphy⁸ have variously interpreted and applied Franck's theory of legitimacy to various aspects of international legal situations.

Franck discussed the concept of legitimacy starting from Max Weber to the strategic concept of legitimacy where contracting parties for the mutualizing advantage adopt the voluntary compliance. Weber emphasized the greater adherence of subjects to the rule of law if the subjects perceive both the rule and ruler as legitimate whereas Schachter emphasized the role of "competence and authority" for a rule to be perceived to be obligatory¹⁰. Franck while discussing the above examples concluded that the above discussion placed "emphasis on non-coercive factors as conducing to rule - compliant behavior."1

¹ Thomas M. Franck, 'Legitimacy in the International System, 82 American Journal of International Law, p. 705 (1988). [hereinafter Franck (1988)] "The surprising thing about international law is that nations ever obey its strictures or carry out its mandate.' (p. 705)
² Franck (1988), p. 706

³ R. Dworkin, Law's Empire, 1986, pp. 176-224 (Harvard University Press, Cambridge)

⁴ Harold Hongju Koh, 'Why do nations obey international law?' 106, Yale Law Journal, 2599, 2628-29, 2633, 2643 (1997)

⁵ Robert O. Keohane, 'International Relations and International Law: Two Optics', 38 Harvard International Law Journals, 487, 491-93 (1997)

⁶ A. Mark Weisburd, ,'The Emptiness of the Concept of Jus Cogens, as Illustrated by the Warin Bosnia-Herzgovina', 17 Michigan Journal of International Law, 1, 32, 37 (1995)

⁷ Setear, John K., An Iterative Perspective on Treaties: A Synthesis of International Relations Theory and International Law, 37 Harvard International Law Journal, 139, pp. 162-73 (1996)

⁸ Sean D. Murphy, 'The Security Council, Legitimacy, and the Concept of Collective Security After the

Cold War', 32 Columbia Journal of Transnational Law. 201, 249-251 (1994)

M. Weber, 1968, Economy and Society: An Outline of Interpretative Sociology, 31 (G. Roth & C. Wittich

eds.)
¹⁰ Oscar Schacter, 'Towards a Theory of International Obligation', 8 Vanderbilt J. International Law, 300 (1968), [hereinafter Schacter (1968)]

11 Franck (1988) p. 710

Weiler¹² tried to discuss the legitimacy of WTO Dispute Settlement System while Palmeter¹³ has discussed legitimacy in the context of the World Trade Organization (WTO). Aldonas¹⁴ observed that as the Panels and the Appellate Bodies develop a body of jurisprudence that clarifies WTO members' commitments, it "establishes the WTO's legitimacy and commands the respect of its members"

Thomas Franck's Theory of Legitimacy

The study of legitimacy in international rule occupies a very significant place in international relations because it envisages "the possibility of an orderly community functioning by consent and validated obligation" ¹⁵ Franck has further emphasized that the "the legitimacy of a rule, or of rule-making or rule-applying institution, is a function of a perception of those in the community concerned that the rule, or the institutions, has come into being endowed with legitimacy; that is in accordance with right process." ¹⁶ Legitimacy has been defined by Professor Franck as "a property of a rule or rule making institutions which itself exerts a pull towards compliance on those addressed normatively" ¹⁷ and also "the perception of those addressed by a rule or a rule making institution that that rule or institution has come into being and operates in accordance with generally accepted principles of right process." ¹⁸

The primary purpose of Agreement on Trade Related Aspects of Intellectual Property Rights ¹⁹ (TRIPS) was to 'reduce distortion and impediments to international trade' taking into account 'effective and adequate protection' to patents, copyrights and trademarks in private laws of different countries ²⁰. TRIPS is supposed to provide for the protection of many forms of so called intellectual property such as Copyright, Trademarks, Industrial

¹² J.H.H. Weiler, 'The rule of Lawyers and the Ethos of Diplomats: Reflections on the Internal and External Legitimacy of WTO Settlement', Harvard Jean Monnet Working Paper 9/2000, The Jean Monnet Seminar and Workshop on the European Union, NAFTA and the WTO Advanced Issues in Law and Policy, Harvard Law School, Cambridge (2000) [hereinafter Weiler (2000)]

¹³ David Palmeter, 'The WTO as Legal System', 24 Fordham International Law Journal, p. 444, 447

G.D. Aldonas, The World Trade Organization: Revolution in International Trade Dispute Settlements" (1995) 3 Dispute Resolution Journal 73 at 79
 Franck (1988), "Yet there is a stronger motivation for studying legitimacy in the international system

¹⁵ Franck (1988), "Yet there is a stronger motivation for studying legitimacy in the international system than the academic objective of creating a bridge from national to international speculative jurisprudence. A teleology that makes legitimacy its hypothetical center envisages – for purposes of speculative inquiry—the possibility of an orderly community functioning by consent and validated obligation rather than by coercion." (p. 710)

¹⁶ Franck (1988), p. 711

¹⁷ Franck, The Power of Legitimacy Among Nations (1990) p. 16, Oxford University Press, USA [hereinafter Franck (1990)],

¹⁸ Franck (1990), p. 19

¹⁹ Annex 1C – Agreement on Trade Related Aspects of Intellectual Property Rights, The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts

²⁰ Preamble to the TRIPS Agreement, "Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;…"

Designs, Patents, Integrated Circuits Layouts, and Trade Secrets through enactment of national laws to meet certain limited standards. Otten and Wager even insisted that "the protection of intellectual property is one of the three pillars of the WTO, the other two being trade in goods (the area traditionally covered by the General Agreement on Tariffs and Trade (GATT) and the new agreement on trade in services (General Agreement on Trade in Services)."²¹

There was not much divergence of views among the nations once they agreed to include TRIPS in the Uruguay Round Negotiations as far as copyrights and trademarks were concerned but the question of patent got intricately linked with technology transfer and promotion of public policies like public health and emergency and led to a series of frictional developments. A large number of countries appear to evince skepticism about the possibility of TRIPS fulfilling any of its cherished goals of removing distortions and impediments to international trade and promoting "technological innovation" and "the transfer and dissemination of technology" ²².

Reluctance of different countries, including many developed countries to adopt provisions of TRIPS is still keeping scholars busy discussing the approach to be adopted to introduce TRIPS compliant provisions in their domestic laws²³.

In this article an attempt is made to find helpful perspective on this dilemma in the work of international legal scholar Thomas Franck against the background of his theory of international legitimacy. The theory developed in Franck's "The Power of Legitimacy among Nations"²⁴ and in his earlier article "Legitimacy in the International System"²⁵ is based on the presumption that different international law exerts different "pull to compliance" depending upon the extent to which "the rule is characterized by greater or lesser" legitimacy. A major weakness of TRIPS has been uncertainty and unpredictability in its scope and the total reliance for interpretations on the institutions from certain industries and the judicial and the non-judicial institutions in the developed countries. This Theory of Legitimacy isn't only applicable to the states in the international community but also to other international institutions.

Franck has analyzed legitimacy in terms of four factors:

- 1. Determinacy
- 2. Symbolic Validation

²¹ A. Otten and H. Wager, Compliance with TRIPS: The Emerging World View, 29 Vanderbilt J. Transnational Law., 391, 393 (1996)

²² Article 7 of the TRIPS Agreement, "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to t transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

conducive to social and economic welfare, and to a balance of rights and obligations.

23 Jerome H. Reichman, 'The TRIPS Agreement comes of age: Conflict or Cooperation with the Developing Countries?, 32 Case Western Reserve Journal of International Law, p. (2000)

Thomas M. Franck, The Power of Legitimacy Among Nations (1990) Oxford University Press, USA
 Thomas M. Franck, Legitimacy in the International System, 82 A merican Journal of International Law,
 (1988)

- 3. Coherence
- 4. Adherence (to a normative hierarchy)

Franck has used the notion of "justice" when he states "A treaty may be the locus of a lively dispute between those who wish to see it obeyed because it is legitimate even though unjust and others who wish to see it repealed or even violated because it is unjust although legitimate." In his book 'Fairness in International Law and Institutions' Franck argued that "If a decision has been reached by a discursive synthesis of legitimacy and justice, it is less likely to be disobeyed". ²⁸

Determinacy and Legitimacy

Although Franck started with the textual clarity as defining determinacy i.e. "the ability of the text to convey a clear message, to appear transparent in the sense that one can see through the language to the meaning", subsequent discussion by Franck indicates that determinacy in the form of certainty in the treaty interpretation is the fundamental perquisite to legitimize a treaty. Franck observed that, "For present purposes it is enough merely to note once more that clarity and certainty are, usually, but not invariably, synonymous with determinacy." ²⁹ Franck discussed the example of the difference between two textual formulations defining the boundary of the underwater continental shelf to suggest the importance of certainty in an international treaty. In the 1958 Convention on the Continental Shelf³⁰, the boundary of the Continental Shelf was defined as the shelf at "a depth of 200 meters or, beyond that limit, to where the depth of the superjacent waters admits of the exploitation of the natural resources of the said areas." Compared to the 1958 Convention, the 1982 Convention on the Law of the Sea³¹ is far more definite and specific and the definition of the continental shelf has been given as "the natural prolongation of ...land territory to the outer edge of the continental margin, or to a distance of 200 nautical miles from the baselines from which the breadth of the territorial shelf is measured" and certain important factors such as "the thickness of sedimentary rocks" and a limit on outermost line that' shall not exceed 100 nautical miles from the 2,500 meters isobath" are specifically mentioned. The isobath has also been specifically defined as a line connecting the points where the waters are 2500 meters deep.³² Franck concluded that, "The 1982 standard, despite its complexity is far more determinate than the elastic standard in the 1958 Convention, which, in a sense,

²⁶ Franck (1990), p. 238

Thomas M. Franck, 1995, Fairness in International Law and Institutions, Oxford Clarendon Press,
 Franck (1995), p. 481

²⁹ Franck (1990), p. 60

³⁰ Convention on the Continental Shelf, Art 1, April 29, 1958, 15 UST 471, TIAS No. 5578, 499 UNTS 311

³¹ United Nations Convention on the Law of the Sea, Art. 76, opened for signature Dec. 10, 1982, UN Doc. A/CONF.62/122, reprinted in United Nations, Official Text of the United Nations Convention of the Law of the Sea with Annexes and Index, UN Sales No. E. 83.V.5 (1983), 21 ILM 1261 (1982)

³² Franck (1988), p. 714

established no rule at all...Indeterminate normative standards not only made it harder to know what conformity is expected, but also make it easier to justify noncompliance" ³³

Franck has maintained that states are normally inclined to violate a rule of conduct to take advantage of sudden opportunity but this temptation may be checked if the rule is "sufficiently specific to support reasonable expectations that benefit can be derived in a contingent future by strengthening the rule in the present instance."³⁴

Franck gave an example of the cost of indeterminacy by the rules prohibiting and defining aggression by the United Nations General Assembly after 7 years of debate. While dealing with determinacy, Franck made another very pertinent point that "A clearly determinate treaty or custom may be rendered incoherent …by inconsistent state conduct…"³⁵

However, Franck did not confine his concept of determinacy within the situation, which happened to be 'essentially binary', or is applicable of a true-false test. In situations of exceptional complexity and ambiguity which normally happens in the case of international treaties, the ambiguities and the errors of interpretations can be resolved by a forum or fora which in its turn must have attributes of legitimacy.

Process determinacy is the situation where "ambiguity can be resolved case by case" through the introduction of a forum which can mitigate "the textual elasticity of the rule." However, the forum itself should be perceived as "having come into being in accordance with right process. In practice legitimacy of a forum can be tested in the same way as that of a rule: by reference to the determinacy of its charter, its pedigree, the coherence of its mandate and its adherence to the normative institutional hierarchy of international organization." Franck gave a number examples of situations where determinacy in specific conflict was introduced in the treaty through such fora³⁷.

This article will show that the TRIPS Agreement particularly Articles 1.1, 27 and 33 have used language, which has resulted in introduction of extreme forms of ambiguity and uncertainty in the TRIPS Agreement. This article further shows that an examination of the Panel and the Appellate Body Reports dealing with patenting and similar provisions suggests that these fora are creating significant problems in process determinacy and the results have been more adverse than useful especially for developing countries.

³³ Franck (1988), p. 714

³⁴ Franck (1988), p. 716

³⁵ Franck (1990), p. 238

³⁶ Franck, (1988) p. 725. Franck was quite categorical about the legitimacy of forum to arrive at process determinacy when he observed, "They (forums) will only succeed, however, if they are seen to be acting in accordance with their specific mandate and the general principles of fairness; that is, in a disinterested, principle fashion and not simply to gratify some short-term self-interest of a faction. Moreover, each rule decision emanating from legitimate forum is itself subject to the test of its perceived legitimacy; its determinacy, coherence, and so forth" p. 725

³⁷ Franck (1988) gave examples from Continental Shelf (Libyan Arab Jamahiriya/Malta), 1985 ICJ REP. 13, 30 31 (judgement of June 3), North Sea continental Shelf (FRG/Den.; FRG/Neth.), 1969 ICJ REP. 3, 54 (Judgement of Feb. 20), Continental Shelf (Tunisia/Libyan Arab Jamahiriya), 1982 ICJ REP. 18, 35 (Judgement of Feb. 24)

Symbolic Validation and legitimacy

Just like determinacy, symbolic validation, ritual and pedigree also influence voluntary obedience and pull to compliance. Symbolic validation, ritual and pedigree are related but not identical. Whereas symbolic validation uses certain cues for obedience, ritual is a specialized form of symbolic validation. Rituals are normally seen as ceremonies and provide unspoken basis for compliance pull like the oath of office sworn by the US President. In this article, rituals as a major force have not been adopted. However, the notion of pedigree is quite important for explaining the compliance pull of "rules or rulemaking institutions by emphasizing their historical origins, their cultural or anthropological deeprootedness." ³⁸. State recognition has been described by Franck as illustrating the importance of pedigree. Schachter has tried to emphasize the long lineage of rules such as codification practice followed by the International Law Commission after long deliberations as being more attractive for compliance than a fresh development.³⁵ Franck also suggested that a "new rule may be taken more seriously if it arrives on the scene under the aegis of a particularly venerable sponsor such as a widely ratified multilateral convention, or a virtually unanimous decision of the International Court of Justice.",40

In the context of the World Bank, Franck suggested that, "This equality of participation is itself the symbolic representation of a confluence between sovereignty and interdependence that holds together the "community" of states" Franck has subsequently developed the concept of pedigree as having its own rules and standards and that these standards provide a fairly high degree of formal determinacy prohibiting "self-serving interpretations". Franck also cautioned against the general acceptance of symbolic validation and pedigree in the context of compliance and asserted that the rituals themselves have to be legitimate and the standards for pedigreeing are applied coherently to give legitimacy to an international treaty.

This article argues that because of the way the TRIPS Agreement was prepared, the circumstances contemporaneous with its completion, and certain aspects of its treatment of questions related to patents, there are substantial problems associated with pedigree which does not attract compliance by the parties involved.

Coherence and Legitimacy

Coherence or symbolic equality creates "presumption against all purported interpretations of existing rules—and against proposed new rules—that would make arbitrary distinctions between the rights and duties of different states or governments". ⁴² Using the definition of coherence from Ronald Dworkin, that "a rule is coherent when like cases are

³⁸ Franck, (1988) p. 726

³⁹ Oscar Schachter, Towards a theory of International Obligation, 8 Vanderbilt Journal of International Law 300, 310 (1968)

Law, 300, 310 (1968) 40 Franck (1988) p. 727

⁴¹ Franck (1988), p. 731

⁴² Franck, 1988, p. 737

treated alike in application of the rule and when the rule relates in a principled fashion to other rules of the same system" 43, Franck noted that incoherence directly questions the effect of validity by undermining the standard, rules and processes used which in turn question the legitimacy of the institutions responsible for validating. Weiner while interpreting Franck's theory of legitimacy opined that incoherence leads to establishment of "cognitive dissonance in the audience to which it is addressed." ⁴⁴ Dworkin has used the word "integrity" or "consistency" which requires that a rule must be applied uniformly in every "similar" or "applicable" instance.

Franck has tried to identify another aspect of coherence, which he called the "underlying general principle" connecting rule, standard, or symbolic validation to a network of other rules. Franck concluded that "coherence mandates a connectedness between various component parts of a rule or code; between several applications of a rule in various instances; and between the general principles underlying a rule's application and those implicated in other rules."45

Franck further elaborated the role of coherence in his book 'The Power of Legitimacy Among Nations' and observed that coherence legitimates a rule, principle, or implementing institution because it provides a reasonable connection between a rule, or the application of a rule, to (1) its own principle purpose, (2) principles previously employed to solve similar problems, and (3) a lattice of principles in use to resolve different problems. 46 The given rule must be in certain harmony with the existing network of rules of which the present rule is a part.

This article argues that as a consequence of the introduction of certain provisions in TRIPS in the form of extending monopoly to import and extend and discriminatory extension of patent provisions, TRIPS severely compromises the extent to which its terms show some of the qualities of Franck's coherence. This article suggests that one reason TRIPS will not experience success in terms of its acceptability is that the TRIPS Agreement is, in the sense of Franck's theory, substantially illegitimate. Accordingly, this article concludes that if the TRIPS is to be treated as an internationally accepted agreement, a number of changes have to be introduced into the TRIPS Agreement

Adherence (to a Normative Hierarchy) and Community

The lack of crucial procedural "secondary" rules in the international legal system makes the whole system primitive if not illusory. Hart has also alleged that the lack of a "uniform rule of recognition" ⁴⁷ such as the U.S. Constitution or British Rule of Parliamentary Supremacy, and specific sources of law are a serious disqualification for an international legal system. Franck adopted Hart's concept of hierarchy of secondary

⁴³ R. Dworkin, Laws Empire, 176-224 (1986)

⁴⁴ Anthony S. Weiner, 'The CISG Convention and Thomas Franck's Theory of legitimacy', Journal of International Law & Business, Fall 1998, 19, p. 1, 22

⁵ Franck, 1988, p. 750

⁴⁶ Franck (1990), pp. 147-148

⁴⁷ Franck (1988) p. 752

rules starting from the "ultimate rule of recognition" ⁴⁸ corresponding to H.L.A. Hart's concept of a "rule of recognition" and going down to a "pyramid of secondary rules about how rules are made, interpreted and applied: rules, in other words, about rules." The primary rule of obligations without adherence to a system of secondary rules of process has been termed by Franck as nothing but ad hoc reciprocal arrangements. However, Franck observed that the international system is better developed than had been visualized by Hart and as shown by a number of institutions such as the International Court of Justice and the European Court of Justice and the presence of arbitrators that "it has an extensive network of horizontally coherent rules, rule making institutions, and judicial and quasi-judicial bodies to apply the rules impartially", 49. Franck has described the rule of ultimate recognition as having such extraordinary power so as to validate the primary rule of obligations as well as the secondary rule of procedural nature.

Palmeter has discussed Hart's ⁵⁰ primary and secondary rule concept in connection with the World Trade Organization as a Egal system although his interpretation appears to be little too simple. 51 However, Palmeter has used a very valid term "thickening of legality" coined by Professor Celso Lafer, former Ambassador and permanent Representative of Brazil to the WTO to denote the proliferation of rules in the WTO.⁵² According to Hart, the secondary rules specify the manner of conclusively ascertaining, introducing, eliminating, varying and determining the violations of primary rules. Although Hart has described three types of secondary rules, i.e. (1) rules of recognition, (2) rules of adjudication, and (3) rules of change, the rules of recognition are by Franck as the most important.

The ultimate rule of recognition is more in the nature of peremptory norms when Franck observed that, "Ultimate rules of recognition cannot be validated by reference to any other rule. All other secondary rules of the community are inferior to, and validated by, the ultimate rule or set of rules."53 If sovereignty resides in anything, it is in the rules themselves and States are aware of this "rule's autochthony" as illustrated by the advisory opinion rendered by the International Court of Justice (ICJ) on April 26, 1988. The ICJ stated unequivocally that it is "the fundamental principle of international law that it prevails over domestic law, "and that "the provisions of municipal law cannot prevail over those of a treaty."54

⁴⁸ Franck (1990) p. 184

⁴⁹ Franck (1988), p. 753

⁵⁰ H.L.A. Hart, The Concept of Law, Chapter 10, 2nd Edition, 1994

⁵¹ David Palmeter, 'The WTO as Legal System', Fordham International Law Journal, vol. 24, p. 444, 447 (2000) [hereinafter Palmeter (2000)]
⁵² Palmeter, 2000, p. 467

⁵³ Franck (1988), p. 754 Franck while looking for such ultimate rule did ask, "It is the nature of community, therefore, both to empower authority and to circumscribe it by an ultimate rule or set of rules of recognition that exists above, and itself is not circumscribed by, the system of normative authority. Does such a notion of community exist internationally, among states? Do nations recognize an ultimate rule or set of rules of recognition or process by which the legitimacy of all other international rules and procedures can be tested, a rule not itself to a higher normative test of its legitimacy, a rule that simply is, because it is accepted as font of the community's collective self-definition?", p. 754

1988 I.C.J. REP. 12, 34, para. 57 (Advisory Opinion of 26th April, 1988). The observer Mission of the

Palestine Liberation Organization was created by GA Res. 3237, 29 UN GAOR Supp. (No. 31) at 4, UN

In fact, Franck put the adherence as peremptory norms as described in Article 53 of the Vienna Convention on the Law of Treaties along with pacta sunt servanda, the good faith doctrine and the concept of primary and secondary rules as envisioned by Hart as important elements providing legitimacy to international treaty. State equality has been identified by Franck as an example of the ultimate rule of recognition.

Ultimately, Franck concluded that, "It is therefore circumstantially demonstrable that there are obligations that states acknowledge to be necessary incidents of community membership. These are not perceived to obligate because they have been accepted by the individual state but, rather, are rules in which states acquiesce as part of their own validation; that is, as an inseparable aspect of "joining" a community of states that is defined by its ultimate secondary rules of process."55

Franck used Dworkin's term "associative obligations" for secondary rules of recognition, which gets attached to all states because they are validated members of the international community. This is not consensual but is acquired by association. The true community has been defined by Dworkin where "the members accept that they are governed by common principles, not just by rules hammered out in political compromise...Members of a society of principle accept that their political rights and duties are not exhausted by the particular decisions their political institutions have reached, but depend, more generally, on the scheme of principles those decisions presuppose and endorse." ⁵⁷

Dworkin confirmed that what a community of principle, "does is to validate behavior in accordance with rules and applications of rules that confirm principled coherence and adherence, rather than acknowledging only power of power." The problems in defining and delineating a cohesive community of states by the TRIPS Agreement impair the development of this kind of adherence for its rules.

Doc. A/9631 (1974). The closure of the mission was required by the Anti-Terrorism Act of 1987, title X of the Foreign Relations Authorization Act, 1988 and 1989, Pub. L. No. 100-204, tit. X, s. 1001, 101 Stat. 1331, 1406 (codified at 22 U.S.C.A. s 5201-5203 (West Supp. 1988)

⁵⁵ Franck (1988) p. 758. Franck further observed, "It is even possible to conclude that the members of the global community acknowledge –for example-- each time they sign a treaty or recognize a new government—that statehood is incompatible with sovereignty. They acknowledge this because they must, so as to obtain and retain the advantages of belonging to an organized, sophisticated community, advantages only available if ultimate sovereignty resides in a set of rules of universal application. That is why states behave as if such rules existed and obligated" p. 758

⁵⁶ R. Dworkin, p. 196

⁵⁷ R. Dworkin, p. 211

⁵⁸ Franck (1988), p. 759

Compliance with TRIPS

The obedience to a rule is based on the perception by those to whom it is addressed as legitimate. ⁵⁹ Reichman⁶⁰, Reichman⁶¹, Gerhart⁶², Maskus ⁶³, Giust⁶⁴ among others have discussed in details the compliance of both developed and developing countries with TRIPS Agreement.

Two aspects of TRIPS, one, that it imposes a wholly positive obligations as compared to negative obligations and the other, that it is an international agreement which tests the ability of international law to influence private actors through obligations imposed on the state, are relevant for compliance scholarships.

Gerhart while discussing the 'substantive validity' that is "whether the obligation in question meets an articulated standard of welfare" tried to distinguish it from Franck's theory of legitimacy. According to Gerhart, "The literature of legitimacy looks at the process by which the international law is made and seeks to define the contours of processes that add to the moral weight and functional acceptability of international standards. The issue of substantive validity of a standard looks at the standard "on the merits" and asks whether the measure is, in fact merited" However, Gerhart immediately suggests that compliance issues are closely intertwined with issues of the substantive validity of international obligations.

Reichman appears to be of the view that the TRIPS Agreement is a revolutionary agreement where developed countries were able to impose "a comprehensive set of intellectual property standards on the rest of the world. As ultimately enacted, these were not 'minimum' standards of intellectual property protection in the classical sense of the term; rather, they collectively expressed most of standards of protection on which the developed countries could agree among themselves." According to Reichman, however, the TRIPS standards are "likely to impose heavy social costs on most developing countries in the short and medium terms, if only because these countries will now have to

⁵⁹ Franck (1988), "...in a community organized around rules, compliance is secured –to whatever degree it is-at least in part by perception of a rule as legitimate by those to whom it is addressed. Their legitimacy will vary in degree from rule to rule and time to time. It becomes a crucial factor, however, in the capacity of any rule to secure compliance when, as in the international system, there are no other compliance inducing mechanisms." (p. 706)

inducing mechanisms." (p. 706)

60 Jerome H. Reichman, 1998, 'Securing compliance with the TRIPS Agreement After US v India', Journal of International Economic Law (1998) p. 586-601

of International Economic Law (1998) p. 586-601

Gramman, 'The TRIPS Agreement comes of Age: Conflict or Cooperation with the Developing Countries', 32 Case Western Res. Journal Of International Law, p. 423-452 (2000)

⁶² Peter M. Gerhart, 'Reflections: Beyond Compliance Theory – TRIPS as a Substantive Issue', 32 Case Western Res. Journal of International Law, 393 (2000)

⁶³ Keith E. Maskus, (2000) Intellectual Property Rights and Economic Development, Case Western Reserve Journal Of International Law, Vol. 32, p. 471

⁶⁴ John E Giust, 1997, Noncompliance with TRIPS by Developed and Developing Countries: Is TRIPS Working?, Indiana International Law and Comparative Law Review, vol. 8, p. 69-97

⁶⁵ Gerhart (2000) p. 361

⁶⁶ Thomas M. Franck, (1995), Fairness in International Law and Institutions, Oxford, Clarendon Press

⁶⁷ Gerhart (2000) p. 362

⁶⁸ Reichman (1998) p.586

pay more in order to acquire the tools they need to overcome the technology gap."⁶⁹ Reichman appears to be advocating that imposition of the TRIPS Agreement was a justified act on the part of developed countries when he says that

"...a relentless series of questionnaires emanating from the WTO has sought to focus the attention of the Council for TRIPS on the state of play in the different member countries. The developing countries have also been subjected to overt and covert pressures for early implementation of the TRIPS Agreement, although it seems fair to observe that such pressures are not necessarily inconsistent with the short transitional period this Agreement makes available to developing countries-as distinct from least-developing countries."

Both developed and developing countries have been found wanting in enacting TRIPS compliant legislation. Giust has given examples from Ireland, the UK, the USA, and Japan from the developed countries and India from developing countries to show that some of the provisions in these countries were not in agreement with TRIPS. However, while giving examples, Giust does not appear to have shown deep critical approach while examining the issue of non-compliance of these countries with the TRIPS Agreement. In case of Ireland and the UK, the presence of 'local working was regarded as violative of Article 27.1 of TRIPS dealing with non-discrimination in enjoyability of patent rights with respect to technology, locally produced or imported and the place of inventions⁷¹ without realising that non-local working is an abuse of patent right under Article 5A(2) of the Paris Convention.

This article examines the extent of non-compliance of developed countries with TRIPS and the impossibility of developing countries to comply with the provisions of the TRIPS because of indeterminate nature of TRIPS provisions and the continuous changes in the interpretations by the judicial and non-judicial institutions in the USA and other developed countries. In case of the USA, Giust has mentioned the 35 U.S.C. s. 102 (e) and Section 337 of the Tariff Act of 1930 as not complying with the provisions of the TRIPS Agreement. Giust also discussed Section 337 of the US Tariff Act of 1930 which permits US companies to file a complaint at the United States ITC against a foreign company for infringing US companies intellectual property rights. Section 337

⁶⁹ Reichman (1998) p. 587.

⁷⁰ Reichman (1998) p. 593

⁷¹ Giust, (1997), pp. 86-87

Giust, 1997, pp. 87-88, "Even though the US Patent laws were amended by the Uruguay Round Agreements Act (URAA), the amendment left 35 U.S.C. 102(e) in place as interpreted in the two In re Hilmer decisions. In these decisions, the court held that a U.S. patent was available for prior art purposes, i.e. "filed" as of its U.S. filing date, but a U.S. patent based on a foreign Paris Convention application was not available for prior art purposes, i.e. was not "filed" as of its earlier international (Paris convention) filing date. This interpretation of 35 U.S.C. 102(e) has been criticized as incorrect and a violating national treatment in that equal treatment, for prior art purposes, is not given to U.S. patents based on foreign-filed patents. Despite the scholarly controversy, the United States has thus far successfully maintained that 35 U.S.C. 102 (e) is consistent with its obligations of national treatment under the Paris Convention and GATT. Barring some further event or the raising of the current level of scrutiny, it is likely that 102 (e) will continue to walk border of compliance and non-compliance with the TRIPS national treatment requirements."

authorizes the ITC (International Trade Commission of the USA) to issue a general exclusion orders that would exclude the importation of products manufactured by nonparties to the ITC investigation. In 1987, the European Economic Community requested a GATT dispute resolution with the United States. The GATT panel held that the United States did not afford national treatment to foreigners under Section 337.73 Certain superficial changes were made to section 337 through the Uruguay Round Agreement Act (URAA)⁷⁴ but in practice, Section 337 did not show much change.

Similar developments took place in Sections 301-310 of the Trade Act of 1974 of the USA. The Panel in *United States-Sections 301-310 of the Trade Act of 1974*⁷⁵ ruled that Section 304 of the US Patent Act violated Article 23 of the Dispute Settlement Understanding ⁷⁶. The Panel in *United States 301-310* observed:

"On this reading, the very discretion granted under Section 304, which under the US argument absolves the legislation, is what, in our eyes, creates the presumptive violation. The statutory language, which gives the USTR this discretion on its face, precludes the US from abiding by its obligations under the WTO. In each and every case when a determination is made whilst DSU proceedings are not yet exhausted. Members locked in a dispute with the United States will be subject to a mandatory determination by the USTR under a state which explicitly puts them in that very danger which Article 23 was intended to remove."77

Some of the important compliance issues have been analyzed by Daya Shanker⁷⁸ in 'India, Pharmaceutical Industry and the Validity of TRIPS' who expressed his doubt that the developing countries would ever be able to comply with the provisions of the TRIPS not only because of the text used in the TRIPS Agreement, but because of the attempt to continuously change the contours of TRIPS Agreement by judicial and non-judicial institutions in the developed countries which has made it nearly impossible for the developing countries to bring their Patent Acts in line with the obligations under TRIPS. Apart from non-compliance by the USA mentioned by Giust, Daya Shanker⁷⁹ has mentioned the absence of the requirement of invention in the US Patent Act which has been affirmed by the Court of Appeals in *State Street*⁸⁰ while extending patenting to

⁷³ GATT Panel Report on United States – Section 337 of the Tariff Act of 1990, L/6439-36S/345, 1989 GATTPD Lexis 2 (Nov. 7, 1989) (unpublished)

⁷⁴ URAA Title III, Subtitle C, 321 (amending Section 337)

⁷⁵ United States-Sections 301-310 of the Trade Act of 1974, WTO Doc WT/DS152/R dated 22 December

⁷⁶ Annex 2 of The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts-Understanding on Rules and Procedures Governing the Settlement of Disputes [hereinafter Understanding] ⁷⁷ WTO 1999, Panel Report in United States-Sections 301-310 of the Trade Act of 1974, WT/DS152/R dated 22 December 1999

78 Daya Shanker, India, Pharmaceutical Industry and the Validity of TRIPS, Working Paper, Department

of Economics, University of Wollongong, Australia (2001). The paper is available in SSRN Journals at SSRN ID295384 code011231510.pdf [hereinafter Daya Shanker-India, Pharmaceutical Industry and the Validity of TRIPS (2001)] An edited version is forthcoming.

79 Daya Shanker – 'India, Pharmaceutical Industry and the Validity of TRIPS' (2001)

⁸⁰ State Street Bank & Trust Co. v. Signature Financial Group, 149 F. 3d 1368 (Fed. Circuit. 1998)

business methods, as a very crucial mn-compliance of the TRIPS Agreement by a major proponent of TRIPS. Article 27.1 of TRIPS makes it clear makes that "Subject to the provisions of Article 2 and 3, patents shall be available for any inventions, whether products or processes in all fields of technology provided that they are new involve an inventive step and are capable of industrial application." Note 5 of the TRIPS Agreement relating to Article 27.1 of TRIPS accommodates to some extent the position of the USA by deeming "inventive step" as 'non-obvious' and "capable of industrial application" as "useful" but the requirement for invention has not been waived by TRIPS Article 27.

In fact, in the 'Communication from the United States to the Negotiating Group on Trade-Related Aspects of Intellectual property Rights, including Trade in Counterfeit Goods' dated 11th May 1990, the USA did not use the word invention. ⁸¹ The USA Patent Act is in breach of the TRIPS Agreement. Similarly Sections 204⁸² and 209⁸³ of the US Patent Act requiring that the patents developed with the help of the US government finance has to be used for manufacturing the said patented product in the USA, is in violation of the non-discrimination stipulation of Article 27 which enjoins that there shall be no discrimination in enjoyability of patent rights regarding place of invention and whether products are imported or locally produced. Similarly, the Bolar Exemption⁸⁴ giving extension to the patents for pharmaceutical products and which has been an issue in the dispute between Canada and the EC⁸⁵ would be violative of Article 30 of TRIPS in terms of the interpretation given by the Panel in its Report on Canada-Patent Protection⁸⁶. The extension of patents given to pharmaceutical products by the EC⁸⁷, Australia⁸⁸,

⁸¹ MTN.GNG/NG11/W/70 dated 11 May 1990, Article 23 Patentable Subject Matter "Patents shall be

granted for all products and processes, which are new, useful, and unobvious."

82 35 U.S.C.Sec. 204, "Preference for United States Industry: Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirements for such an agreement can be waived by the Federal Agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

Restriction on Licensing of Federally owned inventions (a) No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development and/or marketing of the invention, except that any such plan may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States code. (b) A Federal agency shall normally grant the right to use or sell any federally owned invention in the United States only to a licensee that agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

Bolar Exemption 35 U.S.C. 271 (e)

⁸⁵ Canada-Patent Protection of Pharmaceutical Products Panel Report, WTO Doc. WT/DS114/R dated 17.3.2000 [hereinafter Canada-Patent Protection]

86 In the later part of this article, the incongruity of Canada-Pharmaceuticals with 'customary rules of

interpretation of public international law' has been discussed.

⁸⁷ Special Protection Certificate giving extension up to five years to pharmaceutical products

Israel⁸⁹, Japan⁹⁰, and the USA⁹¹ are provisions violating the non-discrimination stipulation of Article 27.1 of TRIPS.

One of the disconcerting parts of this development is that proposals for extension of patent period in situations invoking regulatory approval has been attempted to be introduced through the use of Dispute Settlement System of the WTO by both the USA⁹² and the EC⁹³ apart from Switzerland and Austria after this proposal had not been agreed to in the final draft of the TRIPS Agreement. Similar provisions were part of the negotiations in NAFTA and are present in the Final Agreement. 94

Another example is the removal of 'local working' from the UK Patent Act and the European Patent Convention as late as 29th July 1999. Before the amendment of the UK Patent Act in July 1999, the 'local working' provisions in Section 48(3) in the UK Patent Act read as

- "(a) Where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being so worked to the fullest extent that is reasonably practicable; (b) Where the patented invention is a product, that a demand for the product in the United Kingdom-
 - (i) is being met to a substantial extent by importation

⁹² MTN.GNG/NG11/W/70 dated 11th May 1990, Article 25 Term of Protection "The term of protection shall be at least 20 years from the date of filing of the application. Contracting parties are encouraged to extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes.

MTN.GNG/NG11/W/68 dated 29th March 1990, Article 25 Term of Protection "The term of protection" made available shall be at least 20 years from the date of filling of the application. Contracting parties are encouraged to extend the term of patent protection, in appropriate cases, to compensate for delays by regulatory approval processes.

Article 1709(12) of the North American Free-Trade Agreement, which was similarly based on the Dunkel Text, expressly says

"Each party shall provide a term of protection for patents of alt least 20 years from the date of filing or 17 years from the date of grant. A party may extend t term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval."

⁸⁸ The Intellectual Property Laws Amendment Act 1998 amended the Australian Patents Act 1990 to give effect to the government's decision to provide for an extension of term scheme for pharmaceutical patents. The amendments entered into force on 27th January 1999 and provide that an extension of up to five years will be available for a standard patent relating to a pharmaceutical subsistence that is the subject of first inclusion on the Australian Register of Therapeutic Goods. The scheme will apply to all existing 20 years patents, as well as those patents granted after the commencement date -Extracts from the Explanatory Memorandum to the Intellectual Property Laws Amendment Act 1998.

⁸⁹ Israel Patent Act permits permission of extension

⁹⁰ Section 67(2) of the Japanese Patent Act: The term of the Patent right may be extended, upon application for registration of an extension, by a period not exceeding five years if, because of the necessity of obtaining an approval or other disposition which is governed by provisions in laws intended to ensure safety, etc. in the working of the patented inventions, and which is provided for in the Cabinet order being such that, in view of the object of the relevant disposition, proceedings, etc., a considerable period of time is required for the proper action for the disposition, it was not possible to work the patented invention for two years.
91 35 U.S.C. s. 156

- (c) Where the patented invention is capable of being commercially worked in the United Kingdom, that it is being prevented or hindered from being so worked-
 - (i) where the invention is a product, by the importation of the product"

The UK High court (Chancery Division-Pates Court) justified the provision in *Extrude Hone v. Heathway Machine Sales* ⁹⁵ by observing

"The grant of a compulsory license is plainly not in terms a qualitative restriction. Nor is it, in my view, a measure having equivalent effect. It is, however, calculated to encourage competition and is entirely in accord with the general concept of the Treaty [Treaty of Rome]"

This provision stayed in the UK Patent Act till 29th July 1999 in spite of adverse comment by the European court of Justice in *Smith-Kline and French Laboratories v. Generics* ⁹⁶. The provision was compatible with Article 5A(2) of the Paris Convention which through incorporation in the TRIPS Agreement vide Article 2.1 and Article 2.2 became an integral part of the WTO ⁹⁸ and as per Article 2.2 of TRIPS, the provisions of Article 5A(2) of the Paris Convention cannot be affected by another provision in Parts I to IV of the TRIPS Agreement. ⁹⁹ A provision which was perfectly compatible with the TRIPS Agreement was modified after more than four years ostensibly to bring it into line with the TRIPS obligations through The Patents and Trade Marks (World Trade Organization) Regulation 1999. As per the EC in *Canada-Patent Protection*, Article 63 does not permit presence of non-compatible provisions in the developed countries' Patent Acts such as the United Kingdom's after 1st January 1996. Further developments such as the United States move against Brazil in the WTO clearly indicate that the purpose of this

⁹⁶ Smith-Kline and French Laboratories v. Generics, [1990] 1 CMLR 416, [1990] RPC 203

⁹⁵ Extrude Hone v. Heathway Machine Sales,[1981] 3 CMLR 379 at 404-5

Paris Convention for the Protection of Industrial Property, March 20, 1883, as last revised at Stockton,
 July 14, 1967, 25 Stat. 1372, 828 U.N.T.S. 305 [hereinafter Paris Convention]
 WTO 2002, United States – Section 211 Omnibus Appropriations Act of 1998, Report of the Appellate

⁹⁸ WTO 2002, United States – Section 211 Omnibus Appropriations Act of 1998, Report of the Appellate Body, WT/DS176/AB/R dated 7.1. 2002, paras 124 and 125. It says

[&]quot;Para 124: Article 2.1 of the TRIPS Agreement provides that "[I]n respect of Parts II, III and IV of this Agreement, Members shall comply with Article 1 through 12, and Article 19, of the Paris convention (1967)." Thus Article 6quinquies of the Paris Convention (1967), have been incorporated by references into the TRIPS Agreement and thus, the WTO Agreement.

Para 125: Consequently, WTO Members, whether they are countries of the Paris Union or not, are obliged, under the WTO Agreement, to implement those provisions of the Paris Convention (1967) that are incorporated into the TRIPS Agreement. AS we have already stated, Article 6quinquies of the Paris Convention (1967) is one such provision."

⁹⁹ Article 2.2 of the TRIPS Agreement says "Nothing in Parts Ito IV of this Agreement shall derogate from existing obligations that members may have to each other under the Paris Convention, the Berne Convention, the Rome convention and the Treaty on Intellectual Property in respect of Integrated Circuits". Daya Shanker in 'Brazil, the Pharmaceutical Industry and the WTO' analyzed the compatibility of 'local working' in connection with the US complaint against Brazil regarding the presence of 'local working' in Brazil's Patent Act. He has also analyzed presence of 'local working' in proposed Indian 2nd Amendment Bill, 1999 to bring the Indian Patent Act in line with the TRIPS obligations in 'India, Pharmaceutical Industry and the Validity of TRIPS'.

amendment was to bring changes in the TRIPS Agreement which the parties didn't arrive at during the Uruguay Round negotiations ¹⁰⁰.

Comparative Legitimacy of TRIPS Agreement

Indeterminacy and TRIPS

Reichman¹⁰¹ is of the view that the TRIPS Agreement is largely indeterminate i.e. the TRIPS Agreement contains standards which are neither clear nor unambiguous and the language is undefined. Gerhart¹⁰² even suggests that the Panel Report in Canada-Patent Protection of Pharmaceutical Patents¹⁰³ allowing imitators to manufacture patented products before expiry of the patent term also introduced indeterminacy. Gerhart ¹⁰⁴ found that the Article 27 provision that a country must grant patents to inventions that are "new, involve an inventive step and are capable of industrial application" is ambiguous as none of these terms were defined nor were meanings completely harmonized.

Gerhart wondered whether their meanings would be attempted to be derived by blending the various concepts from state patent statutes or how far a particular state may deviate from the normal meaning of these terms and still stay in conformity with the TRIPS. Reichman also questioned the role of exceptions in patenting and copyright and Article 6 of TRIPS which permits different regimes in exhaustion of patent rights. The freedom of use of tax and competition policy to restrict intellectual property rights also leaves states free to impair the rights. However, the majority of the points raised by Reichman are pertaining to looking at indeterminacy from the point of view of industry associations such as PhRMA in developed countries. The question of indeterminacy has been dealt with by Daya Shanker in his article "India, Pharmaceutical Industry and the Validity of TRIPS"¹⁰⁵ where he has analyzed indeterminacy in its various forms such as uncertainty, vagueness and malleability.

The major indeterminacy comes from the text of the TRIPS Agreement itself. A badly worded Article 1.1 saying that "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 doesn't contravene the provisions of this Agreement' initiates the indeterminacy leaving practically no control over such extensions of protection except

¹⁰⁰ Brazil – Measures Affecting Patent Protection: Request for the Establishment of a Panel by the United States, WTO Doc. WT/DS199/3 dated 9th January. Daya Shanker, 'Brazil, the Pharmaceutical Industry and the WTO' 5 The Journal of World Intellectual Property January No. 1 (2002) has discussed this issue in detail.

¹⁰¹ Reichman (2000), 439

Gerhart, 2000, n. 59, p. 380 "Even here, ambiguity is present. SEE Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R, Report of the Panel (March 17, 2000) (indicating that the TRIPS obligation to have a twenty year patent term is not violated by allowing imitators to manufacture the drug and apply for regulatory approval before the twenty years is up, but that obligation is violated by allowing imitators to stockpile generic drugs for sale after the twenty year period is over)

¹⁰³ Canada-Patent Protection of Pharmaceutical Products, Report of the Panel, WTO Doc. WT/DS114/R dated 17th March 2000 104 Gerhart 2000, p. 380

¹⁰⁵ Daya Shanker 'India, Pharmaceutical Industry and the validity of TRIPS' (2001)

Article 27.1 stipulating no discrimination between any field of technology, place of invention and whether products are imported or locally produced. However, even this interpretation has been questioned by the EC when in *Canada-Patent Protection*, it insisted that the non-discrimination clause is not applicable to the extensions of protection 106. Every extension of protection is bound to increase the trade protection particularly for patented products which specifically bans import of the patented products through inclusion of word 'import' in Article 28 of the TRIPS Agreement. This is followed by Article 6 of the TRIPS introduced at the instance of developed countries 107 permitting bans on parallel imports by individual countries or regional groups such as the EC against the international commercial norms of exhaustion of rights on sale.

Articles 27.2 and 27.3 of the TRIPS use the term "Members may" regarding exclusion of "inventions to protect human, animal or plant life or health or to avoid serious prejudice to the environment" and "diagnostic, therapeutic and surgical methods for treatment of human or animals" but "may" can be argued as "shall" in certain circumstances but following the textual approach "may" permits all the subject matter mentioned in Articles 27.2 and 27.3 to be patentable subject matter. Article 33 of the TRIPS Agreement dealing with terms of protection is similarly worded. It permits unlimited protection when it says "The term of protection available shall not end before the expiration of a period of twenty years from the filing date" which permits no fixed term of protection and a patent may be extended for any period with its monopolistic rent seeking consequences as happened in the case of pharmaceutical products and extension of copyright period in the USA.

Reichman's ¹⁰⁹ indeterminacy conception of TRIPS was mostly confined to exceptions under Article 30 and 31 of the TRIPS. Exceptions normally don't introduce indeterminacy but the permission to extend protection without any limit in terms of patentability of the subject matter and unlimited extension of term of patents fundamentally changes the concept of TRIPS and raises questions about its validity. Even the smallest increase in the term of protection is an increase in the trade protectionism, a concept totally antithetical to the free trade and the Most Favored Nation Treatment on the basis of which the whole of WTO structure was erected.

Franck has also discussed the introduction of indeterminacy in a treaty through the "inconsistent state conduct". The concept of "inconsistent state conduct" has been analyzed by Daya Shanker¹¹⁰. In brief, the extension of patenting to 'Bus iness Methods' and 'computer programs' on the basis of a flawed interpretation of superior judicial decisions, the direction by the European Patent Office to change the term computer programs into computer inventions, removal of 'local working' from the UK Patent Act through the introduction of The Patents and Trade Marks (World Trade Organization) Regulations 1999 in the UK Patent Act are some of the examples where the "inconsistent state conduct" has introduced indeterminacy in the TRIPS Agreement.

 $^{^{106}}$ Canada-Patent Protection of Pharmaceutical Products, Report of the Panel WTO Doc. WT/DS114/R dated $17^{\rm th}$ March 2000, Note 146

Trips and Pharmaceutical Patents, Fact Sheet, WTO OMC, April 2001

The TRIPS Agreement, Article 27.2 and 27.3

¹⁰⁹ Reichman, 2000, p. 439

Daya Shanker, 'India, Pharmaceutical Industry and the Validity of TRIPS', (2001)

Process Determinacy and DSU

The Panel in *United States Sections 301-310* was quite categorical in stating the importance of determinacy when it observed

"What are the objects and purposes of the DSU¹¹¹, and the WTO more generally, that are relevant to a construction of Article 23? The most relevant in our view are those which relate to the creation of market conditions conducive to individual economic activity in national and global markets and to the provision of a secure and predictable multilateral trading system." ¹¹²

Article 3.2 of the DSU is one of the main instruments, which has aptly described the purpose of the dispute settlement system of the WTO as providing security and predictability. 113

The Panel in *United States Sections 301-310* observed that after creation of free market conditions, the central element of the WTO was to provide "security and predictability to the multilateral trading system" ¹¹⁴ A large number of Appellate Body decisions such as the Appellate Body Report on Japan-Alcoholic Beverages¹¹⁵.

No doubt the Panel is to follow the judicial economy but at the same time "the basic aim of dispute settlement in the WTO is to settle disputes... we do not consider that Article 3.2 of the DSU is meant to encourage either panels or the Appellate Body to make law by clarifying existing provisions of the WTO Agreement outside the context of resolving a particular dispute. As panel need only to consider those claims which must be addressed in order to resolve the matter in issue in the dispute."

Annex 2 – Understanding on Rules and Procedures Governing the Settlement of Disputes of Legal Text [hereinafter DSU]

[[]hereinafter DSU] ¹¹² *United States-Sections 301-310 of the Trade Act of 1974*, WTO Doc. WT/DS152/R dated 22 December 1999, p. 320-321 [hereinafter United States 301 – 310]

Article 3.2 of the DSU provides

[&]quot;The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The members recognize that it serves to preserve the rights and obligations of Members under the covered agreements..."

114 The Panel in *United States 301-310* observed "Providing security and predictability to the multilateral

trading system is another central object and purpose of the system which could be instrumental to achieving the broad objective of the Preamble. Of all WTO disciplines, the DSU is one of the most important instruments to protect the security and predictability of the multilateral trading system and through it that of the market-place and its different operators. DSU provisions must, thus, be interpreted in the light of this object and purpose and in a manner, which would most effectively enhance it. In this respect we are referring not only to preambular language but also to positive law provisions in the DSU itself." p.321 Japanese Alcoholic Beverages, WT/AB..., "WTO rules are reliable, comprehensible and enforceable.

WT rules are not so rigid or so inflexible as not to leave room for reasoned judgements in confronting the endless and ever-changing ebb and flow of real facts in real cases in the real world. They will serve the multilateral trading system best if they are interpreted with that in mind. In that way, we will achieve the 'security and predictability' sought for the multilateral trading system by the Members of the WTO through the establishment of the dispute settlement system" p. 31

¹¹⁶ WT/DS33/AB/R of 25th April 1997

Similarly in India-Patent Protection for Pharmaceutical and Agricultural Chemical Products ¹¹⁷, where the Appellate Body observed, "India is obliged, by Article 70.8(a), to provide a legal mechanism for the filing of mailbox applications that provides a sound legal basis to preserve both the novelty of the inventions and the priority of the applications as of the relevant filing and priority dates". There are a number of other Panel and GATT Reports also which recognize importance of security and predictability as an object and purpose of the Dispute Settlement System and the WTO¹¹⁸

However, in spite of the fact that the dispute settlement system is supposed to provide "security and predictability" to the multilateral trading system, in this case the TRIPS Agreement, as consistently maintained by the Appellate bodies and the Panel Reports, the constitution and the performances of the Dispute Settlement Bodies such as the Panels and the Appellate Bodies do not inspire much confidence in their ability to introduce certainty and predictability. Franck has maintained that the bodies responsible for process determinacy themselves should have the character of being legitimate. The constitution of the Panel lacks the most vital element that its members should have judicial competence or judicial experience. Article 8 of the DSU¹¹⁹ dealing with 'Composition of Panels' says "Panels shall be composed of well-qualified governmental or non-governmental individuals, including persons who have served on or presented a case to a panel, served as a representative of a Member or of a contracting party to GATT 1947 or as a representative to the Council or Committee of any covered agreement or its predecessor agreement or in the Secretariat, taught or published on international trade law or policy, or served as a senior trade policy official of a Member."

Not even one group mentioned in Article 8 of the *Understanding* is supposed to have a judicial experience or judicial competence and the overall emphasis is essentially on the trade officials who have participated in the negotiations. The concept of unbiased nonpartisanship approach, a primary requirement for members of any institution given the responsibility of interpreting a law in case of conflict between the nations is an anachronism to the groups qualified to become members of a Panel in Dispute Settlement System of the WTO. The governmental officials who appear to form the backbone of the DSU Panel invariably suffer from certain biases, a sense of insecurity and the ignorance of judicial approach.

Non-transparency in the dispute settlement proceedings is another crucial issue. Prof. Bhala while discussing the role of 'stare decisis' in the WTO adjudication observed that, 'The fact that public cannot attend oral arguments, that submissions must be kept secret,

¹¹⁷ India-Patent Protection for Pharmaceutical Products, WTO Doc. WT/ DS50/AB/R dated 19th December 1997, para. 58

WTO Panel Report on Argentina- Textiles and Apparel (US), op. Cit., para. 6.29 and the GATT Panel Reports on United States Manufacturing Clause, adopted 15/16 May 1984, BISD 31S/74, para. 39; Japan – Measures on Imports of Leather ("Japan – Leather"), adopted 15/16 May 1984, BISD31S/94, para. 55; EEC - Imports of Newsprint, adopted November 20 1984, BISD 31S/114, para. 52; Norway - Restrictions on Imports of Apples and Pears, adopted 22 June 1989, BISD 36S/306, para. 5.6

119 Annex 2 – Understanding on Rules and Procedures Governing the Settlement of Disputes of Legal Text

and that they would not be accepted at all from NGOs or individuals is harder to justify to the Anglo-American legal mind, 120.

An examination of the Panel and the Appellate Body Reports dealing with TRIPS conflicts show that the performance of the Panels and the Appellate Bodies has not been appropriate and at times, the Panel Reports and the Appellate Body reports have added more to the unpredictability and uncertainty already present in the text of TRIPS through injudicious, incoherent and at times contradictory decisions.

The important Panel and Appellate Body Reports dealing with TRIPS issues are India-Patent Protection for Pharmaceutical and Agricultural Chemical Products¹²¹, Canada – Patent Protection of Pharmaceutical Products¹²², United States – Section 211 Omnibus Appropriations Act of 1998¹²³, United States – Section 110(5) of the US Copyright Act¹²⁴ and a Panel Report in *United States – Sections 301-310 of the Trade Act of 1974*¹²⁵ which is related to the 'Special 301' with the ostensible purpose of threatening the countries with unilateral action by the USA although that country may not be violating any of the provisions of the TRIPS Agreement. There are two more Panel reports dealing with TRIPS issues, one is Canada-Term of Protection¹²⁶ and another Indonesian Automobile¹²⁷ with some argument pertaining to TRIPS. This article will mostly be dealing with the reports pertaining to patent provisions as they are some of the most controversial reports with a wide repercussions. United States – Section 110(5) of the US Copyright Act ¹²⁸ is of little consequence in terms of its impact although the interest of the Irish Rights Performing Organization against this provision of the US Copyright Law, on whose behalf the EC initiated the dispute resolution proceedings against the US exceptions can be questionable.

In India-Patent Protection¹²⁹, the issue was a minor one dealing with establishment of a mechanism under Article 70.8 of the TRIPS Agreement "by which application for patents

¹²⁰ Raj Bhala, The Power of the Past: Towards De Jure Stare Decisis in WTO Adjudication (Part Three of a trilogy), 33 George Washington International Law Review, p. 873, 944 (2001). Bhala also questioned the reasoning process of panels and the Appellate Body and observed that it 'is not as transparent as it might

¹²¹ India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, Report of the Appellate body, WTO Doc. WT/DS50/AB/R dated 19th December 1997

Canada – Patent Protection of Pharmaceutical Products, Report of the Panel, WTO Doc. WT/DS114/R dated 9th March 2000 ¹²³ *United States – Section 211 Omnibus Appropriations Act of 1998*, Report of the Appellate Body, WTO

Doc. WT/DS 176/AB/R January 2002

124 United States – Section 110(5) of the US Copyright Act, Report of the Panel, WTO Doc. WT/DS160/R

dated 15th June 2000 ¹²⁵ *United States – Sections 301-310 of the Trade Act 1974*, Report of the Panel, WT/DS152/R dated 22

December 1999

¹²⁶ Canada-term of Patent Protection, Report of the Appellate Body, WTO Doc. WT/DS170/AB/R dated

^{18&}lt;sup>th</sup> September 2000
¹²⁷ Indonesia – Certain Measures Affecting Automobile Industry, Report of the Panel, WTO Doc. WT/DS54/R, WT/DS55/R, WT/DS59/R and WT/DS64/R dated 2nd July 1998

¹²⁸ United States – Section 110(5) of the US Copyright Act, Report of the Panel, WTO Doc. WT/DS160/R dated 15th June 2000 ¹²⁹ For the purpose of this article, the analysis is confined to Appellate Body Report where it is available.

for such inventions (pharmaceutical and agricultural chemical) can be filed" to preserve novelty of the inventions and the priority of the applications as of the relevant filing and priority dates. Any action on these application is to be taken only after 1 January 2005. India issued "administrative instructions" for this purpose which has been labeled as 'mail box' system. The Panel and the Appellate Body in this dispute found that because the Indian Patent Act had certain provisions which were not required to be changed till 1st January 2005, these provisions may undermine "the administrative instructions" and would not provide a "sound legal basis" 130. The sections of the Indian Patent Act found offensive by the Panel and the Appellate Body were

- (a) substances intended for use, or capable of being used, as food or as medicines or drug are not patentable
- (b) When the complete specification has been led in respect of an application for a patent, section 12(1) of the Indian Patent Act requires the Controller to refer that application and that specification to an examiner
- (c) Section 15(2) of the Indian Patent Act states that the Controller "shall refuse" an application in respect of substance that is not patentable.

None of these provisions were required to be changed and all that was required was "to provide a means" essentially to get the priority date. It is never required that it has to be "sound legal basis" and that this "sound legal basis" can come only from the Indian Parliament.

However, subsequent examination of the Panel and Appellate Body Reports in *United States – Sections 301-310*¹³² and *United States – Section 211 Omnibus Appropriation Act of 1998* suggests a different approach.

In *United States* -301-310, the Panel after observing that, "The risk of a unilateral determination of inconsistency as found in the statutory language of Section 304 itself has an equally apparent "chilling effect" on both members and the market-place even if is not quite certain that such a determination would be made" found Section 304 inconsistent with Article 23.

¹³⁰ India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, Report of the Appellate Body, WTO Doc. WT/DS50/AB/R dated 19th December 1997, para 56. The Appellate Body confirmed the Panel's observation that, "...in order to prevent the loss of novelty of an invention...filing and priority dates need to have a sound legal basis if the provisions of Article 70.8 are to fulfil their purpose.

¹³¹ Ibid, paras 59, 70 and 71

¹³² WTO 1999: United States - Sections 301-310 of the Trade Act of 1974, WT/DS152 R dated 22 December 1999, ""Therefore, pursuant to our examination of text, context and object-and-purpose of Article 23.2(a) we find, at least prima facie, that the statutory language of Section 304 precludes compliance with Article 23.2(a). This is so because of the nature of the obligations under Article 23. Under Article 23 the US promised to have recourse to and abide by the DSU rules and procedures, specifically not to resort to unilateral measures referred to in Article 23.2(a). In Section 304, in contrast, the US statutorily reserves the right to do so. In our view, because of that, the statutory language of Section 304 constitute a prima facie violation of article 23.2(a) para. 7.97

However, the Panel after concluding that the "statutory language of Section 304 constitute a serious threat that determinations contrary to Article 23.2(a) may be taken and in the circumstances of this case, is prima facie inconsistent with Article 23.2(a) read in the light in of Article 23.1" concluded "that this threat had been removed by the aggregate effect of the SAA (Statement of Administrative Action) and the US statements before this Panel in a way that also removes the *prima facie* inconsistency and fulfils the guarantees incumbent on the US under Article 23."¹³³

This acceptance of the US Statement of Administrative Action (SAA) which accompanied the US legislation implementing the results of the Uruguay Round submitted by the President to the US Congress did not suggest need for 'sound legal basis'. The Statement of Administrative Action was accepted in spite of Section 102(a) of the US Uruguay Round Agreements Act 1994 says that

- "(1) UNITTED STATES LAW TO PREVAIL IN CONFLICT. No provision in any of the Uruguay Round Agreements, nor the application of any such provision to any person or circumstance, that is inconsistent with any law of the United States shall have effect.

 (2) CONSTRUCTION. Nothing in this Act shall be construed -...
- (B) to limit any authority conferred under any law of the United States, including section 301 of the Trade Act of 1974 unless specifically provided for in this Act".

It is difficult to reconcile this part of the US Uruguay Round Act with 'sound legal basis' provided by Statement of Administrative Action regarded consistency of Sections 301-310 with the provisions of the WTO particularly when the Panel found them *prima facie* inconsistent.

In fact, President's Statement of Administrative Action also said that "other areas of United States Intellectual property law are unaffected by the Agreement on TRIPS. For example, the Agreement does not require any change in current United States law or practice with respect the parallel importation of goods that are the subject of intellectual property rights." ¹³⁴ It did not prevent the USA from disputing Brazil's parallel import provision, which is similar to US practice before the WTO¹³⁵.

Similar ambiguities from the Dispute Settlement Bodies' decisions have been noticed in *United States – Section 211* where Section 211[a](2) saying "No U.S. court shall recognize, enforce or otherwise validate any assertion of rights by a designated national based on common law rights or registration obtained under such section 515.527 of such a confiscated mark, trade name, or commercial name."

¹³³ United States – Sections 301-310 of the Trade Act of 1974, WTO Doc. WT/DS152/R dated 22 December 1999, para 7.131

December 1999, para 7.131

Message from the President of the United States Transmitting the Uruguay Round Trade Agreements,
Texts of Agreements Implementing Bill, Statement of Administrative Action and Required Supporting
Statements, H.R. Doc No. 316, 103d Cong., 2d Sess. (1994) at 990-91, reprinted in 1994 U.S.C.C.A.N.

¹³⁵ Daya Shanker, 'Brazil, the Pharmaceutical Industry and the WTO, (2002)

Both Sections 211[a](2) and 211[b] denying access to judicial forums violate Article 42 of TRIPS ¹³⁶.

The Appellate Body in this case observed, "Civil judicial procedures would not be fair and equitable if access to courts were not given to both complainants and defendants who purport to be owners of an intellectual property right." ¹³⁷

Notwithstanding the text of the law of Section 211[a](2) and 211[b] expressly prohibiting access of courts to designated national, the Panel and the Appellate Body accepted the assertion of the US representative that the Federal Rules of Civil Procedures and the Federal Rules of Evidence would be available and "after applying the Federal Rules of Civil Procedure and the Federal Rules of Evidence, that an enforcement proceedings has failed to establish ownership – a requirement of substantive law – with the result that it is impossible for the court to rule in favor of that claimant's or that defendant's claim to a trademark right, does not constitute a violation of Article 42."¹³⁸

The net meaning of such interpretation by the Appellate Body would be that Sections 211(a)(2) and (b) are superfluous sections as people who do not have ownership of the intellectual property *prima facie* do not have a right to move the court. Alternatively, the provisions of Sections 211(a)(2) and (b) expressly prohibit designated nationals access to the court. Whatever the interpretation, the "sound legal basis" does not appear to be present anywhere in this case.

The last relevant Panel Report with very wide repercussions is that of *Canada-Patent Protection of Pharmaceutical Products*¹³⁹ which has been analyzed by Daya Shanker ¹⁴⁰ in a number of his articles in view of the excessive constructionism indulged in by the Panel in concluding that Article 27.1 would be applicable to Article 30 dealing with exceptions in the TRIPS Agreement. The analysis of this Panel Report suggests that the arguments of the parties and the conclusion of the Panel ignored the 'customary rules of interpretation of public international law' as developed and applied by various Appellate Bodies of the DSU and the main finding of application of Article 27.1 to exception under Article 30 was based on Canada's acknowledged point that Article 27.1 would be

¹³⁶ Article 42 of the TRIPS Agreement says, "Members shall make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement...All parties to such procedures shall be duly entitled to substantiate their claims and to present all relevant evidence...."

evidence...."

137 United States – Section 211 Omnibus Appropriations Act of 1998, Appellate Body Report, WTO Doc. WT/DS176/AB/R, para 217

¹³⁸ United States – Section 211 Omnibus Appropriations Act of 1998, WTO Doc. WT/DS176/AB/R dated 2.1.2002 adopted on 1st February 2002, paras. 225 and 227

¹³⁹ Canada – Patent Protection of Pharmaceutical Products, WTO Doc. WT/DS114/R dated 17th March 2000

¹⁴⁰ Daya Shanker, 'Brazil, Pharmaceutical Industry and the WTO' (2002), 'India, Pharmaceutical Industry and the Validity of TRIPS' (2001) and The Vienna Convention on the Law of Treaties, The Dispute Settlement System of the WTO, Canada-Pharmaceutical Report and the Doha Declaration on the TRIPS (2002), supra note 140.

applicable to Article 31 and not on uninterested examination of facts and rules. 141 The argument of the EC and the acceptance of this argument by the Panel that objective under Article 7 and purpose under Article 8, do not have any role in the interpretation led the Council of Ministers at Doha to resort to Article IX of the Marrakesh Agreement for the first time since the formation of the WTO to give the interpretation that

"In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreements as expressed, in particular, in its objectives and principles." ¹⁴²

The Panel while accepting the consistency of Canada's Section 55.2(1) of its Patent Act with Article 30 of TRIPS relied on the representations of Canada that products manufactured during the 6 months period would not be sold for profit. 143 Similar acceptance of the Panel's report has been made by the Panel in US-Sections 301-310 where the Panel accepted the representations of the USA as to the manner in which the United States would interpret the measure at issue. However, similar consideration was not shown to India, in India - Patent Protection where the panel, as upheld by the Appellate Body, refused to accept representations made by the Indian Government as to the operation of its patent system and commitments/pledges by the Indian government that it would implement its system in conformity with its WTO obligations.

Weiler while discussing the legitimacy of the WTO Dispute Settlement System questioned the extraordinary influence of the WTO Secretariat on the Panel and Appellate Body Reports in view of the judicial inexperience of the Panel and Appellate Body members although he was kind to the performance of the Appellate Bodies. ¹⁴

Thus the composition of the Panel and the Appellate Bodies, the incoherent approach adopted by the Panels which at times can be called discriminatory approach and ignoring the customary rules of interpretation of public international law suggest that the present

¹⁴¹ Daya Shanker, 'The Vienna Convention on the Law of Treaties, The Dispute Settlement System of the WTO, Canada-Pharmaceutical Report and the Doha Declaration on the TRIPS' (2002), Working Paper, Department of Economics, University of Wollongong, Australia, (2002)

¹⁴² Declaration on the TRIPS Agreement and Public Health, Ministerial Conference, Fourth Session Doha, 9-14 November 2001, WT/MIN(o1)/Dec/W/2 dated 14th November 2001 ¹⁴³ Canada-Patent Protection, Note 404, pp. 158-159

¹⁴⁴ J.H.H. Weiler (2000), The Rule of Lawyers and the Ethos of Diplomats: Reflections on the Internal and External Legitimacy of WTO Dispute Settlement, Harvard Jean Monnet Working Paper 9/2000, Harvard Law School, Cambridge. Weiler stated, "Juridification has put the Secretariat in an impossible position. De Jure, they are not even players but the facilitators of the play of others. That of course is a comforting nonsense. In dispute settlement the Secretariat is meant to be purveyors of objective legal advice and legal services to Panels. De facto, inevitably and importantly, they are the repository of institutional memory, of horizontal and temporal coherence, of long term hermeneutic strategy-all the things that the Panel System, as a first instance judicial tier, should be but unable to be. The Secretariat has, and should have, like the Commission of the European Union, a point of view as to the best legal outcome of the dispute. Supposedly the notion of providing "objective legal advice" should protect them from partisanship and the appearance of partisanship. But only non-lawyers with a primitive understanding of hermeneutics and legal process can believe in that...The view of the Secretariat as to the proper outcome of a dispute will, thus, come out and more invidiously will be consciously and subconsciously pushed upon the Panel." p. 12

system of dispute settlement has not been very successful in introducing determinacy in the TRIPS Agreement.

Symbolic Validation

The two forms of symbolic validation envisaged by Franck are "ritual" and "pedigree". As already discussed, ritual does not present relevant issue for discussion in this Article, but the concept of pedigree as developed by Franck is a very relevant question for this analysis. The historical origin and deeprootedness of any treaty along with the codification practice followed by the International Law Commission (ILC) and the unanimous decisions of the International Court of Justice improves the compliance pull of an international treaty. However, Franck did not restrict "pedigree" as merely a matter of hereditary lineage but considered it in the light of a broader concept to the extent the person or institution responsible for the rule is perceived as "deserving to be obeyed" or "deserving to be taken seriously." ¹⁴⁵

Although Reichman¹⁴⁶ has quite repeatedly called the TRIPS Agreement "revolutionary", the Agreement does not appear to be characterized by deeprootedness or the circumstances in which the TRIPS Agreement was prepared or adopted was perceived to be "deserving to be obeyed." An analysis of the circumstances leading to the finalization of the TRIPS would bring out the relevant context of the circumstances in which the TRIPS Agreement was finalized. Trade related aspects of Intellectual Property Rights including trade in Counterfeiting Goods was introduced in the Ministerial Declaration of 20th September 1986. The negotiating objectives were stated as follows:

"In order to reduce the distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights don't themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines." ¹⁴⁷

In spite of the pressure from the developed countries, the negotiations on TRIPS did not proceed until the Ministerial Meeting held in Montreal in December 1988 where they decided that Trade Negotiations Committee (TNC) should meet in Geneva during the first week of April 1989 to continue discussions where the following clarifications were made concerning TRIPS:

"Ministers agree that negotiations on this subject shall continue in the Uruguay Round and shall encompass the following issues:

¹⁴⁵ Franck, Thomas M. (1990), p.95

¹⁴⁶ Reichman, (1998) and Reichman (2000)

Ministerial Declaration on the Uruguay Round: Declaration of 20th September 1986 (Ministerial Declaration), in GATT, Basic Instruments and Selected Documents [BISD] reprinted in 25 ILM 1623, 1626 (1986)

- (a) The applicability of the basic principles of the GATT and of relevant international intellectual property agreements or conventions;
- (b) The provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;
- (c) The provision of effective and appropriate means for the enforcement of trade –related intellectual property rights, taking into account differences in national legal systems;
- (d) The provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments, including the applicability of GAT T procedures; and
- (e) Transitional arrangements aiming at the fullest participation in the results of the negotiations.

Ministers agreed that in the negotiations consideration will be given to concerns raised by participants related to underlying public policy objectives of their national systems for the protection of intellectual property, including development and technological objectives." ¹⁴⁸

By March 1990, the strategy of developed countries changed and a series of draft legal texts starting from the EC ¹⁴⁹, followed by the USA ¹⁵⁰ and ending with the 'Group of 14' ¹⁵¹ were submitted. An examination of the GATT documents during the period suggests that countries like Brazil, India, Thailand and Taiwan opposing the inclusion of TRIPS as a whole and subsequently various provisions were brought in line by the action of the United States under Special 301 although many scholars tend to suggest that the use of Special 301 were accompanied with concession in other fields like textiles and agriculture. On 20th December, 1991 using '5+5' and '10+10' meetings, the TRIPS Agreement was finalized from where majority of the recommendations of the developing countries had been removed or circumscribed. ¹⁵² Introduction of trade secrets and the obligations in Article 2 of the TRIPS Agreement to comply with the major intellectual property conventions contrary to accepted principles of international law were vehemently opposed by the developing countries.

¹⁴⁹ MTN.GNG/NG11/W/68 dated 29th March 1990 : Draft Agreement on Trade-related Aspects of Intellectual Property Rights

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¹⁴⁸ MTN/11, 21 April 1989

Intellectual Property Rights
¹⁵⁰ MTN.GNG/NG11/W/70 dated 11th May 1990 : Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights, - Communication from the United States

¹⁵¹ Annex 1 GATT. Doc. MTN/GNG/NG11/W71 of 14th May 1990

This analysis is based on the proposed draft from the EC, the USA and the combined draft MTN.GNG/NG11/w/76 dated 23rd July 1990 prepared by Anell where the approach marked A were from developed countries and approach marked B were supposed to be from the developing countries. The proposal from the developing countries is still a restricted document along with all the negotiations of '5+5' and '10+10'

¹⁵³ MTN.GNG/NG11/27 dated 14th November 1990

Coercion and Validity of TRIPS

In TNT.GNGTRIPS/1¹⁵⁴, one of the participants expressed grave concerns about the 'Special 30' provisions of the existing United states Trade Law, which empowered the United States Trade Representative to take unilateral retaliatory actions against "offending" countries, enacted during the TRIPS negotiations and suggested that the nomination of "priority foreign countries" was in itself a violation of the commitments under the Punta del Este Declaration on standstill and rollback, which required participants not to take any measures that would have improved their negotiating positions. The complaint was that 'the implementation of the United States Trade Law against other countries, either at the stage of merely identifying priority countries or of actual retaliation, would surely improve or strengthen the positions of the United States and weaken the position of other countries. (para. 5)

This concern was supported by other countries, one of whom said that in spite of the quick pace and positive attitude his country had shown in respect of the protection of IPRs, it had been identified as one of the "Special 301" priority foreign countries. A large number of countries expressed this concern that "Special 301" provisions was being taken "in order to create pressure on countries to change their negotiating positions," 155.

In 1984, the US Trade Act of 1974 underwent significant change with the authorization to USTR to take action against the countries without a showing of injury if they do not give adequate intellectual protection as per the US requirement. 156 After undergoing a number of amendments ¹⁵⁷, the most important amendment was made during the Uruguay Round negotiations through the Omnibus Trade and Competitiveness Act of 1988, called Special 301 158 which gave a unilateral power to the USTR to identify foreign states denying intellectual property protection to the United States firms as per the allegations of the US industry and to designate them as different categories of culprits.

Once a country is designated as a "priority foreign country", the USTR would have to initiate an investigation within thirty days to determine whether foreign practices violated the United States requirements on intellectual property or were unreasonable or discriminatory. ¹⁵⁹ The enhancement of the authority of the USTR laid enabled it to single countries opposed to the TRIPS agreement for punitive action. The countries identified on this list in 1989, immediately after the 'Special 301' was passed were India, Brazil, Taiwan, and Thailand i.e. all the major countries which opposed inclusions of Intellectual Property Rights in the Uruguay Round and were objecting to various provisions in the TRIPS which in certain respect were far more restrictive than the then existing provisions

¹⁵⁴ MTN.GNG/TRIPS/1 dated 25th July 1991, Meeting of Negotiating Group of 27 and 28 June 1991: Note

¹⁵⁵ MTN.GNG.TRIPS/1 dated 25th July 1991, Meeting of Negotiating Group of 27 and 28 June 1991: Note by the Secretariat ¹⁵⁶ Trade and Tariff Act of 1984, Pub. L. No. 98-573, s 301, 98 Stat. 3000 (1984) (codified as amended at

¹⁹ U.S.C. s. 2411 (1988)

See id. s. 501, 98 Stat. At 3001-02 (codified as amended at 19 U.S.C. s. 2461-2465 (2001))

¹⁵⁸ 19 U.S. C. s. 2242(a)(1)(A)(2001)

¹⁵⁹ 19 U.S.C. s. 2212(b)2)(A)

in the developed countries. Gathii ¹⁶⁰ was quite emphatic that the TRIPS Agreement came about in its present form only because of the use of 'Special 301', which threatened the negotiating parties to punitive actions in case of opposition. ¹⁶¹

Brazil's Ambassador, Celso Amorium raised this issue in the GATT Council in May 1993 that," By threatening to make use of unilateral trade measures, the US Government reinforces doubts the international community has as to the sincerity of the US commitments to the multilateral trade rules, as embodied in the GATT, as well as to the negotiations in the Uruguay Round." ¹⁶²

Prohibition of the use of force in international treaty obligations has been accepted by practically all the countries of the world including the USA. The most important one is acceptance of the principle of the prohibition of the use of force in the declaration on principles governing the mutual relations of States participating in the Conference on Security and Cooperation in Europe (Helsinki, 1 August 1975), whereby the "participating States undertake to "refrain in their mutual relations, as well as in their international relations in general, "from the threat or use of force" 163. The International Court of Justice 164 observed that, "Acceptance of a text in these terms confirms the existence of an *opinio juris* of the participating States prohibiting the use of force in international relations."

The International Court of Justice¹⁶⁵ made a very categorical observation regarding prohibition of use of force when it observed

"A further confirmation of the validity as customary international law of the principle of the prohibition of the use of force expressed in Article 2, paragraph 4, of the Charter of the United Nations may be found in the fact that it is frequently referred to in statements by State representatives as being not only a principle of such law. The International Law Commission, in the course of its work on the codification of the law of treaties, expressed the view that "the law of the Charter concerning the prohibitions of the use of force in itself constitutes a conspicuous example of a rule in international

¹⁶⁰ Gathii, James Thuo, Constructing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable Aids Drugs to Low-end Consumers, Florida Law Review, vol. 53, 727-788 (2001)

Gathii (2001) "The bilateral pressures of the United States, which were based primarily on its unilateral retaliatory powers, were critical in leveling opposition to TRIPS in the Uruguay Round Working Group on Intellectual Property. Whereas the IPC's (Intellectual Property Committee the al., Basic framework of GATT Provisions on Intellectual Property- A Statement of the Views of the European, Japanese, and United States Business Communities (1988)) basic framework didn't anticipate all the differences the United States, The European Union, and Japan haggled over during the Uruguay Round, it undoubtedly put IPRs on the international trade agenda" (p. 756)

Raghavan, Chakravarthi, US s. 301 Threats Raised in GATT Council, httt://www.sunsonline.org/trade/process/during/05130193.htm

Helsinki

164 Military and Paramilitary Activities (Nicaragua/United states of America) Merits. J. 27.6.1986, I.C.J.

Reports 1986, p. 14

¹⁶⁵ Military and Paramilitary Activities (Nicaragua/United States of America) Merits. J. 27.6.1986, I.C.J. Reports 1986, pp. 100-101

law having the character of jus cogens" (paragraph (1) of the commentary of the Commission to Article 50 of its draft Articles on the Law of Treaties, ILC Yearbook, 1966-II, p. 247). Nicaragua in its Memorial on the Merits submitted in the present case states that the principle prohibiting the use of force embodied in Article 2, paragraph 4, of the Charter of the United Nations "has come to be recognized as jus cogens". The United States, in its Counter-memorial on the questions of jurisdiction and admissibility, found it material to quote the views of scholars that this principle is a "universal norm", a "universal international law", a "universally recognized principle of international law", a "principle of jus cogens".

Templeman was categorical about use of coercion in the formation of the TRIPS Agreement when he observed "All the increases of patent and copyright protection were obtained by powerful lobbies persuading individual governments to take action and then persuading all others to "harmonize" their legislation, thus obtaining worldwide monopolies. There appears to be no public interest justification for the increases in copyright protection; the extensions were not necessary to encourage authors. The excuse for increases in patent protection are said to be the delay in the testing of pharmaceutical and similar products for health and safety reasons after application has been made for a patent." ¹⁶⁶ Templeman further says, "The Agreement on Trade-Related Aspects of Intellectual Property Rights (The 'TRIPS Agreement') was obtained by the threat and reality of trade sanctions and the withdrawal of aid. The TRIPS Agreement is now being enforced by similar methods." ¹⁶⁷

As against mutual benefit of opening of the borders for free trade, the TRIPS "responded only to the interests of the industrialized countries that would be the principal exporters of intellectual property" ¹⁶⁸.

Gerhart observed that once the USA decided to include intellectual property in the Uruguay Round with the help of other developed countries ¹⁶⁹, the USA took away the option of status quo i.e. the option to have no negotiations by insisting that if the countries did not adopt intellectual property standards they would be left in a worse situation. ¹⁷⁰ In notes 28 and 30, Gerhart made it clear that the developing countries were left with no choice and had to accept the TRIPS Agreement. Section 301 was used to exert significant pressure on target countries and the developing countries were forced to relent. The coercion story shows the underbelly of TRIPS that treaties are consensual and getting an independent arbiter of substantial validity is quite difficult. The fact that TRIPS is not resulted from real consent, does undermine the legitimacy of the TRIPS

"Even Europe and Japan did not have intellectual property on their negotiating agendas until well after the Uruguay Round negotiations were launched" Peter Drahos, Global Property Rights in Information: the Story of TRIPS at the GATT, in Intellectual Property 419, 422

 $^{^{166}}$ Templeman, Lord Sydney, Intellectual Property, Journal of International Economic Law (1998) p. 603-606

Templeman, Lord Sydney, Intellectual Property, Journal of International Economic Law (1998) p. 603-606, 604

¹⁶⁸ Gerhart (2000), p. 368

Story of TRIPS at the GATT, in Intellectual Property 419, 422

170 Bernard M Hoekman & Michel M. Kostecki, 1995, The Political Economy of the World Trading System: From GATT to WTO 156 (1995)

Agreement. It appears that the developing countries went along "not to make themselves better off but to avoid being made worse off" ¹⁷¹

The threat and coercion was discussed in detail by the EC and the Panel in *United States* – *Sections 301-310 of the Trade Act of 1974.* The EC while describing the effect of Sections 301- 310 of the US Trade Act stated

"The European Communities maintains that in particular, the constant threat of imposition of unilateral measures has an influence on the behavior and the decisions of the economic operators. In practice, the fact of the filing of a petition or the simple publication of a notice in the Federal Register announcing the initiation of an investigation, within the concrete context of the provisions contained in Sections 301-310 and the publicly known interpretation given by the US Administration and the Congress created "chilling" trade effects that may range from the slowing down of importation of products to the more radical stoppage of any bilateral trade with the United States in those products."

This observation of the EC was accepted by the Panel in *United States-Section 301-310* where the Panel made observations as follows:

"When a Member imposes unilateral measures in violation of Article 23 in a specific dispute, serious damage is created both to other Members and the market place. However, in our view, the creation of damage is not confined to actual conduct in specific cases. A law reserving the right for unilateral measures to be taken contrary to DSU rules and procedures, may – as is the case here- constitute an ongoing threat and produce a "chilling effect" causing serious damage in a variety of ways." 173

¹⁷² United States – Sections 301-310 of the Trade Act of 1974, Report of the Panel, WT/DS152/R dated 22 December 1999, para 4.45

¹⁷³ United States – Sections 301-310 of the Trade Act of 1974, Report of the Panel, WT/DS152/R dated 22 December 1999, para. 7.88. IN subsequent paras. The Panel has discussed the types of damages. In para 7.89 the Panel has noted

"First, there is the damage caused directly to another member. Members faced with a threat of unilateral action, especially when it emanates from an economically powerful Member, may in effect be forced to give in to the demands imposed by the Member exerting the threat, even before DSU procedures have been activated. To put it differently, merely carrying a big stick is in many cases, as effective a means to having one's way as actually using the stick. The threat alone of conduct prohibited by the WTO would enable t member concerned to exert undue leverage on other Members. It would disrupt the every stability and equilibrium which multilateral dispute resolution was meant to foster and consequently establish, namely equal protection of both large and small, powerful and less powerful Members through the consistent application of a set of rules and procedures."

This was followed by further observation by the Panel of incompatibility of unilateral action with provisions of WTO. It observed

"Second there is the damage cased to the market place itself. The mere fact of having legislation the statutory language of which permits conduct which is WTO prohibited – namely, the impostion of unilateral measures against other members with which it is locked in a trade dispute – may in and of itself prompt economic operators to change their commercial behavior in a way that distorts trade. Economic operators may be afraid, say to continue ongoing trade with, or investment in, the industries or products threatened by unilateral measures. Existing trade may also be distorted because economic operators may feel a need to take out extra insurance to allow of rte illegal possibility that the Egislation contemplates,

¹⁷¹ Gerhart (2000) p. 271

The Panel in *United States- Sections 301-310 of the Trade Act of 1974* made a final observations regarding unilateral action that

"Our textual observation of Article 23.2(a) is thus confirmed when taking account also of the other elements referred to in Article 31 of the Vienna Convention. Under this reading the duty of members under Article 23 to have recourse to and abide by the rules and procedures of the DSU and to abstain from unilateral determinations of inconsistency, is meant to guarantee Members as well as the market-place and those who operate in it that no such determination in respect of WTO rights and obligations will be made."

In spite of the Panel's observations, the Fact Sheet released by the USTR regarding Special "301" ¹⁷⁴ which is not different from Section 301 of the Trade Act, 1974 and was amended vide the Uruguay Round Agreements Act to bring it in conformity with the WTO says that "a country can be found to deny adequate and effective intellectual property protection even if it is in compliance with its obligations under the TRIPS Agreement."

The use of coercion, however, minor role it may have played in the formation of the TRIPS Agreement would not make it easy for the Members to perceive this international treaty as "deserving to be obeyed" or "deserving to taken seriously".

Coherence

One of the fundamental aspects of legitimacy of international rules is a presumption against arbitrariness between rights and duties of different states or governments. A major argument developed by Franck to have coherence in a rule of international law is to provide connection not only with specific principles but also with general principles (a "lattice of principles") used to solve a variety of other problems.

In discussing the determinacy of the TRIPS, two of the arguments forwarded were that TRIPS while providing extraordinary power to patent holders of developed countries to extend the temporary and limited monopoly at the same time insisting that non-discriminatory provisions of the TRIPS would not be applicable to such extension¹⁷⁵

thus reducing the relative competitive opportunity of their products on the market. Other operators may be deterred from trading with such Member altogether, distorting potential trade. The damage thus caused to the market-place may actually increase when national legislation empowers individual economic operators to trigger unilateral State action, as is the case in the US which allows individual petitioners to request the USTR to initiate an investigation under Sections 301-310. This in itself is not illegal. But the ability conferred upon economic operators to relationship and deny certain commercial advantages that foreign competitors would otherwise have. The threat of unilateral action can be as damaging on the market –place as the action itself."

USTR 2000 Special 301 Report: The Protection of Intellectual Property Rights released on May 1 2000
 Argument of the EC, in Canada Patent Protection and indirect application of such argument by the Panel. Note.

questions the presence of equality in an international treaty which makes it attractive for compliance.

Similarly, provisions of TRIPS in Article 27 permitting patenting of all the inventions notwithstanding that all the countries including major proponents of TRIPS had specifically excluded scientific theories, mathematical methods, discoveries and materials or substances, abstract ideas, business methods, computer programs from their patent acts but a similar proposal in the document MTN.GNG/NG11/W/76 darted 23rd July, 1990 was removed from the final draft (Dunkel Text, 20th December 1991). The purpose was to extend the scope of patentable subject matter without any limit particularly when European Patent Conventions and the Patent Acts of its members had specifically excluded these items from the subject matter. The business methods, computer programs, abstract ideas, discoveries, have been excluded through various Supreme Court Judgements in the USA. ¹⁷⁶ Only in 1998, business methods were permitted to be a patentable matter by the Court of Appeal in State Street, which was based more on the US government directive than proper appreciation of the various US Supreme Court Judgments. ¹⁷⁷

This is a curious international agreements which when it was started by the EC through a draft proposal (MTN.GNG/NG/11/W/68 dated 29th March 1990), it started with much more stringent intellectual right provisions than was present in the domestic laws of the major proponent countries. It is quite understandable that the international negotiations start with extreme positions and then through negotiations a compromised middle solution is brought about. However, in case of TRIPS, the negotiations started with protections which were more stringent than the domestic patent laws of the major proponents which became much more stringent during the TRIPS negotiations and practically all the recommendations of the major groups of nations from developing countries were either rejected outright or were circumscribed by the terms which can make such provisions ineffective. One such provision is that of Article 8 of TRIPS which says

- "1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect 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.
- 2. Appropriate measures, provided that they are consistent with provisions of this agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

The contents of the above provisions were essentially proposed by the developing countries and were reflected in paragraph 8 of the part V of MTN.GNG/NG11/W/76 dated 23rd July, 1990 which reads as

8. Principles

¹⁷⁶ Daya Shanker, India, Pharmaceutical Industry and the Validity of TRIPS, (2001)

¹⁷⁷ Daya Shanker, India, Pharmaceutical Industry and the Validity of TRIPS (2001)

8B.1 Parties recognize that intellectual property rights are granted not only in acknowledgement of the contributions of inventors and creators but also to assist in the diffusion of technological knowledge and its dissemination to those who could benefit from it in a manner conducive to social and economic welfare and agree that this balance of rights and obligations inherent in all systems of intellectual property rights should be observed.

8B.2 In formulating or amending their national laws and regulations on IPRs, PARTIES have the right to adopt appropriate measures to protect public morality, national security. Public health and nutrition, or to promote public interest in sectors of vital importance to their socio-economic and technological development."

The circumscribing by the use of term "provided that they are consistent with the provisions of this Agreement" has been used by the EC to argue that objects and purpose of the TRIPS have no meaning as far as interpretations of other provisions of TRIPS are concerned and they perform no other functions except being there. ¹⁷⁸

Similarly, local working was accepted as one of the reasons for granting of compulsory licensing by the EC in its proposed draft. However, on 16th December 1991 in a '10+10' Meeting¹⁸⁰, the last clause of Article 27.1 was added¹⁸¹ which states

"Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

However, in view of Article 5A(2) of the Paris Convention which specifically identified non-local working as one of the abuses for issuing compulsory licenses, local working continued to be a TRIPS compatible provisions and continued to be present in the European Patent Convention and the UK Patent Act till 1999 and in nearly all the Patents

MTN.GNG/NG11/W/68 dated 29th March, 1990: Draft Agreement on Trade-Related Aspects of Intellectual Property rights, Article 26 "Compulsory licenses may not be issued for non-working or insufficiency of working on the territory of granting authority in the right holder can show that the lack or insufficiency of local working is justified by the existence of legal, technical or commercial reasons." ¹⁸⁰ Canada-Pharmaceuticals, Note 74 and 75

Canada-Patent Protection, para. 4.30(a) indent 3. The EC stated that "major feature" of the TRIPS Agreement is its neutrality vis-a-vis societal values and the last part of the sentence in Article 8.1 of the TRIPS Agreement saying that "...provided that such measures are consistent with the provisions of this Agreement", which implicitly does not permit any of the societal values to be taken into consideration.

This is based on the argument of Canada in *Canada-Patent Protection*, in para 4.17 and the accompanying Note 74 and 75. Canada said, "A reference to the drafting history of Article 27.1 was instructive. It structure and wording reflected two separate negotiating thrusts: (a) a desire to ensure that subject to certain listed exceptions, patents would be available for inventions in all fields of technology; and (b) a desire to eliminate compulsory licence provisions respecting food and drug products in national patent laws. (Note 74 and 75: Reference was made to the TRIPS 10+10 meeting, 16th December 1991, Speaking Note of the Chairman (unpublished))". There has been reference to non-discrimination clause previously but it appears to have been finalized at this meeting.

Act of the developing countries under the impression that it is permitted under TRIPS. 182 However, using Article 27.1, the USA raised the question of presence of local working in Brazil's Patent Act and even when it withdrew the complaint, it was withdrawn with the assertion that the USA would pursue the matter aggressively for the removal of local working.

Another point of issue is that of exhaustion of right. In normal commercial transactions, once the goods have been sold the buyer gets all the right in the goods. In case of the TRIPS Agreement, using the presence of term 'power to exclude others from import' in Article 28 has been used as a ground by Pharmaceutical Research and Manufacturers of America (PhRMA) to insist that buyer has no more right except what has been perceived by the right holder. The PhRMA's argument did not have any logical support but the presence of importing patented products put in the market by the right holder in different Patent Acts was taken up by the USA who alleged that such provisions violate Article 28 of TRIPS. 183 In fact, such local working is permitted by the Paris 'Convention as incorporated in the TRIPS Agreement but the local working provisions present in the US Patent Act Sections 204¹⁸⁴ and 209¹⁸⁵ are not permitted and would be covered by Article 27.1 of the TRIPS Agreement.

From the above discussion, it appears that Franck's 'coherence' or Dworkin's 'integrity' or 'consistency' are not the most appropriate words applicable to the TRIPS Agreement. Further, requirement of coherence is that the international rules should be part of the "underlying general principle".

TRIPS was accepted with great reluctance by the majority of countries with the exception of the USA and the EC as a part of the Uruguay Round and even after it was accepted, there was great reluctance by the negotiating parties to reach an agreement. In fact, till the USA by introducing Special 301 and using it to coerce some of the major opponents of TRIPS into compliance, the majority of the WTO members were opposed to the introduction of TRIPS into WTO framework as the provisions of TRIPS were antithetical to the main issue of free trade. Patents and Copyrights were essentially trade restrictive monopolies and only reason for their acceptance was to provide an incentive to the inventors. 186 In fact, each and every provision in the TRIPS has a trade restrictive effect, and longer the monopolies stay, the greater the protection. In this respect, the effect of the TRIPS Agreement has been to distort the free trade structure erected by GATT 1994 and its associated agreements and understandings.

Daya Shanker "Brazil, Pharmaceutical Industry, and the WTO" (2002) and "India, Pharmaceutical Industry and the Validity of TRIPS" (2001), Reichman (2000)

¹⁸³ Daya Shanker, Brazil, Pharmaceutical Industry, and the WTO (2002)¹⁸⁴ Supra note 74

¹⁸⁶ The US Constitution and the Monopolies Act.

Adherence (to a Normative Hierarchy) and Community

While discussing his fourth factor of adherence, Franck identified "state equality" and "the fundamental principle of international law that it prevails over domestic law" as "ultimate rules of recognition". The question of equality between nations has been partly discussed by Dutfield whose analysis of data suggest that when TRIPS emphasizes the adequate and effective protection of intellectual property laws, it is emphasizing something which belongs to a particularly small group of nations.

A large number of instances starting from PhRMA's submission¹⁸⁸, the USTR's ¹⁸⁹ categorization of different countries including the EC as violating the provisions of TRIPS and the discussions at Doha Ministerial Meetings, all suggest the 'true community' where the members accept that they are governed by common principles is not applicable to the TRIPS Agreement.

Conclusion

Setear while trying to promote his view on game-theoretic approach of international law which he called as "An Iterative Perspective", tried to criticize Franck's approach on the basis that, "The legitimacy oriented perspective, therefore, suffers from difficulties in defining the various factors said to comprise legitimacy, and it being sure that legitimacy is in fact the desired metric at all." However, first Setear has ignored the fact that game-theoretic approach in economics is based essentially on a large number of strict assumptions which normally are not applicable in the real world and what Franck has tried to do is to develop an underlying theory as to why international rules are followed in the international relations when the nations are sovereign. There is no measure of determinacy, validity, coherence and adherence but they are not subjective and examination of any treaty would show that a treaty having significant presence of above factors does attract greater compliance. The most significant example is the Vienna Convention on the Law of Treaties. Some of these points have been discussed by Byers. ¹⁹¹

Franck's concept of legitimacy is not based on a very sound empirical foundation and has mostly been supported by a large number of anecdotal evidence. It is more like Michael

 ¹⁸⁷ G. Dutfield, Intellectual Property Rights, Trade and Biodiversity: The Case of Seeds and Plant Varieties,
 IUCN, Gland and Earthscan, London, 2000
 ¹⁸⁸ Submission of the Pharmaceutical Research and Manufacturers Association (PhRMA): Identification of

Countries Under Section 182 ('Special 301') of the Trade Act of 1974, as amended, 66 Federal Register 3640-3641 (January 16, 2001) and Submission of the Pharmaceutical Research and Manufacturer's of America (PhRMA) for the National Trade Estimate Report on foreign Trade Barriers (NTE), 2001, November 27, 2000

¹⁸⁹ Special 301 on Intellectual Property rights, USTR 2000 Special 301 Report: The Protection of Intellectual Property rights, Fact Sheet released by the Office of the U.S. Trade Representative, Washington, DC, May 1, 2001

Setear (1996), p. 174
 Byers, Michael, (1997), Taking the Law out of International Law: A critique of the "Iterative Perspective", 38 Harvard International Law Journal, 201, 202-03

Porter's¹⁹² analysis of competitive strategy and in similar manner provides an extraordinary powerful tool for analyzing the legitimacy of and compliance with international treaty.

There appears to be a reluctance on the part of majority of countries both developed and the developing to accept the provisions of the TRIPS because of the circumstances in which it was prepared, the extraordinary role played by the interested trade associations and the antithetical emphasis on monopolistic control against free trade.

However, greater legitimacy might by achieved by introducing suitable changes through modifications of Articles 1.1, 27 and 33 of the TRIPS Agreement to bring predictability and certainty. There has to be certain norms for extension of monopolies. The extraordinary influence welded by certain industries and certain countries in the introduction and imposition of provisions which were not even part of the existing provisions in the domestic laws have converted TRIPS substantially into an illegitimate treaty. The introduction of appropriate norms is required to ensure that the limited monopolies to encourage progress of science and technical arts should not end up as a perpetuation of monopolies in the international context. The introduction of certainty and predictability in the TRIPS Agreement may help in bringing some form of legitimacy in this international agreement. Alternatively the TRIPS Agreement would be nothing but a system of continuous twisting of arms and hurling of abuses.

¹⁹² Michael Porter (1980) Competitive Strategy: Techniques for Analyzing Industries and Competitors, The Free Press, New York; Michael E. Porter, (1985) Competitive Advantage: Creating and Sustaining Superior Performance, Free Press; Michael E. Porter (1990) The Competitive Advantage of Nations, Free Press, New York