

BARGAINING AROUND THE TRIPS AGREEMENT: THE CASE FOR ONGOING PUBLIC-PRIVATE INITIATIVES TO FACILITATE WORLDWIDE INTELLECTUAL PROPERTY TRANSACTIONS

*A comment on the paper presented by Professors David Lange,
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I. INTRODUCTION

It is generally acknowledged that our society has a continuous need for technological innovations. Without new discoveries and inventions and their resulting marketable processes and products, our future would be endangered. The shortage of food, incurable illnesses, the ever increasing ozone hole, and a need for more energy, to name but a few, are all awaiting solutions to be provided by physicians, biologists, geneticists, chemists, physicists, mechanical engineers, and other representatives of natural and engineering sciences.

While these problems seem quite apparent, it is less apparent that technical innovations alone will sufficiently master the complex set of problems surrounding the research in new technologies. Their development, implementation, exploitation, transfer, and financing within a given national economy and the potential of technical innovations to serve as a cure-all, is even less clear when the problems involve different national economies. To reach these goals, a number of economic, legal, and social issues have to be successfully resolved. For example, some of these issues might be adequately addressed by a regime that reflectively protects intellectual property rights, sufficiently provides favorable tax treatment for research and development (R&D) activities, and adequately circumvents bureaucratic in-

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efficiencies in the approval and maintenance of new production sites.

These key legal features, however, are only one part of the conditions that decisively influence enterprises—especially the large multinational enterprises—to engage in business in a specific country. Other key features that generate spillovers include a country's financial, educational, and management systems, and the degree of competitive rivalry within that nation.¹ Furthermore, globalization involves interaction between the mobilization of resources on a worldwide scale and the international dimension of economic competition. As major actors in this process, multinational enterprises control and coordinate value-added activities across national boundaries, via foreign direct investment, international trade of intermediate goods, and inter-firm agreements.² All of these key features must be satisfactorily resolved before foreign enterprises will invest in unilateral or collaborative R&D and production activities or transfer technology in a given country. Thus, technological innovations are not the only changes necessary to increase a country's attractiveness—economic and legal innovations appear to be at least as important as those in technology, and pose a clear challenge for economists and lawyers.³

The Conference on Public-Private Initiatives After TRIPS (Conference) was, as expressed by Professors Lange and Reichman, aimed at discussing and analyzing legal innovations following the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).⁴ The Conference concentrated on a new and innovative cooperative strategy and its likely institutional framework, the Center for Public-Private Initiatives After the TRIPS Agreement (Center). The Center has been designed to serve as a means for en-

1. See Rémi Barré, *Relationships Between Multinational Firms' Technology Strategies and National Innovation Systems: A Model and an Empirical Analysis*, in INNOVATION, PATENTS AND TECHNOLOGICAL STRATEGIES 201, 206 (1996). See generally Keith Pavitt & Pari Patel, *Technological Strategies of the World's Largest Companies*, 18 SCI. & PUB. POL. 363 (1991).

2. See generally Barré, *supra* note 1, at 202; Jan Maarten de Vet, *Globalization and Local and Regional Competitiveness*, 13 STI REV. 89 (1993); Frédérique Sachwald, *European Competitiveness, the Single Market and Globalization*, in EUROPEAN INTEGRATION AND COMPETITIVENESS 5 (Frédérique Sachwald ed., 1994).

3. See generally Lester C. Thurow, *Needed: A New System of Intellectual Property Rights*, HARV. BUS. REV., Sept.-Oct. 1997, at 100-03 (demonstrating that countries must also resolve these features in relation to intellectual property rights).

4. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31; 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

couraging and improving the international flow of technology and for attracting foreign investments to a given country. Furthermore, as an informal amicable mediator, the Center should help to resolve differences of opinions that are linked predominantly to issues related to intellectual property. The bottom line of this approach will be evident in the cooperation of private parties with public institutions of the interested country in a manner intended to optimize the use of available intellectual property rights (IPRs), design surrogate or complementary solutions in case of a lack of protection, and establish specific market conditions that would allow an economically rewarding engagement. The whole exercise should be for the benefit of all directly involved parties, as well as for macro-economic interests of the respective country.

The idea for the Center is not only original and ambitious, but also realistic enough to be eventually attained. Professors Lange and Reichman offered a number of convincing reasons why this idea should indeed be attained. This Comment will discuss several more. However, prior to undertaking this feat, it is necessary to gain some distance from Lange and Reichman's basic statements concerning the extent to which the newly established international system for the protection of IPRs, under the TRIPS umbrella, may have a particular economic impact on newly-industrialized and developing countries. Although Lange and Reichman have by no means questioned the necessity and overall usefulness of the system,⁵ they have predicted that it will likely result in negative consequences such as increased social costs, rising tensions among the World Trade Organization (WTO) members, and an increased tendency of developing and developed countries to extensively exploit the deficiencies of the system for the benefit of their particular interests.⁶ Consequently, Lange and Reichman eventually recommend that developing countries treat the TRIPS Agreement as set of default rules to be bargained around within the limits provided thereunder, as this will help them regain "some of the negotiating initiative that was lost during the multilat-

5. This view has also been cautiously expressed in a study prepared by the Secretariat of the United Nations Conference on Trade and Development (UNCTAD): "In summary, one can say empirically that intellectual property protection is one of a larger number of factors influencing firms' decisions to transfer technology to, or invest in, a particular country. . . ." U.N. CONF. ON TRADE AND DEV., *THE TRIPS AGREEMENT AND DEVELOPING COUNTRIES* at 18, U.N. Doc. UNCTAD/ITE/1, U.N. Sales No. 96.II.D (1996) [hereinafter UNCTAD].

6. See J.H. Reichman & David Lange, *Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions*, 9 DUKE J. COMP. & INT'L L. 11, 14-15 (1998).

eral trade negotiations of the Uruguay Round.”⁷

In further developing the ideas of Lange and Reichman and responding to their assertions, Part II of this Comment describes the effects of the TRIPS Agreement’s patent protection on worldwide trade. Deficiencies and weaknesses in the Agreement are revealed, and it is observed that countries will benefit unequally from resulting shifts in their competitive market advantage. Part III addresses the flexibility in patent exploitation offered by Article 27 of the TRIPS Agreement, predicting how this flexibility will benefit countries to varying degrees and suggesting ways in which the Center may assist them in maneuvering to their advantage within the bounds of Article 27.

II. THE IMPACT OF THE TRIPS AGREEMENT ON INTERNATIONAL TRADE

Two implications of the TRIPS Agreement are particularly important. First, had the TRIPS Agreement failed to achieve parity between the extra-territorial treatment of immaterial goods and the treatment afforded to other subject matters of international trade, serious frictions in international trade relations would have unavoidably resulted. Clearly, the anomaly of an almost total lack of minimum IPRs was no longer tenable. This is particularly true in the field of patent law, even in countries that have considerable surplus in the balance of payments and trade and that participate in and benefit from the globalization and integration of world markets. It is not possible for a country to invoke principles of territoriality and national treatment, while simultaneously claiming to justify the appropriation of foreign inventions within its national borders and claiming free access and non-discriminatory treatment of goods and services in the markets of the originators of the appropriated technology.⁸ Thus, by accepting obligations under the General Agreement on Tariffs and Trade (GATT) and TRIPS Agreement, WTO members have in principle opened up and allowed mutual access to their markets for both tangible and intangible goods. In this context, process and product inventions originating in foreign countries can be guaranteed market access and sustained market affirmation only through the effective protection of IPRs. More concretely, in the case of the Peo-

7. *Id.* at 61.

8. See Joseph Straus, *Implications of the TRIPs Agreement in the Field of Patent Law*, in FROM GATT TO TRIPS: THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 160, 163-70 (Friedrich-Karl Beier & Gerhard Schrickler eds., 1996).

ple's Republic of China (China), an effective protection of IPRs of foreign origin was a precondition and remains an important component of its successful trade with the European Union (EU) and the United States. This protection has resulted in some \$40 billion of annual trade balance surplus to China. The sensitivity and fragility of the balance between the effective protection of IPRs and international trade is well demonstrated by the bilateral relations between the United States and China, and by the problems the latter continues to face in its efforts to become a WTO member.⁹

Thus, the TRIPS Agreement has to be understood as a cornerstone of today's globalized research, development, production, and trade. It would be naive and unrealistic to believe the TRIPS Agreement will function with few or no problems, or without the parties involved trying to exploit its deficiencies. It would, however, be extremely dangerous and eventually detrimental if the parties involved tried to deliberately circumvent or even discredit the principles underlying the TRIPS Agreement. The TRIPS Agreement has become a precious good not just for developed countries, but for *all* actors in the global economy. The stage of interdependence of these actors, which has been reached in the meantime, simply requires a good tune of the balance of all interests involved. The TRIPS Agreement is one of its most important and indispensable guarantors.

Second, it is doubtful that developing countries and newly industrialized countries (NICs), by their acceptance of the high standards of protection of IPRs imposed by the TRIPS Agreement, will benefit only through the TRIPS Agreement externalities. In other words, thanks to the TRIPS Agreement such countries will not only secure access to world markets for their goods and services, such as textiles, agricultural products, minerals, and shoe-wares, under non-discriminatory conditions.¹⁰ Despite the scarce and non-reliable empirical data, efficient patent protection as provided under the TRIPS Agreement—protection that will result in increased patent activities in NICs as well as in developing countries—will by no means be

9. For the respective statistics, see Tony Walker, *China US over WTO*, FIN. TIMES, Oct. 18, 1995, at 4; Tony Walker, *US-China Copyright Accord 'A Step Forward'*, FIN. TIMES, June 18, 1996, at 4; Tony Walker & Jurek Martin, *Last-gasp Deal Averts US-China Trade War: Beijing to Tighten Enforcement Against Film and Software Industry*, FIN. TIMES, June 18, 1996, at 1. For a discussion of the trade balance between China and the member states of the European Union, see, for example, *Die Europäer wollen besseren Zugang zum chinesischen Markt*, FRANKFURTER ALLGEMEINE ZEITUNG, July 6, 1995, at 13.

10. See Straus, *supra* note 8, at 168.

solely or even predominantly used by foreign patent owners to support importation monopolies.¹¹ Rather, such patent protection will increasingly lead to local R&D and production engagement when the key features mentioned earlier are sufficiently favorable.

It is important not to overlook or ignore the substantial changes that globalization has caused. For example, this phenomenon now offers internationally active enterprises real choice in locating their R&D and production activities at sites where they can expect the most comparative advantages. This freedom of choice is inseparably linked to the free flow of technology, capital, and goods, which can be marketed anywhere in the world markets, irrespective of the place of production. Multinational enterprises, for instance, tend to set innovation activities at sites with a technological specialization, and thus a technological advantage, in their sector of activity.¹² An example of this would be the Daimler-Benz decision to develop software in India, where the human resources are comparably cheap but skillful. According to Cantwell and Hodson, non-resident-owned research tends to be drawn to those sectors in which a recipient country has a comparative patenting advantage.¹³ The correctness of this finding can be best observed in continental Europe through the shift of nearly all industrial R&D activities in the field of biotechnology from Europe to the United States and Japan.¹⁴ Although the uncertainties around the patentability of such biotechnological inventions as human genes, transgenic animals, or plants¹⁵ may be viewed as only one possible reason for that move, the essential influence of comparative advantages cannot be questioned. Thus, the provisions of European patent law that exclude protection for plant or animal varieties¹⁶—

11. As claimed by José L. Solleiro & Elena Arriaga, *Patentes en biotecnología: oportunidades, amenazas y opciones para América Latina*, 12 REVISTA DEL DERECHO INDUSTRIAL 126-28 (1990).

12. See Barré, *supra* note 1.

13. See John Cantwell & Christian Hodson, *Global R&D and UK Competitiveness*, in GLOBAL RESEARCH STRATEGY AND INTERNATIONAL COMPETITIVENESS 133-34 (Mark Casson ed., 1990).

14. See, e.g., David Dickson, *German Biotech Firms Flee Regulatory Climate*, 244 SCI. 1251, 1251-52 (1989).

15. These uncertainties are reflected by the debate in the European Parliament on the Proposal for a European Directive on the Legal Protection of Biotechnological Inventions. Eventually, the European Parliament and the Council on the Legal Protection of Biotechnological Inventions adopted Directive 98/44/EC on July 6, 1998. See Parliament and Council Directive 98/44, 1998 O.J. (L 213) 13.

16. European Patent Convention, Oct. 5, 1973, art. 53(b), *reprinted in* JOHN P. SINNOTT, WORLD PATENT LAW AND PRACTICE 30-32 (1994).

and essentially all biological processes for the production of animals and plants—place in doubt¹⁷ the patentability of hundreds of generic inventions in transgenic plants and animals,¹⁸ and clearly present a comparative patenting disadvantage for Europe.¹⁹ The shift of the industrial R&D activities in this area from Europe to the United States and Japan will also lead to the production of the respective biotechnological products in those countries and, without the clarifications introduced by the EU Biotech Directive,²⁰ may leave Europe

17. In its decision T 356/93 of February 21, 1995 (Plant Cells/Plant Genetic Systems), the Technical Board of Appeal of the European Patent Office rejected a claim that related to a non-biologically transformed plant, possessing in its genome a stable integrated foreign DNA nucleotide sequence encoding a protein having specific useful properties, as a claim directed to “plant varieties” and as such being banned from patent protection under Article 53(b) EPC. See 1995 OJ Eur. Pat. Off. 545, 579 No. 40.4. This decision has been widely criticized in legal literature. See, e.g., Peter Lange, *Patentierungsverbot für Pflanzensorten*, 1996 GEWERBLICHER RECHTSSCHUTZ UND URHEBERRECHT [hereinafter GRUR] [Int.] 586, 589-91; HANS-RAINER JAENICHEN, *THE EUROPEAN PATENT OFFICE’S CASE LAW ON PATENTABILITY OF BIOTECHNOLOGICAL INVENTIONS* 29 (2d ed. 1996); Tim Roberts, *Patenting Plants Around the World*, 18 EUR. INTELL. PROP. REV. 531, 534-35 (1996); Alan W. White & John D. Brown, *EPC Appeal Procedures - Opinion G 03/95 (Inadmissible Referral)*, 18 EUROPEAN INTELL. PROP. REV. 419, 419-21 (1996); Ulrich Schatz, *Zur Patentierbarkeit gentechnischer Erfindungen in der Praxis des EPA*, 1997 GRUR [Int.] 591, 591-93; Joseph Straus, *Völkerrechtliche Verträge und Gemeinschaftsrecht als Auslegungsfaktoren des europäischen Patentübereinkommens*, 1998 GRUR [Int.] 1, 10, 12-14. However, in a similar case the Technical Board of Appeal of the European Patent Office referred four questions related to patentability of transgenic plants per se to the Enlarged Board of Appeals. See *Transgenic Plant/Novartis*, T 1054/96-3.3.4, 1998 O.J. Eur. Pat. Off. 511.

18. Telephone interview with Dr. Christian Gugerell, Director of the Biotech Division of the European Patent Office (May 1997). According to Dr. Gugerell, some 2000 patent applications (1377 for transgenic plants and 580 for transgenic animals) are pending before the European Patent Office. Of these, 90% of applications are directed to animal claims per se; in the case of applications claiming plants, the figure was 60%.

19. It should suffice to recall that claims related to plants and animals have been issued in the United States since the late 1980s. See Ned Hettinger, *Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics*, 22 B.C. ENVTL. AFF. L. REV. 267, 271 (1995); see also Reid Adler, *Can Patents Co-Exist with Breeder’s Rights? Developments in U.S. and International Biotechnology Law*, 17 INT’L REV. INDUS. PROP. & COPYRIGHT L. 195, 195-201 (1986); Robert P. Merges, *Intellectual Property in Higher Life Forms and Controversial Technologies*, 47 MD. L. REV. 1051, 1052, 1068-75 (1988).

20. Although under Article 4(1)(a) of the Directive, plant and animal varieties remain excluded from patent protection, paragraph two of that Article makes it clear that “inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.” Parliament and Council Directive 98/44, *supra* note 15, art. 4(1)(a). Thus, it would appear that generic inventions in plants are explicitly declared patentable subject matter. Further support for this proposition is the clarification contained in Recital 31, according to which a plant grouping which is characterized by a particular gene (and not its whole genome) is not excluded from patentability even if it comprises new varieties of plants. See *id.* Recital 31 at 25. The impact of this Directive on the practice of the European Patent Office, however, remains to be seen. See generally Straus, *supra* note 17 (detailing the complex relationship between the European Patent Convention, the

as predominantly a market for most biotechnological products.

Also, in the areas of pharmaceuticals and chemicals, the examples of Japan²¹ and Korea²² have demonstrated that the introduction of an effective patent protection has eventually led to increased R&D activities and to an improved economic performance of those countries. Moreover, in the past, most developing countries in which there was no protection of chemicals, pharmaceuticals, or biotechnological inventions, were barely in a position to successfully use the unprotected technologies locally. For example, until recently, biotechnological inventions and classical plant breeding activities were completely unprotected in Brazil.²³ Consequently, with the exception of breeding hybrids, foreign companies did not engage in such activities in Brazil. At the same time, local plant breeding activities were more than modest. In other words, it appears the lack of protection was a clear macro-economic disadvantage to Brazil. However, under the conditions altered by the TRIPS Agreement, some companies in NICs and developing countries will be negatively affected.²⁴ In particular, generic drug producers, who previously benefited from the lack of protection for pharmaceuticals, will now experience such negative effects.²⁵ However, under specific patent protections, losses of such companies may not be equated to damages to, or disadvantages of, the respective national economy as a whole.²⁶

Therefore, under the new conditions of globalization, for countries that attract foreign investments in R&D and production activities, the availability of an effective patent protection in a given country should be viewed, not as the scapegoat for increased social costs, but as a “comparative patenting advantage.” A comparative patent-

European Union, and other international agreements, including TRIPS).

21. See Guntram Rahn, *The Role of Industrial Property in Economic Development: The Japanese Experience*, 14 INT'L REV. IND. PROP. & COPYRIGHT L. 449, 465 (1983). From 1940 to 1975, Japanese companies introduced ten pharmaceutical products into the Japanese market; in the first eight years since the introduction of product patent protection for pharmaceuticals in 1976, more than eighty Japanese pharmaceutical products have reached the market. See *Special Questions of Newly Emerging Technologies - Biotechnology*, at E36 WIPO Doc. F/IPCA/9 (Aug. 1989). See generally Mark D. Dibner, *Biotechnology in Pharmaceuticals: The Japanese Challenge*, 229 SCIENCE 1230 (1985).

22. See Siegfried Greif, *Patents and Economic Growth*, 18 INT'L REV. IND. PROP. & COPYRIGHT L. 191, 211 (1987) (describing the Korean experience).

23. See Carlos M. Correa, *Implementing the TRIPs Agreement in the Patent Field - Options for Developing Countries*, 1 J. WORLD INTELL. PROP. 75, 79 (1998).

24. See UNCTAD, *supra* note 5, at 15 (considering the costs and benefits for developing countries that stem from the TRIPS Agreement).

25. See *id.*

26. See *id.*

ing advantage is especially evident in countries where skilled human resources, areas of excellence, lower operating costs, or special or unique circumstances—such as genetic resources—can be found.²⁷

III. MANEUVERING SPACE FOR THE CENTER: PUBLIC-PRIVATE INITIATIVES AND “COMPARATIVE PATENTING ADVANTAGES”

After the TRIPS Agreement it might be possible to doubt the availability of pure comparative patenting advantages because Article 27(1) of the Agreement requires WTO members to make patents available for both product and process inventions in all fields of technology, provided the usual patentability requirements are met.²⁸

However, due to the influence of Europe and the developing countries, the TRIPS Agreement allows members to exclude patent protection of inventions under certain circumstances of products the “commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.”²⁹

This part of the TRIPS Agreement established the first international guidance as to which regulations of a given legal order constitute *ordre public*: regulations that are necessary to protect the life or health of humans, animals, or plants or to avoid serious damage to the environment.³⁰ In contrast, regulations or prohibitions anchored in national laws of the members will not suffice.³¹ As a consequence, the TRIPS Agreement does not prohibit members from obstructing certain technological developments or exploiting their results in certain extremely sensitive areas. For example, a member could, within the context of patent law, prohibit exploitation of pharmaceutical production and marketing of plant or animal biotechnology.³² Thus, patenting of such inventions can be precluded only if the relevant country refrains from commercial exploitation, such as marketing,

27. See generally Barré *supra* note 1; Cantwell & Hodson, *supra* note 13.

28. See TRIPS Agreement, *supra* note 4, art. 27(1).

29. *Id.*

30. See *id.*

31. See *id.*

32. Plant or animal biotechnology is the production and use of transgenic animals or plants that are either resistant to pesticides, insecticides, insects, or certain environmental influences such as humidity or drought.

distribution, or sale of such inventions.³³

Also, under the obvious influence of the exclusionary provisions existing under the European patent law, the TRIPS Agreement permits its members to exclude altogether from patentability “diagnostic, therapeutic and surgical methods for the treatment of humans and animals.”³⁴ As already stated, this provision cannot be interpreted to mean that appliances or diagnostic means used or therapeutic means administered in such methods may remain excluded from patent protection.³⁵ Article 70(8) of the TRIPS Agreement clearly indicates that Article 27(1) obliges WTO members to afford protection for pharmaceutical products, subject to the transitional arrangements.³⁶ Since somatic gene therapy in *in vivo* and *ex vivo* is to be viewed as a combination of patentable methods for producing new pharmaceutically active substances, by employing the special means of recombinant DNA technology and the products obtained as pharmaceutically active substances that function at the molecular level,³⁷ the patentability of intellectual property such as somatic gene therapy for curing cancer or inherited monogenic defects may not be affected by this provision.³⁸

A further influence of the European patent law is reflected in Article 27(3)(b) of the TRIPS Agreement, which allows WTO members to exclude from patentability “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and micro-biological processes.” However, this provision makes it mandatory that members provide for some kind of protection for plant varieties.³⁹ This may be made available as patent protection or under an effective *sui generis* system, or under a combination of both systems. The wording of this obligation, which leaves the choice of the protection system entirely to the members, reflects on the one hand the broad range of existing systems, ranging from the United States where plant varieties may be protected by patents or by specific plant variety protection

33. See Carlos M. Correa, *The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: New Standards for Patent Protection*, 16 EUR. INTELL. PROP. REV. 327, 328 (1994); Straus, *supra* note 8, at 182.

34. TRIPS Agreement, *supra* note 4, art. 27(3)(a).

35. See Straus, *supra* note 8, at 183; see also Correa, *supra* note 33.

36. See Straus, *supra* note 8, at 184.

37. See Joseph Straus, *Patentrechtliche Probleme der Genterapie*, 1996 GRUR [Int.] 10, 12.

38. See *id.*

39. See TRIPS Agreement, *supra* note 4, art. 27.

rights or even by special plant patents,⁴⁰ to the EU countries where plant variety protection is confined to specific variety protection systems only.⁴¹ On the other hand, however, the wording also reflects the fact that the 1991 revision of the International Convention for the Protection of New Varieties of Plants (UPOV) abandoned the so-called prohibition of double protection. The possibility of excluding plant varieties from patent protection as permitted under the TRIPS Agreement and the previous resistance of many developing countries to provide any protection at all in this field, will most likely result in either the adherence of those countries to the 1978 version of the UPOV Convention—which lags well behind the 1991 Revision Act⁴²—or the creation of *sui generis* protection according to their own concepts.⁴³

While the application of the explicit exceptions will result in difficulties similar to those of Europe, other important issues are not even addressed in the TRIPS Agreement. For example, this is true for the patentability of computer programs and the important demarcation between the notion of patentable invention and unpatentable discovery.⁴⁴ The fact that the latter issue is left to the members to resolve may not in principle place into question the patentability of naturally occurring substances such as DNA and cell lines. If micro-

40. See, e.g., Reid G. Adler, *Can Patents Coexist with Breeders' Rights? Developments in U.S. and International Biotechnology Law*, 17 INT. REV. IND. PROP. & COPYRIGHT L. 195, 199-210 (1986).

41. See discussion *supra* note 20.

42. See generally NOEL BYRNE, COMMENTARY ON THE SUBSTANTIVE LAW OF THE 1991 UPOV CONVENTION FOR THE PROTECTION OF PLANT VARIETIES (1992) (discussing the International Convention for the Protection of New Varieties of Plants (UPOV), 1991 Revision Act). Whether the UPOV 1978 Revision Act may be viewed as complying with the requirements set out in Article 27(3)(b) TRIPS Agreement is not discussed at length here. However, in view of the UPOV's Article 4(3)(b)(iii), which allows contracting parties, even after a transitory period of eight years, to provide protection for only twenty-four "genera" or species of plants, thus leaving unprotected a broad area of plant breeding activities, serious doubts may be expressed as to whether such in part non-existing protection may be called effective. See Joseph Straus, *The Relationship Between Plant Variety Protection and Patent Protection for Biotechnological Inventions from an International View Point*, 18 INT. REV. IND. PROP. & COPYRIGHT L. 723, 731 (1987) (discussing the unprotected activities in Europe in the 1980s).

43. This third option has been considered or suggested. See S.K. Verma, *TRIPs and Plant Variety Protection in Developing Countries*, 17 EUR. INTELL. PROP. REV. 281, 288-89 (1995); Correa *supra* note 33, at 334. Also, the latest Indian draft legislation on plant breeders' rights seemingly follows that path. See Biswajit Dhar & Sachin Chatuvedi, *Introducing Plant Breeders' Rights in India – A Critical Evaluation of Proposed Legislation*, 1 J. WORLD INTELL PROP. 245, 249-260 (1998).

44. See TRIPS Agreement, *supra* note 4, art. 27 (defining patentable inventions as "products or processes, in all fields of technology, provided that they are new, [and] involve an inventive step and are capable of industrial application").

organisms are declared subject matter eligible for mandatory patent protection, naturally occurring biochemical substances such as DNA, reasoning from the greater to the smaller, should also to be regarded as subject matter for which WTO members must offer product patent protection. Thus, information embodied in genetic resources can be excluded from patent protection only under the conditions set out in Article 27(2)-(3) of the TRIPS Agreement. From the lack of a definition of the concept of invention in the TRIPS Agreement, it may not be generally concluded that WTO members, whether they are developed or developing countries,⁴⁵ could legitimately follow a definition of invention that broadly excludes materials pre-existing in nature from patentability.⁴⁶

Whether Article 27(1) of the TRIPS Agreement will be able to fulfill its intended purpose, despite its vagueness, as previously discussed, will depend partly on the manner in which it is implemented in legislation and practice in the member countries. Furthermore, stimuli and calls for further precision in the text, such as the inclusion of previously unpatentable creations under the notion of invention, and in the case of computer programs, will depend on the necessity of protecting the creators of such subject matter. This contingency will be especially true in those member countries who are the leading powers in the relevant field of activity.⁴⁷ Regarding the allowable exclusion from patentability of plants and animals, a review of this provision will take place four years after entry into force of the WTO Agreement, by 1999.

As China was at the center of interest during the Conference, it is important to analyze China's patent law⁴⁸ to superficially examine

45. This requirement applies to developing countries only after the expiration of the transitory period. See TRIPS Agreement, *supra* note 4, art. 65.

46. See, e.g., UNCTAD, *supra* note 5, at 34; Correa, *supra* note 23 (referring to Art. 6(b) of Decision 344 of the Andean Group and Art. 6(g) of the new Argentine patent law, which set out that substances pre-existing in nature and their replications, and any kind of life material or substances already existing in nature, respectively, do not constitute an "invention"). In contrast, in Egypt a patent has already been issued on an insecticidal gene that is isolated from a bacterium (*Bacillus thuringiensis*) indigenous to Egypt. See Atef el-Azab, *Egypt*, in INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURAL BIOTECHNOLOGY 65, 71 (F.H. Erbisich & K.M. Mareida eds., 1998).

47. See J.H. Reichman, *The TRIPs Component of the GATT's Uruguay Round: Competitive Prospects for Intellectual Property Owners in an Integrated World Market*, 4 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 171, 198-203 (1993).

48. See Zhonghua Renmin Gongheguo Zhuanlifa [Patent Law of the People's Republic of China] FAGUI HUIBIAN 1992, translated in 2 CHINA L. FOREIGN BUS. (CCH) P 11-600 (1993) (adopted March 12, 1984, amended September 4, 1992).

its compatibility with the patent protection of the TRIPS Agreement. It appears that only the complete lack of protection of plant varieties under Chinese patent law contradicts TRIPS obligations.⁴⁹ This deficiency, however, seems to be cured by the Law on the Protection of New Varieties of Plant Strains.⁵⁰

However, this does not mean that a good opportunity does not exist for the Center for Public-Private Initiatives After the TRIPS Agreement to be involved and to offer its services. There are many good reasons to be involved: On the one hand, China's patent law is clearly designed after the European patent model, excluding from patent protection, among others, methods for the diagnosis or for the treatment of diseases, and animal and plant varieties.⁵¹ Thus, China cannot claim, at least not for the area of biotechnology, to dispose of "comparative patenting advantages." On the other hand, to stay with the same area of technology, China disposes of a number of centers of excellency in plant breeding and also animal breeding. Moreover, in the province of Yunnan alone, more than 18,000 plant types exist.⁵² Thus, China is a country with rich genetic resources, which are gaining increasing importance in the areas of plant and animal breeding, medicine, pharmaceuticals, chemicals, and protection of environment.⁵³

In this context, under Article 3 of the Convention on Biological Diversity,⁵⁴ the sovereign rights of states over their natural resources are explicitly recognized; including their authority to determine access to genetic resources by national legislation.⁵⁵ Thus, notwithstanding the statement that "Each Contracting Party shall endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Conven-

49. *See id.*

50. *See* The Law on the Protection of New Varieties of Plant Strains, published in 12 ZHONGHUA RENMIN GONGHEGUO GUOWUYUAN GONGBAO [Gazette of the State Council of the People's Republic of China] 550 (1997) (adopted March 1997, entered into force October 1997); *see also* 1997 GRUR [Int.] 855.

51. *See id.*

52. *See* James Harding, *Bio-Resources Bloom in Yunnan*, FIN. TIMES, July 2, 1997, at 37.

53. In China, for example, vegetables such as tomatoes, that have been genetically engineered for resistance to viruses, have been on the market since 1993, thus years ahead of Europe or even the United States. *See, e.g.*, Anne S. Moffat, *Developing Nations Adopt Biotech for Own Needs*, 265 SCIENCE 186 (1994).

54. *See* Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818 [hereinafter Biodiversity Convention].

55. *See id.* art. 15(1).

tion,” the foundation for ownership in genetic resources on an international scale has been established.⁵⁶ Access to genetic resources under Article 15(3)-(5) requires prior informed consent,⁵⁷ and must be on mutually agreed terms. Moreover, the country providing genetic resources is entitled to share benefits from the commercial use of its genetic resources, such sharing based upon mutually agreed terms.⁵⁸ In this context, it is important to understand the double nature of genetic resources: as *phenotypes* (individual plants, animals or micro-organisms) they traditionally constitute private (tangible) goods; as *genotypes* (information embodied in the genetic constitutions of a plant, animal or micro-organism) they a priori conform to the definition of public good. However, genotypes can possess exclusivity. This holds true if the access to genotypes is limited by either tangible property ownership or by IPRs, such as patents or plant breeders’ rights.⁵⁹ Thus, the developments that led to patenting plants, animals, micro-organisms, and other biological materials under the patent law provisions of the developed world have made genetic resources potentially direct or—more probably—indirect subject matter of intellectual property.⁶⁰ The bargaining position of the host countries of genetic resources is further strengthened by Article 16 of the Convention on Biodiversity under which an obligation for each Contracting Party was established to undertake “to provide and/or facili-

56. *Id.* art. 15(2). Due to the balanced obligations of host countries, however, the right of the states to control access to genetic resources is not an absolute right. See *Access to Genetic Resources and Benefit Sharing: Legislative, Administrative and Policy Information*, Conference of the Parties to the Convention of Biological Diversity, 2d mtg., U.N. Doc. UNEP/CBD/COP/2/13 (1995); see also LYLE GLOWKA, ET AL., A GUIDE TO THE CONVENTION ON BIOLOGICAL DIVERSITY, INTERNATIONAL UNION FOR THE CONSERVATION OF NATURE AND NATURAL RESOURCES (IUCN) 26 (1994).

57. See Biodiversity Convention, *supra* note 54, art 15(5). “Prior informed consent” involves, in chronological order:

- (i) consent of the Contracting Party providing genetic resources;
- (ii) based on information provided by the Party interested in access to and use of genetic resources; and
- (iii) prior to consent for access being granted, the provider has the authority to require information, *inter alia*, on the subsequent use, etc., of genetic resources.

Joseph Straus, *Biodiversity and Intellectual Property*, 1998/IX AIPPI Y.B. 99, 104-105.

58. See *id.* art. 15(6)-(7). Terms are mutually agreed upon if they are reciprocally accepted. See *Access to Genetic Resources*, Conference of the Parties to the Convention of Biological Diversity, 3d mtg., U.N. Doc. UNEP/CBND/COP/3/20 (1996).

59. See Roger A. Sedjo, *Property Rights, Genetic Resources and Biotechnological Change*, 35 J.L. & ECON. 199, 201, 206-08 (1992).

60. See Joseph Straus, *The Rio Biodiversity Convention and Intellectual Property*, 24 IIC: INTERNATIONAL REVIEW OF INDUSTRIAL PROPERTY AND COPYRIGHT LAW 602, 603-04 (1993).

tate access for and transfer to other Contracting Parties” of, inter alia, technologies that make use of genetic resources or are relevant to the conservation of biological diversity and the sustainable use of its components.⁶¹ Moreover, Article 16(2) further clarifies this obligation by stating that said access and transfer must be provided and/or facilitated under fair and most favorable terms, including on concessional and preferential terms when mutually agreed. This new situation is well reflected by novel forms of cooperation between companies and universities interested in prospecting for pharmaceutical use chemicals in plants, animals, and insects of the tropics, and public or private institutions in countries disposing of such genetic resources. A number of well-known examples exists for such cooperative agreements between U.S. companies and universities and publicly administered or funded institutions in Argentina, Brazil, Cameroon, Chile, Costa Rica, Mexico, Nigeria, and Suriname.⁶² The basic design of the agreements is to establish research activities in the host countries (in cooperation with local institutions) to screen biological materials, pay a lump sum for the access to that material, and provide for the sharing of expected revenues from the commercial product in the form of royalties.⁶³

Although it is premature to predict the final benefit, it should be beyond doubt that in this area countries like China, private companies, and academic institutions from the developed world should see a new field of activity with great potential for the future in which intellectual property rights will play an important role. To some extent it has not yet been fully realized by the host countries of genetic resources that the only effective form of protection for the international exploitation of these resources are patents or other forms of IPRs. This is due to the specific trait of self-reproduction of those resources. Once biological material has left the country, it is practically out of control of the original owner of the tangible good. Therefore, only IPRs can control the exploitation and secure a reward.⁶⁴ In view of the fact that China is not currently taking full advantage of its rich

61. Biodiversity Convention, *supra* note 54, art. 16(1).

62. See, e.g., Joshua P. Rosenthal, *Equitable Sharing of Biodiversity Benefits: Agreements on Genetic Resources*, in OECD PROCEEDINGS: INVESTING IN BIOLOGICAL DIVERSITY: THE CAIRNS CONFERENCE 253 (1997).

63. For more details, see generally Thomas Eisner, *Chemical Prospecting: A Global Imperative*, 138 PROC. AM. PHIL. SOC'Y 385 (1994); Rosenthal, *supra* note 62.

64. See R.S. CRESPI & JOSEPH STRAUS, INTELLECTUAL PROPERTY, TECHNOLOGY TRANSFER AND GENETIC RESOURCES, AN OECD SURVEY OF CURRENT PRACTICES AND POLICIES 15 (1996).

genetic resources or its highly skilled human resources in the area of plant and animal breeding and molecular biology and genetics, the Center could find in this area one of its first fields of activity. Therefore, the Center should do as follows: focus on the search for competent public institutions in China entitled to negotiate the access and exploitation of genetic resources; discuss the legal problems linked to the access and exploitation of those resources and the access of the respective biotechnology—especially related to the question of national legislation specifically dealing with these issues;⁶⁵ establish links with private parties interested in chemical prospecting; and help establish local research facilities necessary for screening activities as the basis for further research and development. The Center may also serve as a neutral mediator in helping the responsible Chinese authorities to better understand the following issues: the economic implications of the existing exclusionary provisions related to biotechnological innovation; the potential comparative competitive position of China in globalized research, development, and production activities; and the necessity of balanced and attractive legislation on access to and benefit sharing from genetic resources for a prosperous development of biotechnology research industry in China.

IV. CONCLUSION

In sum, the idea of a Center on Public-Private Initiatives After the TRIPS Agreement is a sound one. Such a center could essentially contribute to an optimized use of IPRs for an economically well balanced benefit of developed countries, developing countries, as well as NICs. However, all of the involved parties have to understand and accept the TRIPS Agreement as one of the cornerstones of present international trade and a guarantor of its future. Moreover, such parties should also become acquainted with the idea that strong intellectual property protection is to be viewed as an increasingly important comparative advantage in the current globalized world, which should

65. So far, only the Philippines, see Exec. Order No. 247 of 1995, *Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-Products and Derivatives, for Scientific and Commercial Purposes, and other Purposes, with Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources* of 1996 (Phil.), and the five Latin-American States forming the so-called "Andean Pact" (Venezuela, Columbia, Bolivia, Ecuador, and Peru), see Decision 391 *On The Common System on Access to Genetic Resources*, have introduced comprehensive legislation in this area. For more details and legislative endeavors of some other countries, see *Access to Genetic Resources*, Conference of the Parties to the Convention of Biological Diversity, 3d mtg., U.N. Doc. UNEP/CBND/COP/3/20 (1996).

be used to the best possible extent. The case of genetic resources could serve as a good example.